AstraZeneca Annual Report and Form 20-F Information 2009

## Health in the real world

林志術 13號



#### Important information for readers of this Annual Report and Form 20-F Information

### Cautionary statement regarding forward-looking statements

The purpose of this Annual Report and Form 20-F Information is to provide information to the members of the Company. The Company and its Directors, employees, agents and advisors do not accept or assume responsibility to any other person to whom this Annual Report and Form 20-F Information is shown or into whose hands it may come and any such responsibility or liability is expressly disclaimed. In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995 and the UK Companies Act 2006, we are providing the following cautionary statement: This Annual Report and Form 20-F Information contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group. Forward-looking statements are statements relating to the future which are based on information available at the time such statements are made. including information relating to risks and uncertainties. Although we believe that the forward-looking statements in this Annual Report and Form 20-F Information are based on reasonable assumptions, the matters discussed in the forward-looking statements may be influenced by factors that could cause actual outcomes and results to be materially different from those expressed or implied by these statements. The forward-looking statements reflect knowledge and information available at the date of the preparation of this Annual Report and Form 20-F Information and the Company undertakes no obligation to update these forward-looking statements. We identify the forwardlooking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things, those factors identified in the Principal risks and uncertainties section from page 80 of this document. Nothing in this Annual Report and Form 20-F Information should be construed as a profit forecast.

Inclusion of reported performance, core financial measures and constant exchange rate growth rates In Our year in brief section on page 2 and throughout the Directors' Report the following measures are referred to:

- > Reported performance. Reported performance takes into account all the factors (including those which we cannot influence, principally currency exchange rates) that have affected the results of our business as reflected in our Group Financial Statements prepared in accordance with IFRS as adopted by the EU and as issued by the IASB.
- > Core financial measures. These are non-GAAP measures because unlike Reported performance they cannot be derived directly from the information in the Group's Financial Statements. These measures are adjusted to exclude certain significant items, such as charges and provisions related to our global restructuring and synergy programmes, amortisation and impairment of the significant intangibles relating to the acquisition of MedImmune in 2007, the amortisation and impairment of the significant intangibles relating to our current and future exit arrangements with Merck in the US, and other specified items. See the Reconciliation of Reported results to Core results table on page 40 for a reconciliation of Reported to Core performance.
- > Constant exchange rate (CER) growth rates. These are also non-GAAP measures. These measures remove the effects of currency movements (by retranslating the current year's performance at the

previous year's exchange rates and adjusting for other exchange effects, including hedging). A reconciliation of Reported results adjusted for the impact of currency movements is provided in the Operating profit (2009 and 2008) table on page 39.

Throughout this Annual Report and Form 20-F Information, growth rates are expressed at CER unless otherwise stated.

AstraZeneca's determination of non-GAAP measures together with our presentation of them within our financial information may differ from similarly titled non-GAAP measures of other companies.

### Statements of competitive position, growth rates and sales

In this Annual Report and Form 20-F Information, except as otherwise stated, market information regarding the position of our business or products relative to its or their competition is based upon published statistical sales data for the 12 months ended 30 September 2009 obtained from IMS Health, a leading supplier of statistical data to the pharmaceutical industry. For the US, dispensed new or total prescription data are taken from the IMS Health National Prescription Audit for the 12 months ended 31 December 2009; such data is not adjusted for Medicaid and similar state rebates. Except as otherwise stated, these market share and industry data from IMS Health have been derived by comparing our sales revenue to competitors' and total market sales revenues for that period. Except as otherwise stated, growth rates and sales are given at CER. For the purposes of this Annual Report and Form 20-F Information, unless otherwise stated, references to the world pharmaceutical market or similar phrases are to the 49 countries contained in the IMS Health MIDAS Quantum database, which amounted to approximately 95% (in value) of the countries audited by IMS Health.

#### AstraZeneca websites

Information on or accessible through our websites, including astrazeneca.com, astrazenecaclinicaltrials.com and medimmune.com, does not form part of and is not incorporated into this document.

#### External/third party websites

Information on or accessible through any third party or external website does not form part of and is not incorporated into this document.

#### Definitions

The glossary and the market definitions table from page 206 are intended to provide a useful guide to terms and AstraZeneca's definition of markets, as well as to acronyms and abbreviations, used in this Annual Report and Form 20-F Information. They are, however, provided solely for the convenience of the reader and should therefore not be relied upon as providing a definitive view of the subject matter to which they relate.

#### Use of terms

In this Annual Report and Form 20-F Information, unless the context otherwise requires, 'AstraZeneca', 'the Group', 'we', 'us' and 'our' refer to AstraZeneca PLC and its consolidated entities and any reference to 'this Annual Report' is a reference to this Annual Report and Form 20-F Information.

#### Statements of dates

Except as otherwise stated, references to days and/or months in this Annual Report and Form 20-F Information are references to days and/or months in 2009.

#### Figures

Figures in parentheses in tables and in the Financial Statements are used to represent negative numbers.

#### Key financial highlights

# Sales up 7% to \$32,804 million

(\$31,601 million in 2008)

Core operating profit up 23% to \$13,621 million (\$10,958 million in 2008)

Strong cash flows reduced net debt by \$7,709 million resulting in net funds of \$535 million



## Welcome to our **Annual Report 2009**

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## Our year in brief Summary financial and operational information for 2009

### **Financial highlights**

Sales \$m (+7%)

2009	32,804
	31,601
2007	29,559

Net cash flow from operating activities \$m

	11,739
	8,742
2007	7,510

Core	operating	profit	\$m	(+23%)
0010	operading	prone	ψΠΙ	

**13,621** 10,958

2009	
2008	

Reported operating profit \$m
-------------------------------

2009	11,543
2008	9,144
2007	8,094

Core gross margin \$m (+10%)

	27,217
2008	25,408

 Reported gross margin \$m (+11%)

 2009
 27

2009	27,029
	25,003
2007	23,140



**Core earnings per Ordinary Share** \$ (+23%)

2009	6.32
	5.10
2007	4.38

**Reported basic earnings per Ordinary Share** \$ (+22%)

2009	5.19
	4.20
2007	3.74

#### Dividend for 2009

Total	2.30	141.4	16.84	
Second interim dividend	1.71	105.4	12.43	15 March 2010
First interim dividend	0.59	36.0	4.41	14 September 2009
	\$	Pence	SEK	Payment date

#### Sales

> Crestor sales were up 29% to \$4,502 million; Symbicort up 23% to \$2,294 million; Seroquel up 12% to \$4,866 million; and Arimidex up 7% to \$1,921 million. Nexium sales fell by 1% to \$4,959 million and Synagis sales fell by 12% to \$1,082 million

Dividend per Ordinary Share 2009

- > Sales of Toprol-XL and H1N1 influenza (swine flu) vaccine in the US accounted for 3 percentage points of the global revenue growth
- Emerging Markets growth was 12%, accounting for 13% of total revenue

Pipeline developments include

- > Four major regulatory submissions made
- > Complete Response Letter submitted for fifth regulatory submission
- In-licensing/acquisition of four late-stage projects
- > 89 projects in clinical development

Restructuring programme delivered annualised savings of \$1.6 billion in 2009 and expanded to deliver further savings

Positioned in the top 6% in the sector in the Dow Jones World and STOXX (European) Indexes

Up to \$1 billion in Ordinary Shares will be re-purchased by the Company during 2010

Note: All growth rates are at CER.

### **Operational overview**

#### Distributions to shareholders \$m

	2009	2008	2007
Dividends	2,977	2,739	2,641
Share re-purchases	-	610	4,170

29%

Crestor up 29% to \$4,502 million

4

Four major regulatory submissions



from restructuring

23%

Symbicort up 23% to \$2,294 million

4

In-licensing/acquisition of four late-stage projects

6% in the sector in the

Dow Jones Indexes

AstraZeneca Annual Report and Form 20-F Information 2009



## **Chairman's Statement**

Despite the difficult world economic conditions, 2009 was a successful year for AstraZeneca. Our strong performance and considerable achievement in making a real difference to patient health around the world meant that our shareholders were also able to benefit.

Group sales increased by 7% in 2009 to a total of \$32,804 million. Reported operating profit was \$11,543 million, up 24%. Reported earnings per share for the full year were \$5.19 (2008: \$4.20). The Board has recommended a second interim dividend of \$1.71, a 14% increase over the second interim dividend awarded in 2008. This brings the dividend for the full year to \$2.30 (141.4 pence, SEK 16.84), an increase of 12% from 2008. In 2009, cash distributions to shareholders through dividends totalled \$2,977 million.

Meeting patient need lies at the heart of what we do. In 2009, immediate need was met when our people and technology enabled us to develop and be the first to market an H1N1 influenza (swine flu) vaccine in the US. Equally, when generic producers proved unable to supply the market for *Toprol-XL*, we successfully rebuilt our supply chain to fill the void.

2009 was also a year in which AstraZeneca science was at the forefront of the industry, ensuring that we are able to meet patient need in the longer term. Two of the biggest landmark clinical trials to report in recent years, the *Crestor* JUPITER and the *Brilinta* PLATO trials, engaged academic and clinical communities across the globe. We have made regulatory submissions based on the results of these trials.

Our strategic focus is on innovation-driven medicines that are valued by patients and payers alike. We continue to invest in new medicines and we work to protect our investments by rigorously defending our patent rights and thereby optimising our intellectual property. To this end, AstraZeneca will vigorously defend the challenge to the *Crestor* US substance patent brought by a number of generic drug manufacturers when the case goes to trial in February 2010.

Worldwide, pharmaceutical industry revenue growth, while positive, is slowing. This is due to pressure on healthcare costs, exacerbated by the current economic downturn, as well as increased competition from generic medicines. We believe pressures on costs are likely to continue, especially in the US.

Nevertheless, the demand for healthcare that will drive the industry's future growth remains strong, especially from economic and demographic growth in Emerging Markets and the growing number of patients there who can afford our medicines. In response to these developments we have continued to drive change in the business. We are reshaping our presence in Established Markets to ensure we remain competitive and investing in Emerging Markets around the world so that we can benefit from their growth.

We used our assessment of the future for the pharmaceutical sector as the basis for the annual strategy review with David Brennan and his executive team. We confirmed our commitment to being an integrated, global and innovation-driven prescription-based biopharmaceutical business. While there has already been much change in the business, the review also highlighted the need to redouble our efforts if we are to stay at the forefront of the sector. Our plans for the business are outlined in more detail in David's Review and the Strategy and Performance section.

In recognition of the Group's strong balance sheet, sustainable significant cash flow and the Board's confidence in the strategic direction and long-term prospects for the business, we have adopted a progressive dividend policy, intending to maintain or grow the dividend each year. In order to ensure that long-term management incentives and shareholder interests remain aligned, we are tabling proposals for a new share-based long-term incentive plan for shareholder approval. This has been developed as part of an overall review of executive remuneration. Further information about this plan and the review can be found in the Directors' Remuneration Report from page 101 and in the Notice of AGM.

During 2009, Håkan Mogren retired from the Board, having been a Director of the Company since its formation in 1999. Before then, he had served as Chief Executive Officer and a Director of Astra AB for more than 10 years. He brought a wealth of experience and sound judgement to the work of the Board which we valued highly. As announced last year, John Patterson also retired in 2009. On behalf of their fellow Directors, I would like to reiterate my thanks to both of them for their service to the Company.

Once again, the Board would like to place on record its appreciation of the leadership shown by David Brennan and his team. On behalf of the Board I would also like to thank AstraZeneca employees around the world for their contribution to what has been a very successful year. Their contribution, which has been the foundation of our past success, is also needed more than ever as we address the challenges to come. I am confident that AstraZeneca has the skills and capabilities to continue that success by harnessing both its own efforts and the efforts of those with whom we work.

Louis Schweitzer Chairman



## **CEO's Review**

2009 was a year of considerable achievement in which I believe we laid firm foundations for the future success of the business. Underpinning all this is excellent execution of our plans, improved organisational flexibility and a committed workforce.

Operational highlights of the year include four significant regulatory filings for new medicines and two product launches. We agreed four late-stage project collaborations and have 89 projects in clinical development. In addition, sales of Toprol-XL and H1N1 influenza (swine flu) vaccine in the US accounted for three percentage points of the global revenue growth at CER, while growth in Emerging Markets was up 12%, accounting for 13% of total revenue. 2009 was also the year in which we reached an agreement in principle with the US Attorney's Office to settle claims relating to Seroquel sales and marketing practices and to make a payment of \$524 million (including interest).

If we are to bring benefits to patients and create value for shareholders, we need a constant flow of new and innovative medicines. Of the four regulatory filings made in 2009, Brilinta is a treatment for acute coronary syndromes. Certriad is for the treatment of lipid abnormalities and Vimovo is for arthritic pain. The fourth submission was for a fixed-dose combination of Onglyza™ and metformin for treating diabetes. 2009 saw Onglyza™ launched in the US and in the EU for the treatment of Type 2 diabetes. Iressa, our anti-cancer medicine, was launched in the EU. Of course, in the process of developing new medicines, we experience setbacks as well as successes. The decision

we made during the year to withdraw the regulatory submissions we had made for our anti-cancer medicine, *Zactima*, came as a disappointment.

As projects leave the development pipeline, we replenish it with new projects that will yield regulatory submissions in future years. We now have 11 projects in Phase III development. Twenty-nine projects entered the pipeline during the year and 53 projects were progressed to their next phase of development. We seek to provide each of these projects with a business case underpinned by a clear scientific rationale and sound financial case.

In strengthening our pipeline we look beyond our own laboratories to access the best science and external sources of innovation. As a result, a significant number of our projects come from our programme of collaboration. These include two of our regulatory filings: *Certriad* was submitted with Abbott and *Vimovo* was submitted by our partner Pozen Inc. In addition, Onglyza<sup>™</sup> was the first product of our diabetes collaboration with BMS.

Other collaborations agreed in 2009 included the in-licence from Forest of ceftaroline, a 'next generation' anti-infective. We enhanced the value of this programme in December with an agreement to acquire Novexel, a private infection research company. We also agreed in-licensing deals with Nektar and Targacept.

A further focus in 2009 was the continued reshaping of the business to give us the organisational flexibility we need to take advantage of opportunities. Initiatives include outsourcing some of our R&D activities, other business processes and support services, such as HR. To meet evolving customer needs we are adapting our methods of sales and marketing and altering our supply chains.

Our drive to improve efficiency and effectiveness across AstraZeneca has resulted in further reductions in our workforce. The executive team and I remain committed to ensuring that we manage these changes in the right way. This means that, in meeting the needs of the business, we deal responsibly and sympathetically with affected individuals and the communities in which they live.

We continue to integrate responsible business considerations into everyday decision-making across all our activities, reinforcing personal accountability for compliance with our Code of Conduct through training and monitoring of business practices. We were pleased to have our efforts recognised externally with improved scores in the 2009 Dow Jones Index. Looking ahead, we have identified areas for improvement and will take action to strengthen further our governance and management processes, building on our progress to date and driving continuous improvement throughout the business.

2009 also saw some changes to the executive team. Jan Lundberg, Executive Vice-President, Discovery Research left AstraZeneca in November. We thank him for his significant contribution to the business. Christer Köhler has taken over the role on an interim basis. Bruno Angelici, Executive Vice-President, International Sales and Marketing Organisation, will be leaving AstraZeneca later in 2010. He has made an enormous contribution and we thank him for his sound judgement and strong leadership.

Finally, the achievements of the year would not have been possible without the dedication and hard work of all our employees, to whom I offer my thanks. For many of our employees 2009 was a year of change. The pace of change is not going to let up in 2010. Indeed, it is going to accelerate. I am confident that our staff will respond with the commitment they have shown in the past.

The Strategy and Performance section from page 14 outlines our plans and priorities for 2010 and beyond, which we need to implement to ensure we prosper in the years ahead. In doing so, we will improve the health of patients around the world and thereby create value for our shareholders.

David R Brennan Chief Executive Officer

## AstraZeneca at a glance



#### AstraZeneca is a global, innovation-driven biopharmaceutical business

Our mission is to make the most meaningful difference to the health of patients through great medicines

We do this with a range of medicines designed to improve patients' health and quality of life around the world

We are committed to developing each activity within our business in a responsible way

Our work is supported by our values and the conduct of employees in working with each other and our stakeholders

We believe that our approach delivers lasting value for patients, society and our shareholders

### What we do

We are focused on the discovery, development and commercialisation of prescription medicines for six important areas of healthcare

We have a broad product range that includes many leaders in the treatment of the world's most serious illnesses

We have 10 medicines with sales of more than \$1 billion each in 2009

We use our scientific and commercial skills to develop a pipeline of innovative new products to meet medical need

Healthcare area	Key product		
Cardiovascular	Crestor (for managing cholesterol levels)		
Gastrointestinal	Nexium (for acid reflux)		
Infection	<i>Synagis</i> (for RSV, a form of respiratory infection in infants)		
Neuroscience	Seroquel (for schizophrenia, bipolar disorder and major depressive disorder)		
Oncology	Arimidex (for breast cancer)		
Respiratory & Inflammation	<i>Symbicort</i> (for asthma and chronic obstructive pulmonary disease)		



10 medicines with sales of over \$1 billion each in 2009



We are committed to working in a spirit of collaboration to achieve our goal of better health for patients

We recognise the value of collaborative work, and so continually seek to develop new ways of working with others who complement our existing skills, enhance our internal innovation or bring extra value to what we do

Our products rely not only on teamwork within AstraZeneca but on working with doctors, patients and other stakeholders to understand what they need and want

We also work with governments and those who pay for healthcare to ensure our products represent value for money

We work with NGOs and others to improve local healthcare in vulnerable communities around the world

### Where we work

We have a global reach but local knowledge, being active in over 100 countries, with a growing presence in emerging markets such as China, Brazil, India and Russia

In 2009 we had sales of \$15,981 million in North America, \$12,471 million in Other Established Markets and \$4,352 million in Emerging Markets

Combining our disease area expertise with countryspecific knowledge helps us to market and sell medicines that best meet local needs

Of our 62,700 employees worldwide, 47% are in Europe, 31% in the Americas and 22% in Asia, Africa and Australasia

Around 11,600 people work in our R&D organisation and we have 17 principal R&D centres in eight countries, including Sweden, the US and the UK

We have 9,500 employees at 20 manufacturing sites in 16 countries

60 major R&D collaborations in the last three years



## Path to a new medicine

The discovery, development and commercialisation of a medicine is a complex process. This is a high level overview of the process for a new small molecule medicine. It is illustrative only. It is not intended to (and nor does it) represent the life-cycle of any particular medicine or of every medicine discovered and/ or developed by AstraZeneca.

#### • AstraZeneca people

• AstraZeneca stakeholders and other third parties

Begin the process of seeking patent protection for the potential medicine

**Find potential medicine** Having identified the unmet medical need and the market opportunity, find a potential medicine, through laboratory research, that is potent. selective and absorbed into and safe in the body

#### academia and external clinicians to access the best external science and medical opinion. These third parties may be involved throughout the medicine's life-cycle

3

**Collaborations with** 

Studies typically in small groups of healthy human volunteers (may include patients in later part of Phase I) to understand how the potential medicine is absorbed in the body, distributed around it and excreted. Also to determine a safe dosage and identify side effects

3

Phase I studies

Begin to develop manufacturing route

to ensure the

manufacturing process is robust and costs

are minimised

**External clinicians** and organisations may be involved in the design and running of these studies. These third parties are typically involved at each study phase

> 5 **Phase III studies** Studies in a larger group of patients to gather information about effectiveness and safety of the medicine and evaluate the overall benefit/risk profile

Years 2 1 During the discovery phase ightarrow

0

4 5 6 During the development phase ightarrow 8

2 **Safety and initial** efficacy studies Studies in the lab and in animals to determine if the potential medicine is safe to introduce into humans and in what quantities

> Understand likely efficacy, side effect profile and maximum dose estimate in humans

4 Phase II studies Studies in small groups of patients to evaluate effectiveness of the medicine

During Phase II studies, design a Phase III programme to deliver data required for regulatory approval and pricing and/or reimbursement throughout the world

> External advisory panels help define the attributes to test in studies to demonstrate whether the potential new medicine can be differentiated from the existing standard treatment of care

**Regulatory authorities** ensure the safety and efficacy of the medicine and grant approval for its marketing. Large numbers of national, regional and local payers grant approval for the pricing and/or reimbursement of the medicine

To ensure

patient safety,

regulatory authorities

approve the testing

of the medicine

in humans

At any stage of the development process the medicine may have been acquired from a collaborating company. The collaborator may remain involved in the future development and commercialisation of the medicine

Create appropriate branding for the new medicine in preparation for its launch Clinicians begin to prescribe medicine and patients begin to benefit

> Market and sell medicine. Continuously monitor, record and analyse reported side effects. Review need to update the side effect warnings to ensure that patients' safety is maintained

Launch new medicine Raise awareness of patient benefit and appropriate use

7

Regulatory authorities approve any extensions to the patient populations to whom the medicine may be prescribed

Work with external advisory groups and regulatory authorities to consider potential additional diseases which might be treated by the medicine or better ways of administering the medicine

9 Life-cycle management Broaden understanding of the full potential of the medicine

10 11 12 13 14 15 16 17 18 20+ Post launch: delivering to patients  $\rightarrow$ 

6 Regulatory submission Seek approval from regulatory authorities to market and sell the medicine

Submit package of clinical data which demonstrates the safety and efficacy of the medicine to the regulatory authorities 8 Post-launch clinical safety studies Studies to further understand the safety profile of the medicine in larger populations

Conduct any required or indicated post-launch follow-up clinical trials

Regulatory authorities advise on any changes required to the prescribing information for the medicine as a result of greater understanding of the safety profile 10 Patent expiry Typically when patents protecting the medicine expire, generic versions of the medicine may enter the market

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This Directors' Report includes information that fulfils the requirements of a business review under the Companies Act 2006.

The Development Pipeline, Shareholder Information and Corporate Information sections from pages 196, 199 and 204, respectively, are incorporated into this Directors' Report.

Details of the more significant risks to AstraZeneca are set out in the Principal risks and uncertainties section from page 80.

Many of our products are subject to litigation. Detailed information about material legal proceedings can be found in Note 25 to the Financial Statements from page 166.

References to prevalence of disease have been derived from a variety of sources and are not intended to be indicative of the current market or any potential market for AstraZeneca's pharmaceutical products since, among other things, there may be no correlation between the prevalence of a disease and the number of individuals who are treated for such a disease.

The glossary and the market definitions table from page 206 are intended to provide a useful guide to terms and AstraZeneca's definitions of markets, as well as to acronyms and abbreviations, used in this Directors' Report.

In this Annual Report and Form 20-F Information, unless the context otherwise requires, 'AstraZeneca', 'the Group', 'we', 'us' and 'our' refer to AstraZeneca PLC and its consolidated entities and any reference to 'this Annual Report' is a reference to this Annual Report and Form 20-F Information.

Except as otherwise stated, references to days and/or months in this Annual Report are references to days and/or months in 2009.

Figures in parentheses in tables and in the Financial Statements are used to represent negative numbers.

Members of the Senior Executive Team address questions from an audience of employees at a Town Hall meeting in Westborough, Massachusetts, US.

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## **Business Environment**

AstraZeneca operates in a rapidly changing business environment that presents both opportunities and challenges. Although industry revenue growth is slowing due to continuing pressure on healthcare costs and pricing, as well as increased competition from generic medicines, the demand for healthcare that will drive the industry's future growth remains strong.

Historically, the pharmaceutical industry has been less exposed than other sectors to changes in global economic conditions, but continued constraints on payers impacted the sector and its prospects in 2009. However, the current economic environment also presents opportunities for the sector, such as strategic alliances with smaller companies seeking funding and development expertise. Indeed, partnering activity across the pharmaceutical sector remained strong during 2009.

#### **World markets**

The world pharmaceutical market in 2009 was valued at \$709 billion, an increase of 5% over 2008 at CER (maintaining the rate of growth for the period 2007 to 2008). As shown in the figure opposite the 2009 growth rate in North America recovered from its 2008 decline while the 2009 growth rate in Other Established Markets fell back from its 2008 level. On the other hand, Emerging Markets, in particular Emerging Asia Pacific, saw strong double-digit growth.

In 2009 the top five markets in the world remained the US, Japan, France, Germany and Italy, with the US representing 42% of global sales (2008: 42%). Further down the rankings, China moved into sixth place, displacing the UK to eighth place behind Spain.

#### Growth drivers Expanding patient populations

The world population has doubled in the last 50 years from three billion to over six billion and is expected to reach nine billion by 2050. In addition, the number of people who can access the highest standards of healthcare continues to increase, particularly among the elderly, who represent a rising proportion of populations in developed nations. Furthermore, the faster-developing economies, such as China, India and Brazil, continue to offer new opportunities for the industry to supply an expanding number of patients who can benefit from medicines. As shown by the figures, Emerging Markets now represent approximately 85% of the world population and 16% of the total pharmaceutical market. Pharmaceutical industry growth in Emerging Markets was more than triple the rate of growth in Established Markets in 2009.

#### **Unmet medical need**

In most Established Markets, ageing populations and certain lifestyle choices drive an increased incidence of chronic diseases such as cancer, cardiovascular/metabolic and respiratory diseases which require long-term management. The prevalence of chronic disease is also increasing in middle-income countries, and is now beginning to have an impact in the least developed countries. Many diseases remain under-diagnosed or sub-optimally treated and, as diagnostic techniques and treatments improve and access to medicines widens, the burden of disease is projected to continue increasing over the next 20 years. In addition, the appearance of new medical challenges such as the H1N1 influenza (swine flu) pandemic potentially adds to the burden.

#### Advances in science and technology

Existing medicines will continue to be vital in meeting the demand for healthcare, particularly in an increasingly genericised market. In addition, innovation resulting from advances in both the understanding of the key processes involved in the initiation and progression of disease and the application of new technologies will be critical to meeting current and future unmet medical need. As we noted last year, the use of large molecules, or biologics, is becoming an increasingly important driver of innovation. It has been predicted that within the world's top 100 pharmaceutical products, 50% of sales will come from biologics based on forecasts for 2014. This compares with only 28% in 2008 and 11% in 2000. With advances in the technologies for the design and testing of novel compounds, new opportunities also exist for the use of innovative small molecules as new medicines.

#### The challenges Pricing pressure

The growing demand for healthcare continues to increase pressure on payer budgets. Whilst payers may recognise the need to reward innovation, they have a duty to spend their limited financial resources wisely. As a result, cost-containment in healthcare, including containment of pharmaceutical spending, continues to be a focus. This is particularly the case as the current global economic downturn increases cost pressures on healthcare payers and those patients who pay directly for all, or a significant proportion, of the cost of their medicines.

The research-based pharmaceutical industry's challenge is to manage this downward pressure on the price of its products, whilst continuing to invest in the discovery, development, manufacture and marketing of new medicines. In addition, most of our sales are generated in highly regulated markets where governments exert various levels of control on price and reimbursement.

Multiple pricing systems exist across the globe, which create a complex matrix that must be managed to optimise revenues. This may be further complicated by currency fluctuations within regions. The principal aspects of price regulation in our major markets are described further in the Geographical Review from page 50.

Payers increasingly require that the economic as well as therapeutic value of medicines be demonstrated and that this value be supported by evidence of real outcomes. Meeting these needs across a diverse range of national and local reimbursement systems requires significant additional investment of resources and funds by the industry. Personalised healthcare (PHC) offers one way of increasing the value of medicines to patients, physicians and payers. Under PHC the optimal treatment for each individual, in terms of the choice of medicine and dose, is determined by analysis of the patient's biochemical or genetic make-up. An example of this approach is the use of a companion diagnostic test to allow use of Iressa for the treatment of lung cancer, specifically in those patients who have an activating mutation of the endothelial growth factor receptor.

#### **R&D** productivity

The research-based pharmaceutical industry continues to drive for increased productivity in R&D to ensure a strong pipeline of commercially viable medicines for launch. Companies have addressed this challenge in a variety of ways. Some have sought to increase output with limited incremental cost and others have restructured R&D functions to promote innovation and entrepreneurship. Others have acquired companies with synergistic development pipelines.

#### **Regulatory requirements**

The pharmaceutical industry is one of the most regulated of all industries. Whilst efforts to harmonise regulations globally are increasing, the number and impact of these regulations continue to grow. Since the withdrawal of Vioxx<sup>™</sup>, regulators have been applying a more systematic approach to safety assessment and the management of known and emerging risks both before and after a medicine is approved. Today, regulators also require greater amounts of safety data before approval than in the past. This has led to a change in the structure of development programmes and to the need for additional resources to carry them out. For example, companies might initially seek approval for a narrower list of medical indications, or request conditional approvals that may later be expanded through additional studies as part of a medicine's life-cycle management.

#### Competition

Our main competitors are other researchbased pharmaceutical companies that sell innovative, patent-protected, prescription medicines. Competition also comes from collaborations between traditional pharmaceutical companies and smaller biotechnology and vaccine companies.

Generic versions of drugs that are no longer patent protected also compete in the market. Manufacturers of generic drugs price them at a significantly lower level than the innovator equivalents. This is partly because generic manufacturers do not invest the same amounts in R&D or market development as research-based pharmaceutical companies, and therefore do not need to recoup that investment. Such competition generally occurs when patents expire but can also occur where the validity of patents is being disputed or has been successfully challenged before expiry. In addition, competition can occur when a generic medicine in the same product class as an innovator product (a product which does not yet have a generic equivalent) enters the market and competes to meet the same medical need.

To date, biologics have sustained longer life-cycles than traditional pharmaceuticals and have faced less generic competition. This is because the manufacturing process for biologics is generally more complex than it is for small molecule medicines and it is significantly harder to produce an identical copy of a biologic compared to a small molecule medicine. However, biologics are now becoming subject to competition from 'biosimilars' and, while the regulatory regimes for 'biosimilars' are less well established than those for generic small molecule medicines, regulatory authorities in Europe and the US are currently reviewing abbreviated approvals processes. Further information about the specific risk of the early loss and expiry of patents is explained in the Intellectual property section on page 31 and more general information regarding the principal risks and uncertainties faced by AstraZeneca can be found in the Principal risks and uncertainties section from page 80.

#### World pharmaceutical markets



Data based on world market sales using AstraZeneca's market definitions as set out in the market definitions table on page 206. Source: IMS Health.

#### **Expanding patient populations**



Population: 897 million GDP growth: 4.8% GDP per capita: \$44,466 Emerging Markets Population: 5,763 million GDP growth: 9.4% GDP per capita: \$3,640

Source: International Monetary Fund, World Economic Outlook Database, October 2009 Population figures are for 2008 GDP growth is based on real GDP in US dollars for the years 2003-2008

GDP per capita is nominal GDP per capita for 2008.

## Strategy and Performance How we did in 2009 and our plans for the future



"We face near-term challenges but I am confident that we can be among the best performers in this sector." Each year, at the beginning of our business planning cycle, we assess the challenges and opportunities presented by the market, stress test our short and long-term planning assumptions, and critically assess our strengths and weaknesses as an organisation. We do so to assure ourselves that, whatever our past successes, the strategic path we are following is the right one for the future.

This section summarises our strategic plans for the future as well as our performance against those plans in 2009.

#### **Our challenge**

In our Business Environment section from page 12 we outline the opportunities presented by expanding patient populations in Emerging Markets, unmet medical need and advances in science, as well as the pricing pressure and other challenges facing the pharmaceutical sector. Over the last 10 years, our healthcare revenue has grown from \$15 billion to almost \$33 billion and our Emerging Markets business has grown from 6% of our global revenue to 13%. Our challenge as a business is to be nimble in seizing the opportunities and managing the risks in order to build our competitive advantage.

We estimate that in the next five years, more than half our current revenue is subject to

potential loss through the ordinary course of patent expiries and loss of Regulatory Exclusivity protecting our products. This loss of intellectual property is an inherent feature of our industry that occurs naturally as part of the cycle of innovation, growth and renewal. It is, however, challenging to be able to synchronise the cycles of patent expiry and portfolio renewal. The goal for our planning process is to ensure that we can continue to sustain the cycle of successful innovation and thus continue to refresh our portfolio of patented products and generate value for shareholders.

#### Our strategy

The executive team, with the endorsement of the Board, believes that the most value-creating strategy for AstraZeneca is to remain a focused, integrated, innovationdriven, global, prescription-based biopharmaceutical business:

- > focused in that we will continue to be selective about those areas of the industry in which we choose to compete, targeting those product categories where medical innovation or brand equity continues to enable us to make acceptable levels of returns on our investments
- > integrated in that we believe the best way to capture value within this industry is to span the full value chain of discovery, development and commercialisation

- > innovation-driven in that we believe our technology base will continue to deliver innovative products that patients will want and for which payers will pay
- > global in that we believe we have the ability efficiently and effectively to meet healthcare needs in both Established and Emerging Markets.

We believe that there are continued opportunities to create value for those who invest in pharmaceutical innovation and that AstraZeneca has the skills and capabilities to turn these opportunities into long-term value.

#### Our priorities to 2014

The initiatives we are pursuing in the coming years are in line with those we reported on last year and we do so again overleaf in this Annual Report. These show that we are already on a path of change. Our 2009 review emphasised the need for the pace of that change to accelerate.

#### **Pipeline**

While remaining committed to scientific innovation to deliver a flow of new medicines, the need to further improve the productivity of R&D is a central part of our plans. Meeting this challenge will require continued investment in new skills and capabilities. It will also require our R&D organisation to undertake more transformational change than ever before. Our plans include a reduction in the number of disease area targets within our core Therapy Areas, a continued focus on external collaboration, some consolidation of our activities onto a smaller R&D site footprint, and other efficiency measures, subject to consultations with work councils, trades unions and other employee representatives and in accordance with local employment laws.

Our commitment to scientific innovation is coupled with our belief that successful delivery of our plans will require more external collaboration than ever before, including more extensive collaboration with industry and academic partners. External project opportunities will compete alongside in-house developments for funding from our new Portfolio Investment Board which will replace the R&D Executive Committee.

#### **Business growth**

Our enhanced programme of external collaboration includes working with payers. We are setting out to build an industry-leading capability in 'payer partnering' to ensure that the needs of our customers are clearly understood throughout R&D and included in our decision-making. In terms of the commercialisation of our products, we will continue to build on our leading positions in Established Markets. Our plans for growth will also build on the investments we have already made in Emerging Markets. In addition to commercialising the current and new product offerings being developed internally, we believe we can drive further growth by selectively supplementing our Emerging Markets portfolio with branded generic products sourced externally and marketed under the AstraZeneca brand.

#### **Business shape**

We will continue to use business improvement programmes, such as Lean Sigma, to drive efficiencies across the Group. We will also move further towards a more flexible cost base which will enable us to respond rapidly as our requirements change. To do this we will make greater use of outsourcing and strategic collaborations with other organisations.

#### **Culture and behaviour**

We define success not only by what we do but also by how we do it. Acting responsibly ensures we do things in the right way and in line with the expectations of shareholders, customers, payers, regulators and other stakeholders. We will continue to embed a culture of accountability across the Group, nurturing a spirit of innovation in all functions.

#### Implementation

Good progress has been made in the implementation of previously announced restructuring programmes. This has involved a reduction of 12,600 positions. Annualised benefits of \$1.6 billion were realised by the end of 2009, which are on track to grow to around \$2.4 billion by the end of 2010.

The next phase of restructuring, which includes completion of the previous programmes, some additional initiatives in supply chain and in selling, general & administration, as well as the R&D initiatives, will result in the realisation of a further \$1.9 billion in estimated annual benefits by the end of 2014. These programmes may, when fully implemented, involve up to an additional 10,400 job reductions.

#### **Our performance in 2009**

Set out in the next column is more information about how we measure and review our performance on an annual basis. For each of our strategic priority areas, the table overleaf summarises the initiatives we have been undertaking in support of them, our 2010 objectives, our KPIs and our performance against them in 2009.

#### Measuring our performance

Each business function is subject to an annual budget and target-setting process that includes developing financial and business forecasts, conducting sensitivity and risk analyses and setting relevant performance measures. Regular reviews are undertaken in each part of the business in order to monitor and assess progress against business and budget targets, and to assess key risks and mitigating actions. Longer term, 10-year forecasts are developed as part of our annual strategy review.

Quarterly internal reports provide the Board and SET with shared insight into progress against current year objectives and milestones for longer-term strategic goals. Performance is assessed using quantitative, comparative market, operational and financial measures and qualitative analysis.

In relation to our overall goal of creating enduring value for shareholders by being one of the best-performing pharmaceutical companies, we track shareholder value using the following financial performance metrics: sales growth (operating profit and margins); earnings per share growth; net operating cash flow (before debt repayment and shareholder distributions); shareholder distributions through dividends and share re-purchases; and TSR. We report our performance against those measures on pages 2 and 3 of this Annual Report, and with TSR graphs on page 114.

### Strategy, objectives and 2009 performance

Strategic priority	Initiatives	Objective for three years to end 2010
Strengthen the pipeline	initiatives	
To be one of the fastest and most productive companies in the industry through continuous improvement in	Accessing the best potential innovative medicines to meet unmet patient need through > small molecule and biologics R&D	Deliver two new product launches on average per year from 2010
our in-house R&D. Seek leading science outside AstraZeneca to broaden our research base and further strengthen	> externalisation	In order to achieve the above ensure we have 10 or more products in Phase III development or registration
our pipeline of new products	Embedding culture of continuous improvement through	
	<ul> <li>&gt; leading-edge science</li> <li>&gt; collaborations</li> <li>&gt; business efficiency</li> </ul>	
		Achieve a median composite eight-year product development cycle
Grow the business		
To maintain our position among the industry leaders through a continued	Building on leadership positions in existing markets	Deliver sales growth in line with market growth to provide a return on our investment
focus on driving commercial excellence	Expanding presence in important emerging markets	
	Driving high standards of sales force effectiveness, marketing excellence and customer support	
	Developing our brands to maximise patient benefit	Profitably launch in-licensed and existing projects
	and commercial potential	Securing new external commercial collaborations
Reshape the business		
To create an organisation with the flexibility and financial strength to	Implementing and expanding restructuring programme	Annual benefits of \$2.1 billion from restructuring
adapt quickly and effectively within a challenging and rapidly changing business environment	Operations' asset and sourcing strategy	Maintain margins
	Delivering continuous improvement across R&D through	Improve R&D unit costs by 15%
	<ul> <li>&gt; smarter working</li> <li>&gt; business process outsourcing</li> </ul>	
	G&A strategy	Achieve planned improvement in selling, general and administrative (SG&A) costs
	<ul> <li>Marketing, sales and commercial strategies</li> <li>&gt; Western Europe and Emerging Markets resource optimisation plans</li> <li>&gt; North America – customer-driven interactions</li> </ul>	
	Procurement strategy	Procurement savings
Promote a culture of responsibility and acco	ountability	
To create an organisation that is recognised not only for the skills, experience and quality of its people,	Maintain/improve levels of employee engagement	Upper quartile industry ranking for employee engagement
but also for the integrity with which it conducts its business	Strengthening leadership development frameworks	Achieve step change in leadership and management capability
	Integrating responsible business considerations into everyday business thinking and decision-making	Ensure that a culture of responsible business, including compliance, is embedded across all our activities

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	Measure	2009 performance summary
	Regulatory approvals	Onglyza <sup>™</sup> approved in 36 countries; <i>Iressa</i> approved in the EU H1N1 influenza vaccine approved in the US. See Therapy Area Review from page 55
I	Projects entering development	29 projects entering development. See Strengthening the pipeline section on page 24
	Value-creating collaborations and business development activities	Major late-stage in-licensing deals signed with Targacept, Forest and Nektar Agreed to acquire Novexel. See Working with others section from page 22
	Major regulatory submissions	Submissions made for <i>Brilinta, Certriad, Vimovo</i> and Onglyza <sup>™</sup> /metformin; <i>Zactima</i> submission withdrawn H1N1 influenza vaccine approved in the US. See Therapy Area Review from page 55
	Development cycle times for small molecule and biologics/vaccines	On track to deliver 2010 targets. See Improving productivity section from page 24
	Deliver targeted sales and contribution	Global sales +7% at CER. See 2009 Results of operations section from page 38
	growth (at CER)	
:	Successful life-cycle projects	Additional approvals in the US for <i>Seroquel</i> and <i>Seroquel XR</i> ; presented results of <i>Crestor</i> JUPITER trials and regulatory submissions made in the US and the EU. See Therapy Area Review from page 55
	Successful launches	Onglyza <sup>™</sup> launched in the US and the EU; <i>Iressa</i> launched in the EU <i>Symbicort</i> approved in Japan and launched in January 2010. See Therapy Area Review from page 55
(	Commercial collaborations	Four major co-promotion collaborations signed (Abbott, Astellas, UCB and Salix). See Working with others section on page 22
(	Cost savings	Annualised benefits of \$1.6 billion in 2009. See Strategy and Performance section from page 14
(	Gross margin	Target exceeded: core gross margin of 83%. See 2009 Results of operations section from page 38
-	Operating profit margin	Core operating profit margin of 41.5%. See 2009 Results of operations section from page 38
l	Unit cost metrics	Progress towards target. See Improving productivity section from page 24
	SG&A cost growth rates	Core SG&A growth of 5%. See 2009 Results of operations section from page 38
	Cost savings	Delivered savings of \$555 million against a target of \$500 million
	Levels of employee engagement as measured by our global employee survey (FOCUS)	86% of our employees completed the FOCUS survey, and employee engagement improved by 2 percentage points from 2008. This is above the industry average. See Engagement and dialogue section on page 34
	Improve senior leadership clarity of direction as measured by our FOCUS survey	2009 score improved by 3 percentage points over 2008 to 72% favourable. This follows significant efforts to improve the quality and effectiveness of senior leaders' communication to the organisation. See Engagement and dialogue section on page 34
	Number of confirmed breaches of external sales and marketing regulations or codes	24 confirmed breaches of external sales and marketing regulations or codes. See Sales and marketing ethics section from page 29
-	Greenhouse gas emissions <sup>1</sup>	9% reduction in $CO_2$ emissions. See Climate change section on page 76
1	Waste production <sup>1, 2</sup>	8% reduction in total waste production. See Waste management section on page 76
-	Rate of accidents with serious injury <sup>1</sup>	2% reduction in accidents with serious injury. See Safety, health and wellbeing section on page 35
-	Rate of occupational illness <sup>1</sup>	32% increase in cases of occupational illness. See Safety, health and wellbeing section on page 35

<sup>1</sup> Data exclude MedImmune. <sup>2</sup>We have replaced our previous ozone depleting potential (ODP) KPI with waste production, as we believe it is now a more meaningful environmental sustainability indicator for AstraZeneca. ODP data continue to be published on our website, astrazeneca.com/responsibility.

## Resources, Skills and Capabilities How we deliver our strategy

#### We believe that the following resources, skills and capabilities are key to achieving our goals for the longer-term success of our business:

- > a world-class R&D function focused on delivering a range of innovative and differentiated medicines that meet unmet medical need and for which customers are prepared to pay
- > a sales and marketing activity which is truly global in its approach, listens to customers and focuses on their needs
- > a cost-effective supply and manufacturing operation that ensures our customers receive a reliable supply of medicines when they want them.

We also need to have cost-effective and flexible support services and infrastructure to ensure we meet our customers' needs as efficiently as possible.

To optimise our use of these resources, skills and capabilities, we need to:

- > protect our investment in R&D through a rigorous process of patent protection that optimises our intellectual property
- > have access to the best external sources of innovation to complement and build on our internal skills and capabilities.

Above all, we cannot achieve our goals without AstraZeneca **people** and the diverse skills and capabilities that a global workforce brings to our business. In everything we do we seek to act as a **responsible business** and are committed to developing in a sustainable way.

In this section we describe how we are using our resources, skills and capabilities to deliver our goals.

#### **Our products**

We focus on six Therapy Areas: Cardiovascular, Gastrointestinal, Infection, Neuroscience, Oncology and Respiratory & Inflammation. These represent a significant proportion of the world's burden of disease.

#### **Our medicines** Our heritage

Backed by our 70 year track record of pharmaceutical innovation, we have a broad range of marketed medicines that continue to make a positive difference in important areas of healthcare.

Our range of medicines includes 10 products each with annual sales of over \$1 billion in 2009. Our business growth in the short to medium term is expected to be driven by three factors: (1) our key products *Crestor*, *Seroquel XR* and *Symbicort*; (2) the successful launch of the next wave of products from our pipeline, which includes Onglyza<sup>™</sup>, *Brilinta*, *Certriad*, *Vimovo*, *Recentin*, motavizumab, dapagliflozin, zibotentan, NKTR-118, TC-5214, ceftaroline and CAZ104; and (3) from expansion in Emerging Markets, through 70 year track record of pharmaceutical innovation

organic growth of products from our current portfolio and pipeline but also through selective additions of AstraZeneca branded generics. For further information about our branded generics strategy see the Sales and marketing section from page 28.

#### A collaborative approach

Our medicines are testament to the combined skills of AstraZeneca people, our collaborators and our commitment to working closely with physicians, patients and others to understand what they need and what they value. Such relationships have helped us develop families of medicines, generation by generation, such as our hormone-based cancer treatments, including *Arimidex*, which have played a part in increasing the five year survival rate for women with breast cancer from under 70% 50 years ago to around 90% today.

Our collaborations are crucial to what we do and how we do it. For example, a programme of externalisation and our own internal project work has been at the heart of our work since 2006 in developing a world-class diabetes portfolio. From a position where we had no clinical projects in diabetes, we now have a portfolio with three medicines in Phase I studies and a further one in Phase IIb studies. Dapagliflozin is undergoing Phase III studies and is one of the compounds we are developing in collaboration with BMS. In 2009, this collaboration resulted in the approval of Onglyza<sup>™</sup> in both the US and EU for the treatment of Type 2 diabetes.

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#### Medicines for more patients

Even before a medicine comes to market, we develop programmes which are designed to optimise both the benefit medicines bring to patients' lives and their commercial potential within the timeframe that patent protection is available to us. We continue to do so throughout the whole life of a medicine. In particular, we continue to look for new disease indications for which a marketed product might have efficacy.

For example, *Crestor*, our statin for managing cholesterol levels, has been used to treat over 19 million people since its launch in 2003. Subsequent studies showed that *Crestor* also slows the progress of atherosclerosis (hardening of the arteries) in patients with elevated cholesterol levels. The JUPITER study in 2008 demonstrated a significant reduction in major cardiovascular events (44% compared to placebo) in men (over 50) and women (over 60) with elevated high-sensitivity C-reactive protein but low/normal cholesterol levels. In 2009 regulatory submissions were made in the US and the EU to reflect the significant reductions in such events.

Similarly, we first introduced Seroguel as a treatment for schizophrenia. Subsequent studies have shown that it is also effective in treating both the manic and depressive dimensions of bipolar disorder. Seroguel and Seroquel XR are the only agents approved in the EU to treat all phases of bipolar disorder. In the US, in 2009, Seroquel was approved for the treatment of schizophrenia in adolescents and for the acute treatment of manic episodes associated with bipolar disorder in children and adolescents. Seroquel XR was also approved in the US as an adjunct treatment in adults with major depressive disorder (MDD). Our approach to developing generations of drugs to meet new areas of unmet medical need continues and is illustrated by the announcement of a further collaboration and licence agreement with Targacept for the global development and commercialisation of TC-5214, their late-stage investigational product for MDD.

We also continue to develop better ways in which our medicines can be used. Our *Symbicort* maintenance and reliever therapy (*Symbicort SMART*) was the first asthma treatment regime to combine both regular maintenance and as-needed reliever therapies. This allows patients to control daily symptoms and reduce the severity and number of asthma attacks using a single inhaler.

#### Product performance summary \$m

<b>Nexium</b> (-1%)	
2009	4,959
2008	
2007	5,216

#### **Crestor** (+29%)

2009 2008 2007	<b>4,502</b> 3,597 2,796
Symbicort (+23%)	
2009	2.294

2009 2008 2007	
Pulm	<i>icort</i> (-10%)

### **Zoladex** (0%)

2008

<sup>1</sup> Acquired in June 2007.

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First approved in 1997, *Seroquel* is now approved in 94 countries Symbicort is approved for use in 97 countries

### **Seroquel** (+12%)

2009	 4,866
	4,452
2007	4,027

#### Seloken/Toprol-XL (+84%)

2009	1,443
2008	807
2007	1,438

#### Arimidex (+7%)

Arimidex (+7%)	
2009 2008 2007	<b>1,921</b> 1,857 1,730
<b>Atacand</b> (+5%)	
2009 2008 2007	<b>1,436</b> 1,471 1,287
<b>Synagis</b> <sup>1</sup> (-12%)	
2009 2008	<b>1,082</b> 1,230 618
	2009 2008 2007 <i>Atacand</i> (+5%) 2009 2008 2007 <i>Synagis</i> <sup>1</sup> (-12%) 2009 2008

AstraZeneca Annual Report and Form 20-F Information 2009

# The safety of patients is a fundamental consideration



Christer Köhler Interim Executive Vice-President, Discovery Research

"Having the best science is not enough – people with the capabilities to turn that knowledge into great medicines is what brings success."

Other developments with *Symbicort* exemplify our approach to optimising the benefit of our medicines for patient health both in terms of bringing benefits to additional patient groups and working with third parties. In 2009, *Symbicort Turbuhaler* was approved in Japan to treat adult asthma and it was launched in Japan in January 2010. In August, we signed an agreement with Astellas to co-promote *Symbicort Turbuhaler* in Japan. *Symbicort Turbuhaler* is also now approved in 96 countries for use in treating chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

In addition to small molecules we also have a strong capability in biologics. For example, *Synagis* is routinely used by hospitals for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV), a respiratory infection in infants, and has been administered to over one million premature babies. *Synagis* was the first MAb approved in the US for the prevention of an infectious disease. Since its launch in 1998 it has become the standard of care for RSV prevention.

Our biologics capability is also exemplified by our influenza vaccines, where we have developed technologies that enable innovative ways of reverse-engineering new vaccines. *FluMist*, the first nasal spray influenza vaccine to be approved in the US, represented the first innovation in flu vaccination in more than 60 years. Our total product supply of approximately 10 million *FluMist* doses sold out in 2009. Our technology also enabled us to develop, and to be the first to market in the US, a vaccine designed to prevent H1N1 influenza (swine flu). We received approval for our H1N1 influenza vaccine in September and then contracted with the US Department of Health and Human Services for 42 million doses, which we manufactured and distributed on time and to schedule.

Further information about all our major products can be found in the Therapy Area Review from page 55. Many of our products, for example, *Seroquel* and *Crestor*, are the subject of product liability claims and patent challenges. Information about material legal proceedings can be found in Note 25 to the Financial Statements from page 166.

#### Investing for the future

Within each of our Therapy Areas, the individual disease areas in which we work are agreed using a regular review process that enables us to deploy our resources in the best way to meet our commercial and scientific objectives. We evaluate market opportunities against a set of criteria, including unmet medical need, competitive position and our capabilities. Our R&D Executive Committee, which will be replaced in 2010 by the Portfolio Investment Board (further details of which are set out in the R&D Executive Committee section on page 92) uses the reviews to determine the levels of investment we will make in different disease areas.

### Our approach Patient safety

The safety of the patients who take our medicines is a fundamental consideration for us. All drugs have potential side effects and we aim to minimise the risks and maximise the benefits of each of our medicines – starting with the discovery of a potential new medicine and continuing throughout its development, launch and marketing.

After launch, we continually monitor the use of all our medicines to ensure that we become aware of any side effects not identified during the development process. This is known as pharmacovigilance and is core to our ongoing responsibility to patients. We have comprehensive and rigorous pharmacovigilance systems in place for detecting and rapidly evaluating such effects, including mechanisms for highlighting those that require immediate attention. We also work to ensure that accurate, well-informed and up-to-date information concerning the safety profile of our drugs is provided to regulators, doctors, other healthcare professionals and, where appropriate, patients. Clinical studies, although extensive, cannot replicate the complete range of patient circumstances. Rare side effects can often only be identified after a medicine has been launched and used in far greater numbers of patients and over longer periods of time.

We have an experienced, in-house team of around 350 clinical patient safety professionals working around the world who are dedicated to the task of ensuring that we meet our commitment to patient safety. This number of people is lower than in 2008 because data entry of individual case reports is now managed by an external provider (as described below). At a global level, every medicine in development and on the market is allocated a Global Safety Physician and a team of patient safety scientists. In each of our markets we also have dedicated safety managers with responsibility for patient safety at a local level.

Our two Chief Medical Officers (CMOs) have overall accountability for the benefit/ risk profiles of the products we have in development and those on the market. One CMO is responsible for our small molecule products, the other for our biologics. They provide medical oversight and ensure that appropriate risk assessment processes are in place to enable informed decisions to be made about safety as quickly as possible.

In 2009, we appointed Tata Consultancy Services Sverige AB to manage the data entry process for safety reports relating to AstraZeneca products. This is designed to improve efficiency and consistency of data entry across AstraZeneca, and allow our patient safety teams to focus on case prioritisation, the medical aspects of patient safety and continuing to improve our safety science.

Our commitment to patient safety includes ensuring the security of our medicines throughout their manufacture and supply. We continuously monitor our business environment to identify any new or emerging product security risks and work to ensure that these are managed quickly and effectively. In addition to our internal processes, we use a range of measures against counterfeit medicines and continue to develop our capabilities in this area. These include introducing technologies that make it more difficult for counterfeiters to copy our products; conducting market surveillance and monitoring the supply chain to identify potential counterfeiting operations; responding rapidly to any reports of counterfeit AstraZeneca medicines: and working with regulators. healthcare professionals, distributors, law enforcement agencies and other organisations to protect patient interests. We also participate in a variety of anti-counterfeiting forums and programmes in the public and private sector, including WHO/Interpol's International Medical Products Anti-Counterfeiting Taskforce and

the Pharmaceutical Security Institute. Further information on counterfeiting can be found in the Product counterfeiting section on page 82.

#### **Pricing our medicines**

Continued innovation is required to address unmet medical need. Our challenge is to deliver innovations that bring benefits for patients and society at a level of investment and internal productivity that reflects the downward pressure on pricing.

Our global pricing policy provides the framework for optimising the profitability of all our products in a sustainable way. It balances many different factors, including ensuring appropriate patient access. When setting the price of a medicine, we take into consideration its full value to patients, those who pay for healthcare and society in general. Our pricing also takes account of the fact that, as a publicly owned company, we have a duty to ensure that we continue to deliver an appropriate return on investment to our shareholders.

We continually review our range of medicines (both those on the market and in the pipeline) to identify any that may be regarded as particularly critical to meeting healthcare needs. This may be either because they treat diseases that are (or are becoming) prevalent in developing countries, or because they are potentially a leading or unique therapy addressing an unmet need and offering significant patient benefit in treating a serious or life-threatening condition. In such cases, we aim to provide patient access to these medicines through expanded patient access programmes across all markets, including the US. We also support the concept of differential pricing in this context, provided that safeguards are in place to ensure that differentially priced products are not diverted from patients who need them, to be sold and used in more affluent markets.

#### Economic benefit

Our medicines play an important role in treating medical needs and in doing so they bring economic as well as therapeutic benefits. Effective treatments can help to save healthcare costs by reducing the need for more expensive care, such as hospital stays or surgery. They also contribute to increased productivity by reducing or preventing the incidence of diseases that keep people away from work.

"Our medicines... bring economic as well as therapeutic benefits."

60 We developed the first innovation in

influenza vaccines in over 60 years

AstraZeneca Annual Report and Form 20-F Information 2009



Executive Vice-President, Development

"I am passionate about creating a world-class R&D organisation that develops medicines which make a real difference to the health of people around the world."

#### Research and Development Strategy

Our R&D strategy is centred on delivering sustained business growth through a continuous flow of new and innovative medicines that meet unmet medical need at prices payers find acceptable. Our strategic objective is to deliver a flow of new medicines (two new molecular entities per year on average). In line with our ongoing externalisation strategy, we continue to look beyond our own laboratories, and actively seek acquisitions and alliances with third parties to gain access to the best science and/or technology platforms. In 2009, we completed three Phase III ready in-licence deals (2008: three). In addition, we have acquired Novexel (completion of the acquisition is subject to the expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act) thus gaining access to two further compounds: one of which is Phase III ready and the other of which is Phase II ready.

We are creating a knowledge-driven organisation by investing in information sources and tools to allow our scientists to integrate and exploit internal and external knowledge, as well as share this knowledge and enable innovative ways of working across the organisation. This information sharing culture is allowing our pre-clinical and clinical scientists to work together to select high quality targets and compounds and to design clinical studies to establish quickly whether our compounds could become safe and effective medicines of the future. We are also focused on integrating our tools and databases to develop predictive platforms across R&D.

#### **Our capabilities**

AstraZeneca has had a long history of successful research leading to innovative, effective and valued medicines. We recognise the need to build on this tradition and this is reflected in our strategy.

As we develop potential medicines through a structured programme of studies, our focus is on ensuring that they are developed effectively to meet the needs of patients, regulators and payers. We do so by applying the best science to clinical need by designing appropriate programmes that ultimately deliver successful submissions to regulators. To this end, our cross-functional project and product teams bring together all the relevant skills and experience needed to ensure the rapid development of effective new medicines. They also manage the associated risks and ensure that quality and safety remain fundamental considerations at every stage.

Our R&D function has access to leading-edge technologies and capabilities such as stem cells and RNA interference technology which support the development of therapeutic agents across a range of Therapy Areas. Our medicines' pipeline spans all modalities with the majority of our late-stage pipeline

#### Working with others

We recognise that we cannot achieve our strategic goals on our own. To deliver successful medicines to market we need to work with doctors, patients and other stakeholders to understand what they need and want. We work with governments and those who pay for healthcare to ensure our products represent value for money. We also look to develop new ways of working with others who complement our existing skills, enhance our internal innovation or bring extra value to what we do. In doing so, we work to ensure that those we work with meet our high ethical standards.

#### Innovation, value and externalisation

In a world of rapidly advancing science and technology, no pharmaceutical company can rely exclusively on its own resources if it is to stay at the forefront of pharmaceutical innovation. Through our strategy of 'externalisation', we seek to expand our product portfolio and geographical presence through, for example, technology licensing arrangements and strategic collaborations and, where appropriate, acquisitions of complementary businesses.

Accessing products through externalisation is a key component of our efforts to both strengthen our pipeline of new products and to access opportunities to drive short-term growth. Our Strategic Planning and Business Development team works closely with our R&D, Global Marketing and Finance teams to deliver this.

We have completed over 60 major externalisation deals in the last three years as well as numerous smaller deals to enhance and strengthen the portfolio. Further details of the current status of a number of the products concerned can be found in the Therapy Area Review from page 55.

Significant late-stage deals completed in 2009 include the in-licence of ceftaroline, a next generation anti-infective, from Forest, and the in-licence of NKTR-118 and NKTR-119 from Nektar to address opioid-induced constipation. In December, we also successfully concluded a major in-licence agreement with Targacept for TC-5214, a late-stage product for major depressive disorder, and acquired Novexel (completion of the acquisition is subject to the expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act) to further build the infection portfolio.

Early-stage deals help build longer-term strength in the portfolio and in June we concluded a ground-breaking deal with Merck under which the two companies will collaborate to research a novel combination anti-cancer regimen composed of two investigational compounds, MK-2206 from Merck and AZD6244 from AstraZeneca (in-licensed from Array). Other significant early-stage deals included a risk-share collaboration with Jubilant aimed at multiple neuroscience targets, and a further collaboration with the Institute of Cancer Research (UK) and Cancer Research Technology Limited.

During the year we also signed exclusive worldwide licence agreements with Catalyst Biosciences, Inc. to develop novel engineered proteases and with Trellis Bioscience Inc. to develop and commercialise antibodies focused on respiratory syncytial virus.

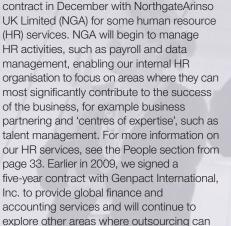
Deals that will help drive short-term growth include a co-promotion agreement for Abbott's Trilipix<sup>™</sup> in the US, a commercialisation agreement with Astellas for *Symbicort* in Japan, a distribution agreement with UCB for Cimzia<sup>™</sup> in Brazil and a co-promotion agreement with Salix for *Nexium* in the US.

Another component of our externalisation strategy is to maximise value from our portfolio through disposals and out-licensing transactions. In 2009, part of our Swedish OTC (over-the-counter) portfolio was divested to GlaxoSmithKline and rights to ophthalmological indications for a number of AstraZeneca assets were granted to Alcon. Other disposals of note included the out-licence of two pre-clinical oncology assets to Celleron Therapeutics Limited and the divestment of a P38 Inhibitor programme to Flexion Therapeutics AG.

#### **Outsourcing and contract manufacturing**

As part of our drive to reshape the business we also outsource certain activities where we believe we can take advantage of third party expertise. Using specialist providers helps us improve efficiency and focus on our core business. Outsourcing also reduces costs and creates a more flexible cost base which can be changed as our needs change.

We have already contracted out a significant portion of our supply and manufacturing activity and are undertaking a programme of outsourcing other services and activities, including some R&D processes, information services, facilities management and other internal support functions.



As part of our effort to ensure we have

cost-effective and flexible support services,

we signed a seven-year global outsourcing

Responsible procurement

service and reducing cost.

Our commitment to responsible business extends to ensuring that we work only with suppliers who embrace standards of ethical behaviour consistent with our own. This is required by our Code of Conduct and applies across the full range of our procurement activities worldwide.

bring benefits to the business by improving

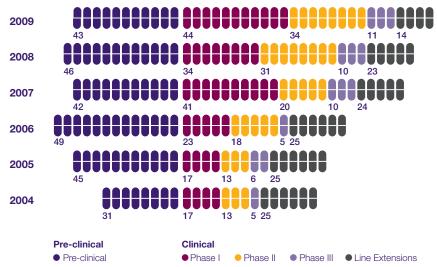
Implementing our approach across the many thousands of suppliers we have around the world is a significant challenge for a global company the size of AstraZeneca. We have made some good progress in recent years and to further strengthen our effort in this area, in 2009 we published a new Global Responsible Procurement Standard. This standard defines our Responsible Procurement Process and provides clear direction about our risk-based approach to integrating ethical standards into our procurement to incorporate a responsible business clause in contracts with suppliers. Training in the new standard was provided for procurement professionals during 2009. For all AstraZeneca employees, our Code of Conduct training now includes a responsible procurement awareness module.

Our Responsible Procurement Process is based on an escalating set of risk-based due diligence activities, applied in a pragmatic way. We assess a supplier's ethical risk areas and identify whether further assessment is needed to assure us that the supplier has appropriate systems and controls in place to meet our ethical expectations. The same initial assessment process is used for all suppliers and more detailed, specific assessments are then made as required, proportionate to the level of risk a supplier presents. Our process allows us to share issues with suppliers and encourage them to improve their standards, rather than automatically excluding them from our supply chain. However, we will not use suppliers who are unable or unwilling to embrace, in a timely way, standards of ethical behaviour that are consistent with our own.

In 2009, we completed responsible procurement assessments of over 800 of our suppliers (representing over 65% of our total spend on third parties) and implemented further assessments where required. This ongoing assessment programme will continue throughout 2010.

Our existing supplier evaluation procedure requires that comprehensive on-site supplier audits of all our high-risk manufacturing suppliers are conducted at least once every four years. Medium-risk suppliers are audited at the start of the business relationship and additional audits conducted if there are significant changes at a supplier. These Integrated Supplier Evaluation Protocol (ISEP) audits cover a range of risk areas, including product security and waste handling as well as social elements, such as human rights and labour standards. During 2009, we conducted ISEP audits at 51 manufacturing sites at 45 different suppliers (2008: 34 sites at 31 suppliers). The 2008 figures are higher than reported last year because a post year end review identified that more audits had been conducted than reported in 2008.

Performance



**Development projects – new products and line extensions** 

comprising small molecules. We also have a pipeline of biological approaches to targeting disease which includes antibodies, antibody derivatives, therapeutic proteins, peptides, and various types of live attenuated and sub-unit vaccines.

Our R&D activities cover the entire life-cycle of a medicine – from the initial discovery of a new chemical/molecular entity, through the rigorous phases of pre-clinical and clinical studies in man. After a medicine's launch, our life-cycle management process (including line extensions) is designed to ensure both its continued safe use and to explore its potential for treating other diseases or extending its use into additional patient populations.

Our research process starts with the analysis of many thousands of compounds for their potential to become a new medicine. Only a few make it through the various stages and we work continuously to improve the quality of our chemical leads and biological targets, while working to eliminate, at an early stage, those compounds that are unlikely to succeed. We have also invested in a number of key academic collaborations to identify potential new targets, disease mechanisms and technology platforms. We continue to use Lean Sigma-based business improvement programmes. For example, through improvements in novel compound flow, material handling, and enhancement of many key decision-making tests, we have seen significant reductions in the turnaround time of data in drug hunting projects. We have also extended this way of working to a key supplier of compounds from China to improve our joint processes.

We use biomarkers to help identify the efficacy and safety of our compounds. Biomarkers are biological factors or measures that can be used to quantify the progress of a disease and/or the effects of a treatment, although it is not always easy to identify a marker for each molecule.

As responsible participants in the provision of valued medicines for patients we believe strongly in helping to ensure that the right medicines are prescribed to the right patients at the right doses - this is our interpretation of 'personalised healthcare'. With this in mind we are investing in finding new ways to differentiate patients with apparently similar diagnoses. A successful example of this approach is the recent European regulatory approval of Iressa for patients with lung cancer who have an activating mutation of the endothelial growth factor receptor. As part of this approach we signed a collaboration agreement in December with Dako, a world leader in cancer diagnostics. We will work together with Dako to develop new medicines linked to diagnostic tests to predict which patients are most likely to respond to potential oncology treatments.

Even before clinical studies begin, safety assessment is a critical part of our research. A process including both *in vitro* and using computer modelling allows for 'high throughput testing' for safety early in the stages of selecting the best compounds for development. Our Lean Sigma approach has driven a series of process improvements which have reduced the loss of compounds in late-stage clinical development on account of safety concerns and cut the time taken to deliver key safety studies, without compromising quality. Testing for safety is also carried out on animals before it is carried out in man. For further information see the Animal research section from page 26.

#### Strengthening the pipeline

In the short term, we have continued to build on the strong portfolio growth achieved over the last few years. Our portfolio volume in clinical phases has grown by 5% in 2009 and the distribution of the projects between the various phases of development continues to improve. In the medium term, we will continue to drive our pre-clinical and clinical Phase I and II projects towards proof of concept as rapidly as possible. We have a wide range of compounds across all modalities in early development and a total of 44 projects in Phase I, 34 projects in Phase II and 11 projects in Phase III/Registration development and are running 14 significant life-cycle management projects.

Further details are set out in the Development projects chart above and the Pipeline by Therapy Area chart opposite and in the Development Pipeline table from page 196.

#### Improving productivity

The progress we are making in our drive to increase productivity continues to be reflected in the delivery of projects from the pre-clinical study phase (Discovery) and the growth of our early clinical study (Development) portfolio where we have embedded a culture of Lean Sigma. During 2009, 29 projects were selected for Development (2008: 32). Throughout 2009, we focused on driving continuous improvement activities across the entire R&D value chain. We maintained and improved the performance gains in cycle times achieved in 2008 for small molecules.

The use of predictive approaches in pre-screening of candidate molecules has had notably increased success rates in some areas in recent years. For example, we have seen failure in early Development due to genotoxicity fall to zero, and failure due to drug metabolism and pharmacokinetics has reduced significantly. Further application of these predictive approaches to the design and simulation of clinical trials using data from previous studies reduced the duration of the clinical trial for one Phase II project by one to two years, and its full projected development cost reduced by over \$100 million.

Despite this improvement in productivity, we recognise the need to improve our rate of success in progressing projects from Phase II to Phase III. This is a focus for our future efforts.

#### Our resources

At the end of 2009, we had a global R&D organisation with around 11,600 people (10,500 full time equivalent employees) at 17 principal centres in eight countries.

Our main small molecule facilities are in the UK (Alderley Park, Macclesfield and Charnwood); Sweden (Lund, Mölndal and Södertälje); and the US (Waltham, Massachusetts and Wilmington, Delaware). Other sites which have a focus on research are in Canada (Montreal, Quebec); France (Reims); and the UK (KuDOS and Arrow Therapeutics' sites). We have a clinical development facility in Osaka, Japan. Our principal sites for biologics and vaccines are in the US (Gaithersburg, Maryland and Mountain View, California) and the UK (Cambridge).

As part of our strategic expansion in important Emerging Markets, we continue to strengthen our research capabilities in Asia Pacific. Investment continued during 2009 at our 'Innovation Centre China' research facility in Shanghai, which opened in 2007. Our research facility in Bangalore also continues to grow with capital investment supporting increases to R&D resources in India. Both facilities are increasingly involved in Development activities.

In 2009, we invested \$4.4 billion in R&D (2008: \$5.2 billion; 2007: \$5.2 billion), \$764 million on acquiring product rights (such as in-licensing), and additionally approved \$329 million of R&D capital investment to strengthen our resources in line with our strategic objectives.

Several major capital projects were completed during 2009, and the facilities handed over to the business, including laboratory and office expansions in Boston (US), a new laboratory facility in Macclesfield (UK) and a new manufacturing facility in Mölndal (Sweden). Of the approved capital investment of \$329 million, there were no new major small molecule R&D investments authorised during 2009. The focus of the \$79 million that has been authorised is on improving and enhancing existing facilities. The remaining \$250 million of approved investment was associated with our biologics laboratories in the US and the UK, and influenza vaccine programmes.

#### Pipeline by Therapy Area at 28 January 2010

				<i>Recentin</i> (NSCLC) ▲ AZD6244 <sup>#</sup> (ARRY-142886) ▲			
		MEDI-534 🔺		Olaparib (formerly AZD2281) (gBRCA breast cancer) ▲			
		MEDI-560 🔺		Olaparib (formerly			
		MEDI-550 🔺		AZD2281) (serious			
	AZD4769 🔺	(formerly MEDI	-566) AZD0837	ovarian cancer) 💸			
	AZD8931 🔺	MEDI-557 🔺	AZD6370 🔺	AZD1152			
	AZD7762	MEDI-559 🔺	AZD1656	AZD7295			
AZD6482 🔺	AZD8330#	AZD9742 🛠	Lesogaberan	CytoFab <sup>™#</sup> ▲	Onglyza™# ◆		
AZD4017 🔺	(ARRY-424704) 🛦	CEF104#* �	(AZD3355) 🔺	MEDI-3250 �	Brilinta/Brilique 🕨		Seroquel (bipolar) ♦
AZD6714 🛠	CAT-8015 🔺	AZD5847 🗇	AZD1386 🕂	CAZ104#* �	Certriad# D	_	Seroquel XR (MDD) 🖈
AZD8329 🛠	AZD8055 🔺	CAM-3001# 🔺	AZD3480#	AZD1981 🔺	Dapagliflozin# 🔺	_	Seroquel XR (GAD) 🔺
AZD7687 🛠	MEDI-573 🛠	AZD8566	AZD6765 🔺	MEDI-528#	Vimovo# 🕨	Crestor	Iressa 🔶
AZD2066 🔺	MEDI-575 🛠	AZD8075	AZD2327 🔺	CAT-354 🔺	Zactima <sup>+</sup>	(elevated CRP) ▶	Faslodex (500mg) 🕨
AZD2516 🚸	AZD1480 🛠	AZD5985 🔺	AZD2066 🕂	AZD9668	Recentin (CRC) 🔺	Onglyza <sup>™</sup> /	Faslodex
AZD3241 🔺	MEDI-547# 🛠	AZD2551 🛠	AZD8529 +	AZD1236	Recentin (recurrent	metformin FDC# D	(1st line advanced
AZD6280 🔺	AZD2014 🛠	AZD5423 🛠	NKTR-118# �	AZD3199 🔺	glioblastoma)+ 🔺	Dapagliflozin/	breast cancer) 🔺
AZD2516 🔺	AZD6244	AZD5122 🛠	TC-5214# 🛠	MEDI-563#	Zibotentan	metformin FDC#	FluMist 🔺
AZD3043# 🛠	(ARRY-142886)	AZD8683 🛠	TC-5619# 🛨	MEDI-545#	(ZD4054) 🔺	Nexium (peptic	Motavizumab# 🔺
AZD8418 🛠	/MK2206# �	AZD5069 �	AZD7268 +	AZD9164 🛠	Motavizumab# 🔺	ulcer bleeding) 🔶	MEDI-3414
AZD2423 🛠	AZD4547 🛠	MEDI-546# 🛠	AZD1446# 🛨	AZD8848 🛨	Ceftaroline <sup>#</sup> 🛠	Axanum 🕨	(H1N1 influenza) �◆
Phase I			Phase II		Phase III/ Registration	Line extensions	
Кеу					registration		
Cardiovascular	Gastroin	testinal	Infection	<ul> <li>Additi</li> </ul>	on	New filing	Reclassified
Neuroscience	Oncolog	у	Respiratory & Inf ammat		0	★ Approved	
				+ Progre	esion	Launched	

+ Orphan Drug.

R&D investment Core	\$m
2009 2008	<b>4,334</b> 4,953
R&D investment Reported	\$m
2008 2007	<b>4,409</b> 5,179 5,162

#### Externalisation

Our externalisation strategy continues to focus on enhancing our internal innovation through investment, external collaborations and acquisitions that further strengthen our pipeline of products. Further information on our activities can be found in the Working with others section from page 22.

Our New Opportunities group has continued to seek additional value from our portfolio by facilitating re-profiling across our Therapy Areas and by identifying additional disease areas in which our compounds can meet unmet medical need. For example, in 2009 we concluded a strategic alliance with the ophthalmology company, Alcon, to identify innovative eye care products using AstraZeneca compounds in areas adjacent to our Therapy Areas of focus.

#### **R&D** ethics

We are committed to delivering innovation responsibly by setting and working to consistently high ethical standards across all aspects of our R&D worldwide. Compliance with relevant laws and regulations is a minimum baseline and underpins our own global principles and standards, as outlined in our global Bioethics Policy.

Further information about our commitment to responsible research is available on our website, astrazeneca.com/responsibility.

#### **Clinical trials**

We conduct an increasing number of our clinical trials at multiple sites in several different countries. A broad geographic span helps us to ensure that those taking part reflect the diversity of patients around the world for whom the new medicine is intended. This approach also helps to identify the types of people for whom the treatment may be most beneficial.

We take a number of factors into account when choosing a trial location. These include the availability of experienced and independent ethics committees and a robust regulatory regime, as well as sufficient numbers of trained healthcare professionals and patients willing to participate in a trial.

When conducting a trial anywhere in the world, we operate to the highest of the standards required by the external international, regional or local regulations, and our own internal standards.

Before a trial begins, we work to make sure that those taking part understand the nature and purpose of the research and that proper procedures for gaining informed consent are followed (including managing any special circumstances such as different levels of literacy). We also have procedures in place to ensure that the privacy of participants' health information is protected.

We take very seriously our responsibility to protect trial participants from any unnecessary risks and avoid any serious adverse reactions. Throughout the research process, we continuously review, and make judgements on whether the potential benefits of a new medicine continue to outweigh the risk of side effects.

Whilst all our AstraZeneca clinical studies are conceptually designed and finally interpreted in-house, some of them are run for us by external contract research organisations (CROs). The percentage of studies we place with CROs varies, depending on the number of trials we have underway and the amount of internal resources available to do the work. In 2009, around 24% of patients in our global studies of our small molecule portfolio and around 89% of patients in our biologics studies were monitored by CROs on our behalf.

Our clinical data handling is outsourced to Cognizant Technology Solutions Sweden AB, a business process solution company and during the year, we announced a strategic alliance with Quintiles Limited to provide integrated services for the majority of our clinical pharmacology studies. These sourcing decisions have helped us to promote consistency, drive resource efficiency and, importantly, helped to speed up our internal data interpretation and decision-making.

We remain committed to making information about our clinical trial activities publicly available. We publish information on the registration and results of all new and ongoing AstraZeneca sponsored clinical trials for all products in all phases, including marketed medicines, medicines in development and those whose further development has been discontinued. We post results, irrespective of whether they are favourable or unfavourable to AstraZeneca on public websites, including (for small molecule compounds) on our own dedicated website, astrazenecaclinicaltrials. com. By the end of 2009, we had registered over 1,100 trials and published the results of more than 600 trials.

#### Animal research

Our pre-clinical research includes animal studies, which continue to play a vital role in the R&D of new medicines. They provide essential information, not available through other methods, about the effects of a potential new therapy on disease and the living body.

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Regulatory authorities around the world also require safety data from pre-clinical testing in animals before a new medicine can be tested in man.

We are committed to the responsible use of animals. All our research using animals is carefully considered and justified and, backed by our Bioethics Policy, we continue to drive the application of the 3Rs (Replacement, Reduction and Refinement of animal studies) across our research activity. Wherever possible, we use non-animal methods such as cell culture, computer modelling and 'high-throughput screening' that eliminate the need to use animals early in drug development, or reduce the number needed. As part of our drive for continuous improvement, we continue to use statistical design to optimise our studies and reduce the numbers of animals needed. We also work to refine our existing animal models to ensure that the animals we use are exposed to as little pain and stress as possible. We continuously review all our animal studies to make sure that they continue to add value to our research decision-making processes.

The number of animals we use each year depends on the amount of pre-clinical research we are doing and the complexity of the diseases under investigation. We remain focused on making sure that we minimise the use of animals without compromising the quality of the research data. In 2009, we used approximately 393,000 animals in-house (2008: 347,000). In addition, approximately 17,000 animals were used by external contract research organisations on our behalf (2008: 29,000). We believe that this number would be much greater without our active commitment to the 3Rs. We no longer report, as a KPI, the number of animals we use in our research, although we will continue to publish the figures each year. This reflects our commitment to continuous improvement through the application of the 3Rs and good scientific practice, which we believe is the true indicator of our performance. More information about our commitment is available on our website, astrazeneca.com/responsibility.

We only use primates in circumstances where no other species or non-animal methods can provide the safety or clinical benefit information that we are seeking in a study, and where the outcomes of the study are likely to bring significant advances for the development of new medicines. Our expanding biologics capability means that we will be increasing our primate use over time, particularly in the development of MAbs targeted at important areas such as cancer and respiratory disease. MAbs are highly specific to human physiology, so primates are, in most cases, the only relevant animal model because of their similarity to humans.

In line with our global Bioethics Policy, AstraZeneca does not currently conduct or outsource work using wild caught primates or great ape species. In the rare case where there is a substantial medical need and no credible alternative model is available, exceptions may be considered. However, this will require rigorous secondary ethical and scientific review, in addition to our normal review processes, to challenge the need for the study, followed by appropriate Board level approval.

The welfare of all the animals we use continues to be a top priority. Compliance with relevant laws and regulations is a minimum baseline and underpins our own global Bioethics Policy and standards of animal care and welfare which apply worldwide. Qualified veterinary staff are involved in the development and implementation of our animal welfare programmes and everyone working with laboratory animals is trained and competent in their allocated responsibilities. As well as mandatory inspections by government authorities, we have a formal programme of regular audits carried out by our own qualified staff.

External contract research organisations that conduct animal studies on AstraZeneca's behalf are also required to comply with our ethical standards, and we conduct regular audits to ensure our requirements are being met.

In November 2008, the European Commission published its proposal to revise the 1986 EU Directive 86/609 (Directive) on the protection of animals used for scientific purposes. We support the need for Europe-wide legislation concerning the use of animals in research and revision of the Directive to reflect advances in science and technology. However, we are contributing to discussions about changes in a number of areas that we believe are necessary to ensure that, alongside the promotion of high standards of animal welfare, the new legislation supports the ability to conduct, in Europe, R&D that addresses patient needs.

#### Stem cell research

As a company whose success is built on leading-edge science, we continuously monitor and assess new research capabilities to identify opportunities that could help us deliver better medicines for patients worldwide. We believe that stem cell research may present several such opportunities in enhancing the drug discovery process as well as providing therapeutic options.

Significant scientific progress has been made in the development of stem cell-based research models for improved prediction of safety, metabolism and efficacy of emerging candidate drugs, with promising results. Our interest is in the potential of stem cells to differentiate into normal human cells, such as hepatocytes (liver cells) and cardiac myocytes (heart muscle cells) and use those cells in biological assays. We believe this could represent a significant step forward in increasing the clinical relevance of studies at an earlier stage of development of a potential new medicine and would help us to overcome the current limitations that a restricted supply of human cells presents. However, more work is needed to understand the full potential of this type of research. It is a relatively new area and we do not have all the necessary skills and technologies in-house. We are therefore working with external partners who have expertise and an ethical commitment consistent with our own, such as Cellartis AB (Cellartis), a biotech company focused on applications of human embryonic stem cells, cell technologies and the UK public-private partnership, Stem Cells for Safer Medicines. We also participated in a European Framework Research VI programme working with stem cells. Further collaborations will include the use of induced pluripotent stem cells.

Increasingly, we are also exploring the potential to treat disease by modulation of stem cells within target organs using either small molecules or biological therapies, an exciting new area often referred to as regenerative medicine. Here, we are embarking on several external collaborations, such as the one with Cellartis, combining the best ideas and latest innovation in academic research with our ability to search for new drugs. We are looking for the potential of molecules to direct the fate of stem cells towards therapeutic benefit in diseases such as diabetes and emphysema, thus identifying potentially new candidate drugs. Further investments will follow in this area.

Our commitment to ensuring high ethical standards is reflected in our Human Embryonic Stem Cell Research Policy framework, as set out in our Bioethics Policy, which demands compliance both with external legislation, regulations and guidelines, and with our own codes of practice.

# Medicines that patients will want and payers will pay for



"Wherever they are in the world, those who pay for our medicines and the patients who use them must remain the focus of everything we do."

#### Sales and marketing Customer focus

Our international sales and marketing organisation is active in over 100 countries. We have an extensive network focused on growing our business and driving levels of commercial excellence to maintain our position among the industry world leaders. As well as building on our leading positions in North America and Other Established Markets, such as Japan and Western Europe, we continue to increase our strength through strategic investment in Emerging Markets, where GDP growth and changing disease demographics present significant opportunities. See the market definitions table on page 206 for more information on AstraZeneca's market definitions.

Our Global Marketing function is responsible for developing and leading our global brand strategy. It ensures a strong customer focus and commercial direction in the management of our pipeline and marketed products. At an early stage in the medicine discovery process we define what we believe the profile of a medicine needs to be to work most effectively in combating a particular disease. These disease target product profiles (TPPs) are based on the insights we gain through our relationships with healthcare professionals, patients and others for whom the medicine must add value, including regulators and payers. The attitudes and needs of these groups are key drivers of the development of the TPPs which are used throughout the

life-cycle of a medicine to guide our R&D activity and help shape the Therapy Area and marketing strategies. Early in the development of new products, we also consider how best to demonstrate the value of our medicines to payers.

#### **Emerging Markets growth**

During the course of 2009, AstraZeneca continued to execute its ambitious investment strategy across Emerging Markets in large markets such as China, Mexico, Brazil and Russia, as well as in medium-sized and smaller markets where there is significant unmet medical need.

In China (including Hong Kong), as a result of its current strategic focus on 'Big Cities Big Hospitals', AstraZeneca is the second largest multinational pharmaceutical company in the prescription market.

Our strategy for Emerging Markets is based upon a rapid expansion of the commercial organisation across areas where we assess there to be significant market potential. In this context we provide our country leaders with the autonomy to tailor their strategies to local customer needs. These local plans are supported by AstraZeneca's global capabilities, one of which is a highly disciplined approach to sales force management.

To maximise these local opportunities, AstraZeneca has started to launch a range of branded genericised medicines. These medicines, which are within our key areas of therapy expertise, will make our products available to more patients and at lower price levels than is possible with patentprotected medicines.

As an example, to support our new branded generics business in India, we significantly increased our level of investment, enabling the launch of eight new products of which five were launched in the second half of 2009. This initiative will be rolled out in more than 20 Emerging Markets where we assess there to be potential.

#### **Customer choice in North America**

We continue to develop our sales and marketing effort in the US as we strive to best meet our customers' needs. The focus for 2009 was to ensure that our interactions with healthcare professional (HCP) customers match their desire for more flexible methods to access our products that are not solely dependent on the traditional sales representative.

As a result, two new customer teams have been created to deliver services and information. One team was charged with delivering all the traditional services, but to do so remotely and at a time that matched the HCP's schedule. The second team simply focused on delivering samples and patient support materials to the HCP's practice. At the same time, we have expanded our web-based capabilities to improve the way we deliver service over the internet.

The intended result of these changes is to offer customers choices about how we can best meet their needs and the needs of their patients.

#### **Reshaping in Other Established Markets**

Across Europe, we have significantly reshaped the organisation in order to stay competitive in an evolving market place. By focusing on core activities and building capabilities around these, we have strengthened focus in the critical area of market access, whilst also being able to significantly improve productivity in the sales force.

Market access is an increasingly important area. In order to develop products that meet the needs of payers we are focusing even more on understanding the priorities and agendas of both payers and healthcare providers. Building on this information, we seek to demonstrate how our products offer value and support cost-effective healthcare.

# Eight new products launched in India in 2009

#### An effective sales force

In the majority of markets, we sell through wholly-owned local marketing companies. Elsewhere, we sell through distributors or local representative offices. Our products are marketed primarily to physicians (both primary care and specialist) as well as to other healthcare professionals. Marketing efforts are also directed towards explaining the economic as well as the therapeutic benefits of our products to governments and others who pay for healthcare. Face-to-face contact is still the single most effective marketing method but, increasingly, the efforts of our sales force are being complemented by our use of the internet. In the US, where it is an approved and normal practice, we also use direct-toconsumer advertising campaigns for some products.

To improve our commercial effectiveness we are benchmarking with leading industries in the area of customer insight. This helps develop a better understanding of real needs of customers upon which we can plan and act. It allows us to be more focused in our communications with customers.

Our rapid growth in Emerging Markets is driving demand for central commercial support, particularly in respect of sales force effectiveness. Core sales and marketing training programmes have been adapted for, and deployed in, local environments. The main focus of these programmes is to embed core commercial skills and to strengthen sales managers' coaching and planning skills.

#### Working in collaboration

The preparations and launch of Onglyza<sup>™</sup>, the first brand in the AstraZeneca/BMS diabetes alliance, has brought significant experience and learning to both organisations. The joint work between our companies has improved planning, time to market and execution of the launch. In June, we entered into an agreement under which AstraZeneca obtained the non-exclusive right to co-promote Trilipix<sup>™</sup>, alongside Abbott in the US (excluding Puerto Rico). This is the second co-promotion agreement between AstraZeneca and Abbott, the first being for *Crestor*. We will continue to explore opportunities to work in collaborations at local or regional levels as a model to improve success. This could either be through getting access to commercial capabilities, such as the collaboration to sell *Symbicort* with Astellas in Japan, or to strengthen the portfolio, such as the collaboration with UCB for the commercialisation of UCB's Cimzia<sup>™</sup> in Brazil.

More information on our collaborations can be found in the Working with others section from page 22.

#### Sales and marketing ethics

Driving high ethical standards across all our sales and marketing activity is one of our top priorities. It is an important part of our overall commitment to patient health and safety, and to delivering business success responsibly.

Our business is global and culturally diverse. Societal expectations and legal requirements often vary significantly between the different countries in which we operate. We work to manage these differences effectively and deliver consistently high standards worldwide.

Everyone involved in sales and marketing activities is required to adopt the same core standards, regardless of their particular role or location. These standards are outlined in our Code of Conduct and supporting policies, and more detail is given in our regional and local marketing codes. Our local codes reflect differences in national legislation and healthcare systems. In cases where our standards differ from local law, we adopt whichever standard is higher. Our policies are regularly reviewed and updated, and targeted training is provided for our staff on an ongoing basis.

Compliance with our Code of Conduct and supporting policies is mandatory and monitored by line managers locally, with support from dedicated compliance professionals. We also have a nominated signatory network that works to ensure that our promotional materials meet all applicable internal and external code requirements.

Information concerning instances where our practices may not be up to the standards we require is collected through our various compliance and continuous assurance reporting routes and reviewed by senior management in local and/or regional compliance committees. As appropriate, serious breaches are reviewed by the Board and the Audit Committee. More information

### Breaches of external sales and marketing regulations or codes

2009	24
	15
2007	32

"Driving high ethical standards across all our sales and marketing activity is one of our top priorities."

about our compliance and risk assurance processes is contained in the Managing risk section from page 79.

In 2009, we identified a total of 24 confirmed breaches of external sales and marketing regulations or codes globally (2008: 15; 2007: 32). The increase over 2008 is, we believe, largely due to increased self-reporting (ie where we have identified that a breach has occurred and voluntarily reported it to the relevant national authorities). This reflects our continued internal vigilance and determination to identify and follow through on possible breaches of the high standards we set ourselves. The number should also be viewed in the context of the continuing diligence of external code of practice agencies and regulatory authorities in identifying and processing complaints.

We also received a number of approaches about sales and marketing practices from regulatory authorities and other bodies that did not result in any formal ruling. Although these incidents are not included in our KPI number, we did follow-up with appropriate actions to help ensure that all relevant learning is taken fully into account in our future activities.

We take all breaches very seriously and take appropriate action to prevent repeat occurrences. This may include retraining or other corrective action, up to and including dismissal.

In September 2009, AstraZeneca reached an agreement in principle with the US Attorney's Office to settle claims relating to *Seroquel* sales and marketing practices and to make a payment of \$524 million (including interest).

Final settlement is subject to negotiation of a civil settlement agreement and a corporate integrity agreement. More information can be found in Note 25 to the Financial Statements from page 166.

We will continue to work to strengthen our governance of our sales and marketing activity through 2010, including additional monitoring and audit programmes, and performance measurement. Whilst our current KPI has provided a benchmark against which to measure our performance in recent years, the variations among the national external regulatory frameworks continue to create a challenge for us in interpreting the number of cases of confirmed breaches of external regulations or codes. In addition, a single confirmed breach by AstraZeneca can involve more than one employee failing to meet the standards required and we are aware that there may be failures to meet standards which are not 'confirmed' and so will not affect the KPI. We are therefore currently reviewing more meaningful ways in which to measure our performance and plan to introduce a new KPI during 2010 which will drive further improvement and support increased transparency in this key aspect of our activity.



"Patent protection underpins the research-based pharmaceutical industry – we recognise it brings responsibilities as well as privileges."

# Innovative and differentiated medicines

#### Intellectual property

The discovery and development of a new medicine requires a significant investment of resources by researchbased pharmaceutical companies over a period of 10 or more years. For this to be a viable investment, the results – new medicines – must be safeguarded from copying with a reasonable amount of certainty for a reasonable period of time.

The principal safeguard in our industry is a well-functioning patent system that recognises our effort and rewards our innovation with appropriate protection, allowing time to generate the revenue we need to re-invest in new pharmaceutical innovation. We are confident of our innovations and therefore commit significant resources to establishing effective patent protection for them, and to defending vigorously our patent and related intellectual property rights if they are challenged.

#### **Patent process**

We apply for patent protection relatively early in the R&D process to safeguard our increasing investment. Further innovation will mean that we frequently take out additional patents as we develop a product and its uses. We pursue these patents through patent offices around the world. In some countries, our competitors can challenge our patents in the patent offices, and in all countries competitors can challenge our patents in the courts. We can face challenges early in the patent process and throughout the life of the patent. These challenges can be to the validity of a patent and/or to the effective scope of a patent and are based on ever-evolving legal precedents. There can be no guarantee of success for either party in patent proceedings. For information about third party challenges to the patents protecting our products, see Note 25 to the Financial Statements from page 166.

The generic industry is increasingly challenging innovators' patents, and almost all leading pharmaceutical products in the US have faced or are facing patent challenges from generic manufacturers. The research-based pharmaceutical industry is also experiencing increased challenges elsewhere in the world, for example in Europe, Canada, Asia and Latin America. Further information about the risk of the early loss and expiry of patents is contained in the Principal risks and uncertainties section from page 80.

#### **Data exclusivity**

Regulatory Data Protection (RDP or 'data exclusivity') is an important intellectual property right which arises in respect of certain data generated by our research activities, including clinical studies. Data which is required to be submitted to regulatory authorities in order to obtain marketing approvals for our medicines may be protected from use by third parties (such as generic manufacturers) for a specific number of years. The period of such protection differs significantly between countries. We believe in enforcing our rights to RDP and consider it an important protection for our innovations, particularly as patent rights are being increasingly challenged.

#### **Compulsory licensing**

Compulsory licensing (the overruling of patent rights to allow patented medicines to be manufactured and sold by other parties) is increasingly being included in the access to medicines debate. We recognise the right of developing countries to use the flexibilities in the World Trade Organization's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement (including the Doha amendment) in certain limited circumstances, such as a public health emergency. We believe that this should apply only when all other ways of meeting the emergency needs have been considered and where healthcare frameworks and safeguards are in place to ensure that the medicines reach those who need them.

#### **Patent expiries**

The following table sets out certain patent expiry dates for our key marketed products. These expiry dates relate to the basic substance patent relevant to that product unless indicated otherwise. The expiry dates shown include any Patent Term Extension and Paediatric Exclusivity periods. Additional patents relating to the stated products may have terms extending beyond the quoted dates.

US patent expiry
20151
2016
Expired
2012
2014 (substance combination)
2019 <sup>2</sup> (formulation)
2010
Expired
2012 (substance)/2017 (XR formulation)
2015

<sup>1</sup> Licence agreements with Teva and Ranbaxy allow each to launch a generic version in the US from May 2014, subject to regulatory approval.

<sup>2</sup> A licence agreement with Teva permits their ongoing US sale of a generic version from December 2009.



David Smith Executive Vice-President, Operations

"As we drive for ever-greater efficiency in producing our medicines, we work harder to ensure we control the quality of our products."

#### Supply and manufacturing

Core to our continued business success is our ability to provide our customers with a reliable supply of high quality medicines worldwide, when they want them, and to do so in the most costeffective way.

#### **Operational excellence**

We seek to maximise the efficiency of our supply chain through a culture of continuous improvement. We focus on what adds value for our customers and patients, and eliminates waste. Improvements have delivered significant benefits in recent years, including reduced manufacturing lead times and lower stock levels, which both improve our ability to respond to customer needs and reduce inventory costs. Changes have also been achieved without compromising customer service and quality.

We have been applying Lean business improvement tools and ways of working to improve the efficiency of our manufacturing plants for a number of years and have recently started to apply it to the whole of our supply chain. In 2009, we seconded two Lean experts from Jaguar Land Rover to apply their knowledge of efficient car manufacturing techniques to our pharmaceutical supply chain.

Our customer focus means our supply chains change as the needs of our local markets evolve. In 2009, we established regional offices. This included sourcing centres in Shanghai, China and Bangalore, India, which were created to identify local high quality suppliers to support growing market demand. We also established a regional packing strategy to improve our ability to respond to customer requirements, retain control over quality and thereby equip the business for growth in emerging markets.

During 2009, as part of our commitment to strategic sourcing, we sold our Dunkirk active pharmaceutical ingredient (API) facility and entered into a contract manufacture agreement with the purchaser for the supply of certain APIs from that site. As part of our continuous review of our manufacturing assets to make sure that they are being used in the most effective way we also completed the sale of facilities in Caponago, Italy and Porriño, Spain. We closed our manufacturing site at Destelbergen, Belgium and announced our intention to exit from the plant at North Ryde, Australia. We recognise the impact that these changes can have on our employees' morale and productivity and the increased risk of industrial action. We manage these risks by consulting fully with staff representatives and acting in line with local employment laws. Our human resources policies and processes are also focused on ensuring that the people affected are treated with respect, sensitivity, fairness and integrity. This commitment is covered in the People section from page 33.

#### **Product quality**

We are committed to delivering assured product quality that underpins both the safety and efficacy of our medicines.

Manufacturing processes for medicines can be very complex and must observe rigorous standards of quality. Both manufacturing plants and processes are subject to inspections by regulatory authorities to ensure compliance with prescribed standards which can vary between different regulatory authorities. Such authorities have the power to require changes and improvements, to halt production and impose conditions that must be satisfied before production can resume. Regulatory standards, and therefore manufacturing processes, can also change over time. We hosted inspections from many different regulatory authorities in 2009. All observations are reviewed along with the outcomes of our own internal inspections and improvement actions are put in place as required to ensure ongoing compliance with expectations. If required, we take action to improve quality and enhance compliance across the organisation. The knowledge obtained from the inspections is shared across the Group.

We continue to be actively involved in influencing new product manufacturing regulations, both at national and international levels, through our membership of industry associations primarily in the EU, the US and Japan.

#### Our resources

At the end of 2009, we had approximately 9,500 people at 20 manufacturing sites in 16 countries working on the supply of our products.

Capital expenditure on supply and manufacturing facilities totalled approximately \$360 million' in 2009 (2008: \$369 million'; 2007: \$336 million'). As part of our overall risk management, we carefully consider the timing of investment to ensure that secure supply chains are in place for our products. We have a programme in place to provide appropriate supply capabilities for our new products.

In addition to our plant at North Ryde, Australia (from which we have announced our intention to exit), our principal small molecule manufacturing facilities are in the UK (Avlon and Macclesfield); Sweden (Snäckviken and Gärtuna, Södertälje); the US (Newark, Delaware and Westborough, Massachusetts); France (Reims); Japan (Maihara); China (Wuxi) and Puerto Rico (Canovanas). Approximately 600 people work in API supply and 8,000 in formulation and packaging. We operate a small number of sites for the manufacture of active ingredients in the UK and Sweden, complemented by efficient use of sourcing. Our principal tablet and capsule formulation sites are in the UK. Sweden. Puerto Rico and the US, and we also have major formulation sites for the global supply of parenteral and/ or inhalation products in Sweden, France and the UK.

With the addition of a seasonal work force to support the production of the H1N1 influenza vaccine, approximately 870 people are employed at our four principal biologics commercial manufacturing facilities in the US (Frederick, Maryland and Philadelphia, Pennsylvania); the UK (Speke); and the Netherlands (Nijmegen) with capabilities in

<sup>1</sup> Figures adjusted to reflect the impact of the Medlmmune acquisition.

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process development, manufacturing and distribution of biologics, including worldwide supply of MAbs and influenza vaccines. Our biologics production capabilities are scalable, which enables efficient management of our combined small molecule and biologics pipeline.

#### Managing sourcing risk

Our global procurement policies and integrated risk management processes are aimed at ensuring uninterrupted supply of sufficiently high quality raw materials and other key supplies, all of which are purchased from a range of suppliers. We focus on a range of risks to global supply, such as disasters that remove supply capability or the unavailability of key raw materials, and work to ensure that these risks are effectively mitigated. Contingency plans include the appropriate use of dual or multiple suppliers and maintenance of appropriate stock levels. Although the price of raw materials may fluctuate from time to time, our global purchasing policies seek to avoid such fluctuations becoming material to our business. We also take steps to ensure the guality of the raw materials that we receive from third parties; for more information see the Product quality section on page 32.

We also take into account reputational risk associated with our use of suppliers and are committed to working only with suppliers that embrace standards of ethical behaviour that are consistent with our own. See the Responsible procurement section from page 23.

#### People

With nearly 63,000 employees worldwide, we value the diverse skills and capabilities that a global workforce brings to our business. We work continuously to align these skills and capabilities with strategic and operational needs, whilst maintaining high levels of employee engagement and commitment. This means providing employees with effective leadership, clear targets, open lines of communication, learning and development opportunities and a healthy and safe workplace. All this needs to take place in a culture in which diversity is valued and individual success depends solely on personal merit and performance.

AstraZeneca is committed to making full use of the talents and resource of all its workers within the organisation. We therefore have policies in place to ensure that we avoid any discrimination, including discrimination on the grounds of disability. These include recruitment and selection, performance management, career development and promotion, transfer and training (including re-training, if needed, for employees who have become disabled) and reward.

#### A strategic approach

Our business strategy drives our approach to managing human resources (HR) issues across AstraZeneca. Identifying and building skills and capability for the long term is critical if we are to deliver that strategy successfully. To that end we have been developing a strategic workforce planning (SWP) capability.

SWP generally takes a longer-term view of five to seven years and is designed to ensure we have the right capabilities in the right location at the right time. SWP also addresses issues such as ensuring a diverse workforce and the challenges of attracting and retaining talent globally.

#### **Targets and accountabilities**

Clear targets and accountabilities are essential for ensuring that people understand what is expected of them as we deliver our business strategy. The Board and the SET are responsible for setting our high-level strategic objectives and managing performance against these (see the Reserved matters and delegation of authority section on page 92). Managers across AstraZeneca are accountable for working with their teams to develop individual and team performance targets that are aligned to our strategic objectives and against which individual and team contributions are measured and rewarded.

Our focus on optimising performance is reinforced by performance-related bonus and incentive plans. AstraZeneca also encourages employee share ownership by offering the opportunity to participate in various employee share plans, some of which are described in the Directors' Remuneration Report from page 101 and also in Note 24 to the Financial Statements from page 161.

#### Learning and development

We encourage and support all our people in achieving their full potential with a range of high quality learning and development (L&D) opportunities around the world.

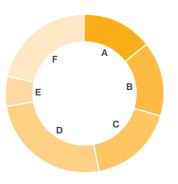
We are implementing a new global approach, backed by the creation of our global L&D organisation, which aims to ensure that standards of best L&D practice are consistently applied in the most efficient way. During 2009, we have continued to develop and deploy global on-line and other development resources, as we seek to make L&D tools and programmes available to all employees, creating a common platform that increases access to learning and supports self-development across the organisation.



Executive Vice-President, Human Resources and Corporate Affairs

#### "Our people are the key to our past and future success – we need to nurture our talent and develop the leaders of tomorrow."

#### **Employees by geographical area**



Geographical area		%
A	UK	14.3
В	Sweden	15.3
С	Rest of Europe	17.5
D	North America	25.3
Е	Latin America	6.1
F	Africa, Asia and Australasia	21.5

The percentage of employees based in the UK as reported last year, included employees who were a cost to AstraZeneca UK Limited although they were not based in the UK. Only employees based in the UK have been counted for the purposes of the above graph. During 2009, we implemented a refreshed on-line L&D portal, with access to all core leadership and management development tools. We also launched a number of specific business area websites.

Our leadership development frameworks are focused on six core capabilities, which we believe are essential for strong and effective leadership: passion for customers, strategic thinking, acting decisively, driving performance, working collaboratively, and developing people and the organisation. These capabilities apply to all employees and are used across our HR processes. In 2009, we complemented the core leadership capabilities with the launch of a set of manager accountabilities. These define what we expect from all managers across the dimensions of ethical conduct and compliance, people management and engagement, as well as fiscal and financial awareness. Building line manager capability has been supported by the launch of a number of global learning programmes, which address key elements of people management.

#### **Talent management**

To ensure we maintain a flow of effective leaders, we work to identify individuals with the potential for more senior and complex roles. These talent pools provide succession candidates for a range of leadership roles across AstraZeneca that are critical to our continued business success. We regard these individuals as key assets to the organisation and we therefore focus on proactively supporting them to reach their potential with, for example, targeted development opportunities.

#### **Engagement and dialogue**

We aim to provide an inclusive environment that encourages open discussion and debate at all levels throughout AstraZeneca. As well as line manager briefings and team meetings, we use a wide range of media to communicate with our employees around the world.

To support our goal of promoting high levels of employee engagement, we also use an annual global employee survey (FOCUS) to track employee opinion across a range of key topic areas. The results, which are communicated to all employees, provide valuable insights that inform strategic planning across the business.

Eighty six percent of our employees participated in our 2009 FOCUS survey, reflecting their continued confidence in this feedback mechanism. Results showed that employee engagement scores which were already very strong had improved compared to 2008 and employees felt that the clarity of direction provided by senior leaders had also improved. The survey also identified key areas that continue to require attention, in particular the need for further strengthening leadership capability in effective communications and change management. In addition, our scores around work-life balance decreased slightly in some functions. Our leaders take this feedback very seriously and targets that address employee engagement and the effectiveness of senior leadership communications in particular are included in the SET business performance management framework for 2010.

#### Managing the impact of business change

Our continuing strategic drive to improve efficiency and effectiveness through our previously announced restructuring programmes has resulted in the delivery of a gross reduction of approximately 12,600 positions during the period 2007 to 2009. To ensure that a consistent approach, based on our core values, was and continues to be adopted throughout the programme, specific guidance was provided for the HR teams and line managers throughout the organisation. Differences in the legal frameworks and the customary practice in the different geographies in which we operate is a challenge. The global guidance provided aims to ensure that the same or similar elements are included in local implementation of business change. These include, for example, open communication and consultation with employees, face-to-face meetings, re-deployment support and appropriate financial arrangements. In line with our core values, we expect the people affected to be treated with respect, sensitivity, fairness and integrity at all times. It was therefore encouraging that the engagement scores in our 2009 FOCUS employee survey continued to improve despite business change that typically involves headcount reduction.

#### Consultation

We work to ensure a level of global consistency in managing employee relations, whilst allowing enough flexibility to support the local markets in building good relations with their workforces that take account of local laws and circumstances. To that end, relations with trades unions are nationally determined and managed locally in line with the applicable legal framework and standards of good practice. Managers throughout AstraZeneca are trained in consultation requirements as well as relevant employment law, where applicable. Training is done at a local level and we have a range of HR and line manager networks for sharing experience and good practice, and promoting alignment across the organisation. At a global level, we have a Head of Employee Relations who supports national management in ensuring that their local

activities are consistent with our high-level principles. As we continue to develop our global platform for managing HR we seek to ensure that the strength of our local management approaches is not undermined.

There are particularly well-developed arrangements for interactions with trades unions and employee representative groups across Europe. Before it became a legal requirement under European law in 1995, both our heritage companies, Astra and Zeneca, had European Consultation Committees (ECCs) in place. Our single AstraZeneca ECC comprises trade union representatives and locally elected employees, and is chaired by a SET member. The committee meets once a year and a sub-committee meets quarterly to discuss, among other things, business developments and any potential impact these may have on the workforce.

We are always striving to improve consultation arrangements. For example, in 2009 the Joint Consultation and Information infrastructure in the UK was changed and a new arrangement was agreed and implemented in full consultation with representatives. The new arrangement enables dialogue, participation and involvement of employees in a process that is more responsive and flexible to changing needs than the one it replaced.

#### Human rights

AstraZeneca is fully supportive of the principles set out in the United Nations Universal Declaration of Human Rights. Our Code of Conduct and supporting policies outline the high standards of employment practice with which everyone in AstraZeneca is expected to comply, both in spirit and letter, worldwide.

Overall accountability for progressing the human rights agenda within AstraZeneca lies with our Global Human Resources function, supported by our Global Corporate Responsibility Team who co-ordinate with relevant functions to ensure that human rights issues continue to be appropriately integrated into responsible business strategies.

In January 2010, AstraZeneca signed up to the United Nations Global Compact (UNGC), a strategic policy initiative for businesses that are committed to aligning their operations and strategies with 10 universally accepted principles in the areas of human rights, employment, environment and anti-corruption. We are now working within the framework of the 10 UNGC principles to understand how these principles apply to our business, what we are doing well and where more work may be needed.

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More information about our commitment in human rights-related areas is included in this Annual Report including access to medicines, diversity, safety, health and wellbeing, employee relations, sales and marketing practice and working with suppliers. Full details are available on our website, astrazeneca.com/responsibility.

#### **Diversity**

With a global workforce comes a rich diversity of skills, capabilities and creativity. We value highly the benefits that such diversity can bring to our individual employees, to our stakeholders and ultimately to our business.

We aim to foster a culture of respect and fairness, where differences are recognised, valued and harnessed, and where individual success depends solely on ability, behaviour, work performance and demonstrated potential. Every manager across AstraZeneca is responsible for ensuring that this happens.

As we continue to reshape our organisation and our global footprint in line with business objectives, our continuing challenge is to ensure that diversity is appropriately supported in our workforce, reflected in our leadership and integrated into business and people strategies.

In 2009, to further strengthen our drive in this area, we appointed a Global Diversity Leader, a new position, whose role is to develop a global Diversity & Inclusion strategy, in partnership with senior leaders who will be accountable for its implementation in the business. We are currently working to identify key areas of strategic focus, considering how best to implement a global strategy with the flexibility needed for local interpretation and implementation, and agreeing KPIs.

As part of this work, during 2009 we identified the need to look more closely at the advancement of women in AstraZeneca. Our data shows that we have 52% of women and 48% of men in our workforce (of the 40,000 people currently in our global HR database) and 24% of 82 senior managers reporting to the SET are women. We are now working with an external expert in this field on a global research project designed to help us better understand some of the causes underlying the data. The outcomes will inform the ongoing development of the Diversity & Inclusion strategy.

#### Safety, health and wellbeing

Providing a safe workplace and promoting the health and wellbeing of all our people remains a core priority. A safe, healthy working environment not only benefits employees, it supports our business through improved employee engagement, retention and productivity.

We continue to make significant investment in providing a wide range of health and wellbeing improvement programmes across AstraZeneca. These vary according to health risk profile, function and local culture, and include general health initiatives aimed at increasing exercise levels, reducing tobacco use, improving nutrition and managing stress. We also have plans in place to deal with the effect of pandemic flu, including the provision of anti-virals for employees based in areas where adequate supplies may not be available through national treatment regimes.

Work-related stress is currently our greatest single cause of occupational illness, with continued business change, high workloads and interpersonal issues being identified as significant factors. As part of our ongoing efforts in this area, we are adopting an increasingly proactive, risk-based approach, using wellbeing risk assessment tools to identify high-risk areas and target interventions more effectively.

We regret that during 2009, one of our sales representatives in Thailand died in a traffic accident whilst driving on AstraZeneca business. We work hard to identify the root causes of any serious accident and use a range of investigation procedures to help us avoid repetition. Learning is shared with management and staff, and our conclusions about underlying causes are used to improve our management systems.

In recent years, our strengthened efforts to promote driver safety worldwide have delivered some improvements and we are maintaining focus in this important area at all levels of the organisation.

Our long-standing 'Road Scholars' scheme in the US (the home to our largest sales force) continues to be a valuable channel for building awareness and improving driver skills. A driver safety objective is now also included in the US performance management framework. Outside the US, our 'Drive Success' programme takes into account the different driving environments in the various countries in which we operate and provides a high-level framework of common standards to be adopted by each country. The 'Drive Success' programme AstraZeneca employees: cases of occupational illness<sup>1, 2</sup> per million hours

2009	1.37
2008	 1.04
2007	0.99

### AstraZeneca employees: accidents with serious injury<sup>1, 2</sup> per million hours

2009	2.24
	2.28
2007	2.65

<sup>1</sup> Data exclude MedImmune. <sup>2</sup> With and without days lost.

was launched in 2008 across Europe, Latin America, the Middle East and Africa. Roll-out was completed during 2009 with the launch in Asia Pacific, including Japan.

During the year, we also commissioned a global assessment of our driver safety programmes by an external expert in this field, the results of which were presented to the SET. Both programmes were reported to have a solid foundation on which to build. Key findings centred on the need for clear global and local improvement targets and closer alignment of the two programmes. In response, we have developed a set of KPIs and global targets, together with a new Global Driver Safety Standard, all of which will be introduced across the organisation during 2010.

Our KPI for safety, health and wellbeing combines the frequency rates for accidents resulting in serious injuries and new cases of occupational illness into one KPI, with an overall target of a 50% reduction in the combined rates by the end of 2010, compared with a 2001/2002 reference point. The overall serious injury accident rate for AstraZeneca employees decreased by 2% in 2009, whilst the occupational illness rate increased by 32%. This equates to a combined increase of 9% compared to 2008. The occupational illness rate increase is due largely to a number of suspected cases in 2008 being confirmed as work-related during 2009 and therefore included in the 2009 data, rather than in the 2008 data. We remain on track to achieve the targeted 50% reduction by the end of 2010. Data on our performance over the last three years is shown above.

We are currently in the process of finalising a new safety, health and environment strategy, including associated safety and health targets.



"Revenue growth and operational efficiencies drove a strong cash performance, reducing net debt well ahead of plan."

## Financial Review Our global financial performance and position

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In 2009, revenue increased by 7% in constant currency terms; 3 percentage points of this growth was accounted for by some unanticipated upsides from the performance of *Toprol-XL* and sales of H1N1 influenza (swine flu) vaccine in the US.

Our Emerging Markets businesses grew strongly, with revenues up 12% in constant currency terms. Core operating margin increased by 5.1 percentage points in constant currency terms, on increased revenue, improved efficiencies throughout the organisation, and some disposal gains within other income.

Cash generation was strong in 2009; cash from operating activities increased by \$3 billion. This enabled us to invest in capital and intangible assets to drive future growth and productivity and fund a 12% increase in the full year dividend. Net debt was reduced by \$7.7 billion in 2009, well ahead of plan, and we entered 2010 with net funds of \$0.5 billion. Since 2007, our restructuring programme has delivered \$1.6 billion in annual savings by the end of 2009, which will grow to \$2.4 billion by the end of 2010. The restructuring costs to deliver these benefits have totalled \$2.5 billion since inception. The next phase of restructuring is planned to deliver a further \$1.9 billion in annual benefits by the end of 2014, with a further \$2.0 billion in restructuring costs anticipated between 2010 and 2013.

Looking forward, our plans to manage the business, as the revenue base transitions through this period of market exclusivity losses and new product launches, should generate strong cash flow to provide for the needs of the business and shareholder returns.

#### Simon Lowth

Chief Financial Officer

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The purpose of this Financial Review is to provide a balanced and comprehensive analysis of the financial performance of the business during 2009, the financial position as at the end of the year and the main business factors and trends which could affect the future financial performance of the business.

All growth rates in this Financial Review are expressed at CER unless noted otherwise.

#### Measuring performance

The following measures are referred to when reporting on our performance both in absolute terms but more often in comparison to earlier years in this Financial Review:

- > Reported performance. Reported performance takes into account all the factors (including those which we cannot influence, principally currency exchange rates) that have affected the results of our business as reflected in our Group Financial Statements prepared in accordance with IFRS as adopted by the EU and as issued by the IASB.
- > Core financial measures. These are non-GAAP measures because unlike Reported performance they cannot be derived directly from the information in the Group's Financial Statements. These measures are adjusted to exclude certain significant items, such as charges and provisions related to our global restructuring and synergy programmes, amortisation and impairment of the significant intangibles relating to the acquisition of MedImmune in 2007, the amortisation and impairment of the significant intangibles relating to our current and future exit arrangements with Merck in the US and other specified items. See the Reconciliation of Reported results to Core results table on page 40 for a reconciliation of Reported to Core performance.
- > Constant exchange rate (CER) growth rates. These are also non-GAAP measures. These measures remove the effects of currency movements (by retranslating the current year's performance at previous year's exchange rates and adjusting for other exchange effects, including hedging). A reconciliation of the Reported results adjusted for the impact of currency movements is provided in the Operating profit (2009 and 2008) table on page 39.
- > Gross margin and operating profit margin percentages. These measures set out the progression of key performance margins and demonstrate the overall quality of the business.

- > Prescription volumes and trends for key products. These measures can represent the real business growth and the progress of individual products better and more immediately than invoiced sales.
- > Net Funds/Debt. This represents our interest bearing loans and borrowings, less cash and cash equivalents, current investments and derivative financial instruments.

CER measures allow us to focus on the changes in sales and expenses driven by volume, prices and cost levels relative to the prior period. Sales and cost growth expressed in CER allows management to understand the true local movement in sales and costs, in order to compare recent trends and relative return on investment. CER growth rates can be used to analyse sales in a number of ways but, most often, we consider CER growth by products and groups of products, and by countries and regions. CER sales growth can be further analysed into the impact of sales volumes and selling price. Similarly, CER cost growth helps us to focus on the real local change in costs so that we can manage the cost base effectively.

We believe that disclosing Core financial and growth measures in addition to our Reported financial information enhances investors' ability to evaluate and analyse the underlying financial performance of our ongoing business and the related key business drivers. The adjustments made to our Reported financial information in order to show Core financial measures illustrate clearly and on a year-on-year or period-by-period basis the impact upon our performance caused by factors such as changes in sales and expenses driven by volume, prices and cost levels relative to such prior years or periods.

Further, as shown in the Reconciliation of Reported results to Core results table on page 40, our reconciliation of Reported financial information to Core financial measures includes a breakdown of the items for which our Reported financial information is adjusted and a further breakdown of those items by specific line item as such items are reflected in our Reported income statement, to illustrate the significant items that are excluded from Core financial measures and their impact on our Reported financial information, both as a whole and in respect of specific line items.

Management presents these results externally to meet investors' requirements for transparency and clarity. Core financial measures are also used internally in the management of our business performance, in our budgeting process and when determining compensation.

Core financial measures are non-GAAP, adjusted measures. All items for which Core financial measures are adjusted are included in our Reported financial information because they represent actual costs of our business in the periods presented. As a result, Core financial measures merely allow investors to differentiate among different kinds of costs and they should not be used in isolation. You should also refer to our Reported financial information in the Operating profit (2009 and 2008) table on page 39, our reconciliation of Core financial measures to Reported financial information in the Reconciliation of Reported results to Core results table on page 40, and to the Results of operations – summary analysis of year to 31 December 2008 section from page 42 for our discussion of comparative Reported growth measures that reflect all of the factors that affect our business. Our determination of non-GAAP measures, together with our presentation of them within this financial information, may differ from similarly titled non-GAAP measures of other companies.

The SET retains strategic management of the costs excluded from Reported financial information in arriving at Core financial measures, tracking their impact on Reported operating profit and EPS, with operational management being delegated on a case-bycase basis to ensure clear accountability and consistency for each cost category.

### Business background and major events affecting 2009

The business background is covered in the Business Environment section, Geographical Review and Therapy Area Review and describes in detail the developments in both our products and geographical regions.

Sales of our products are directly influenced by medical need and are generally paid for by health insurance schemes or national healthcare budgets. Our operating results can be affected by a number of factors other than the delivery of operating plans and normal competition which are:

> The adverse impact on pharmaceutical prices as a result of the regulatory environment. For instance, although there is no direct governmental control on prices in the US, action from individual state programmes and health insurance bodies is leading to downward pressures on realised prices. In other parts of the world, there are a variety of price and volume control mechanisms and retrospective rebates based on sales levels that are imposed by governments.

- > The risk of generic competition following loss of patent protection or patent expiry or an 'at risk' launch by a competitor, with the potential adverse effects on sales volumes and prices, for example, the launch of generic competition to both *Ethyol* and *Pulmicort Respules* in 2008.
- > The timings of new product launches, which can be influenced by national regulators and the risk that such new products do not succeed as anticipated, together with the rate of sales growth and costs following new product launches.
- > Currency fluctuations. Our functional and reporting currency is the US dollar but we have substantial exposures to other currencies, in particular the euro, Japanese yen, pound sterling and Swedish krona.
- Macro factors such as greater demand from an ageing population and increasing requirements of servicing Emerging Markets.

Over the longer term, the success of our R&D is crucial, and we devote substantial resources to this area. The benefits of this investment emerge over the long term and there is considerable inherent uncertainty as to whether and when it will generate future products.

The most significant features of our financial results in 2009 are:

- Reported sales of \$32,804 million, representing CER sales growth of 7% (Reported: 4%).
- Strong performance in Emerging Markets with CER sales growth of 12% (Reported: 2%).
- > Excluded from Core results were specific legal provisions totalling \$636 million (which impacted Reported results in the year). \$524 million of this has been made in respect of the US Attorney's Office investigation into sales and marketing practices involving *Seroquel* and \$112 million relates to average wholesale price litigation. These charges are excluded from Core performance results.
- > Operating profit increased by 24% at CER (Reported: 26%). Core operating profit increased by 23% at CER (Reported: 24%). A reconciliation between these measures is included in the Reconciliation of Reported results to Core results table on page 40.
- > EPS of \$5.19 represented an increase of 22% at CER (Reported: 24%). Core EPS of \$6.32 represented an increase of 23% at CER (Reported: 24%).
- Net cash inflow from operating activities increased to \$11,739 million (2008: \$8,742 million).
- Dividends increased to \$2,977 million (2008: \$2,739 million).

- > Net funds at 31 December were \$535 million, an improvement of \$7,709 million on net debt of \$7,174 million in the previous year.
- > Total restructuring and synergy costs associated with the global programme to reshape the cost base of the business, were \$659 million in 2009 (2008: \$881 million). This brings the total restructuring and synergy costs charged to date to \$2,506 million.

#### Results of operations – summary analysis of year to 31 December 2009

The Sales by Therapy Area (2009 and 2008) table on page 39 shows our sales analysed by Therapy Area. The Operating profit (2009 and 2008) table on page 39 shows operating profit for 2009 compared to 2008. The Reconciliation of Reported results to Core results table on page 40 shows a reconciliation of Reported results to Core results for 2009 and 2008. More details on our sales performance by Therapy Area are given in the Therapy Area Review from page 55 in the Performance 2009 sections.

Sales increased by 4% on a Reported basis and by 7% on a CER basis. Revenue benefited from strong growth of the *Toprol-XL* franchise in the US, as a result of the withdrawal from the market of two other generic metoprolol succinate products and from US government orders for the H1N1 influenza (swine flu) vaccine; adjusting for these factors, global revenue increased by 4%. AstraZeneca expects this impact to reduce as generic competitors re-enter the market. Revenue in Emerging Markets increased by 12% at CER.

Core gross margin of 83% for the full year was 2.4% higher than last year at CER (Reported: up 3.3%). Lower payments to Merck and continued efficiency gains and mix factors were partially offset by higher royalty payments resulting from higher volumes of sales of relevant products.

Core R&D expenditure was \$4,334 million for the full year, 3% lower than last year at CER (Reported: down 15%), as increased investment in biologics was more than offset by the continued productivity initiatives and lower costs associated with late-stage development projects that have progressed to pre-registration.

Core SG&A costs of \$9,890 million for the full year were 5% higher than last year at CER (Reported: up 4%). Stronger than expected revenue performance provided the opportunity to drive future growth through accelerated marketing investment for Emerging Markets and currently marketed brands, and to support launch planning for the new products awaiting registration. SG&A expense growth also included increased legal expenses and impairment of intangible assets related to information systems, which were only partially offset by operational efficiencies.

Core other income of \$926 million was \$192 million higher than 2008, chiefly as a result of the disposal of the co-promotion rights of Abraxane<sup>™</sup> and Nordic OTC portfolio disposals in the first half of the year.

Impairment charges relating to intangible fixed assets totalled \$415 million during the year. Charges totalling \$272 million, being the charges arising from impairments in respect of assets relating to our HPV cervical cancer vaccine income stream and other assets capitalised as part of the MedImmune acquisition have been excluded from Core results.

During the year, developments in several legal matters resulted in provisions totalling \$636 million. Full details of these matters are included in Note 25 to the Financial Statements from page 166.

Restructuring and synergy costs totalling \$659 million, incurred as the Group continues its previously announced efficiency programmes and amortisation totalling \$511 million relating to assets capitalised as part of the MedImmune acquisition and the Merck partial retirement, which impacted Reported operating profit, were also excluded from Core performance.

Core operating profit was \$13,621 million, an increase of 23% at CER (Reported: 26%). Core operating margin increased by 5.1% to 41.5% of revenue, as a result of sales growth, efficiencies across the cost base, lower R&D spend and the disposals within other income.

Net finance expense was \$736 million for the year, versus \$463 million in 2008. The principal factors contributing to this increase were the continued reversal of the fair value gain, reduced interest received due to lower interest rates and a higher net interest expense on pension obligations, partially offset by reduced interest payable on lower net debt balances.

Net finance expense included a net fair value loss of \$145 million for the year (2008: \$130 million gain) as credit spreads have reduced since the previous year end. The net fair value gain of \$130 million recorded in the prior year, mainly related to two long-term bonds. These bonds are swapped to floating interest rates and accounted for using the fair value option under IFRS. Under this accounting treatment both the bonds and the related interest rate swaps are measured at fair value, with changes in fair value reported in the income

#### Sales by Therapy Area (2009 and 2008)

		2009		<b>2009</b> 2008		pared to 2008
	Reported \$m	CER growth \$m	Growth due to exchange effects \$m	Reported \$m	CER growth %	Reported growth %
Cardiovascular	8,376	1,737	(324)	6,963	25	20
Gastrointestinal	6,011	(157)	(176)	6,344	(2)	(5)
Infection and other	2,631	257	(77)	2,451	10	7
Neuroscience	6,237	566	(166)	5,837	10	7
Oncology	4,518	(330)	(106)	4,954	(7)	(9)
Respiratory & Inflammation	4,132	234	(230)	4,128	6	-
Other businesses	899	10	(35)	924	1	(3)
Total	32,804	2,317	(1,114)	31,601	7	4

#### Operating prof t (2009 and 2008)

<b>3 1 1 1 1 1</b>		2009 2008 Percentage of		ntage of sales	2009 com	pared to 2008		
	Reported \$m	CER growth \$m	Growth due to exchange effects \$m	Reported \$m	Reported 2009 %	Reported 2008 %	CER growth %	Reported growth %
Sales	32,804	2,317	(1,114)	31,601			7	4
Cost of sales	(5,775)	540	283	(6,598)	(17.6)	(20.9)	(8)	(12)
Gross profit	27,029	2,857	(831)	25,003	82.4	79.1	11	8
Distribution costs	(298)	(37)	30	(291)	(0.9)	(0.9)	13	3
Research and development	(4,409)	298	472	(5,179)	(13.5)	(16.4)	(6)	(15)
Selling, general and administrative costs	(11,332)	(945)	526	(10,913)	(34.5)	(34.6)	9	4
Other operating income and expense	553	33	(4)	524	1.7	1.7	6	6
Operating profit	11,543	2,206	193	9,144	35.2	28.9	24	26
Net finance expense	(736)			(463)				
Profit before tax	10,807			8,681				
Taxation	(3,263)			(2,551)				
Profit for the period	7,544			6,130				
Earnings per share (\$)	5.19			4.20				

Earnings per share (\$)

Growth rates on line items below operating profit, where meaningful, are given elsewhere in this Annual Report.

statement. The fair value of each instrument reflects changes in market interest rates, which broadly offset, but the fair value of these bonds also reflects changes in credit spreads. The 2008 gain has now reversed fully in 2009 and, as credit spreads continued to reduce in the final quarter of 2009, further losses have been recorded.

The effective tax rate for the year is 30.2%. Excluding the impact of the \$636 million legal provisions, the effective tax rate would be 28.8% (2008: 29.4%). A description of our tax exposures is set out in Note 25 to the Financial Statements from page 166.

Core EPS were \$6.32, an increase of 23% at CER on 2008, as the increase in Core operating profit was partially offset by increased net finance expense. Reported EPS increased 24% to \$5.19.

Total comprehensive income for the year increased by \$3,266 million from 2008. This was principally due to an increase in profit for the period of \$1,414 million, beneficial exchange rate impacts on consolidation of \$1,365 million and reduced actuarial losses of \$663 million compared to 2008.

#### **Geographical analysis**

We discuss the geographical performances in the Geographic Review from page 50.

### Financial position, including cash flow and liquidity – 2009

All data in this section is on a Reported basis (unless noted otherwise).

Net assets increased by \$4,761 million to \$20,821 million. The increase due to Group profit of \$7,521 million was offset by dividends of \$3,026 million. Exchange rate movements arising on consolidation and actuarial losses also reduced net assets during the year.

#### Property, plant and equipment

Property, plant and equipment increased by \$264 million to \$7,307 million primarily due to additions of \$967 million and exchange rate movements of \$391 million offset by depreciation and impairments of \$943 million.

#### Goodwill and intangible assets

Goodwill and intangible assets have increased by \$82 million to \$22,115 million.

Goodwill principally arose on the acquisition of MedImmune and on the restructuring of our US joint venture with Merck in 1998. No goodwill has been capitalised in 2009. Intangible assets have reduced by \$97 million to \$12,226 million. Additions totalled \$1,003 million, amortisation was \$729 million and impairments totalled \$415 million. Exchange rate impacts increased intangible assets by \$178 million.

Additions in 2009 included \$300 million in respect of milestone payments made under our collaboration agreement with BMS, \$200 million in respect of our agreement with Targacept, and \$126 million in respect of our agreement with Nektar.

During 2009, impairments totalled \$415 million. \$150 million was impaired as a result of a reassessment of the licensing income generated by the HPV cervical cancer vaccine. Impairments of other assets acquired with MedImmune totalled \$122 million. Impairments related to our acquisition of MedImmune and therefore excluded from our Core results totalled \$272 million. In addition, \$93 million was written off products in development.

Additions to intangible assets in 2008 included a payment made to Merck under pre-existing arrangements under which Merck's interests in our products in the US will be terminated (subject to the exercise of options beginning in 2010). As a result of the payment,

#### **Reconciliation of Reported results to Core results**

		Restructuring and Merck & MedImmune Intangible				
	Reported	synergy costs	amortisation	impairments	Legal provisions	2009 Core
2009	\$m	\$m	\$m	\$m	\$m	\$m
Gross margin	27,029	188	-	-	-	27,217
Distribution costs	(298)	-	-	-	-	(298)
Research and development	(4,409)	68	_	7	-	(4,334)
Selling, general and administrative costs	(11,332)	403	403	-	636	(9,890)
Other operating income and expense	553	_	108	265	-	926
Operating profit	11,543	659	511	272	636	13,621
Net interest	(736)	-	-	-	-	(736)
Profit before tax	10,807	659	511	272	636	12,885
Taxation	(3,263)	(199)	(125)	(82)	(34)	(3,703)
Profit for the period	7,544	460	386	190	602	9,182
Earnings per share (\$)	5.19	0.32	0.27	0.13	0.41	6.32

		Restructuring and N	Verck & Medlmmune	Intangible		
	Reported	synergy costs	amortisation	impairments	Legal provisions	2008 Core
2008	\$m	\$m	\$m	\$m	\$m	\$m
Gross margin	25,003	405	-	-	-	25,408
Distribution costs	(291)	-	-	-	-	(291)
Research and development	(5,179)	166	-	60	-	(4,953)
Selling, general and administrative costs	(10,913)	310	406	257	-	(9,940)
Other operating income and expense	524	-	120	90	-	734
Operating profit	9,144	881	526	407	-	10,958
Net interest	(463)	-	-	-	-	(463)
Profit before tax	8,681	881	526	407	-	10,495
Taxation	(2,551)	(259)	(125)	(121)	-	(3,056)
Profit for the period	6,130	622	401	286	-	7,439

Earnings per share (\$)	4.20	0.43	0.28	0.19	-	5.10

			2009	2009	2008	2009 co	2009 compared to 2008	
2008 to 2009 Core result	Core \$m	CER growth \$m	Growth due to exchange effects \$m	Core \$m	CER growth %	Total Core growth %		
Gross margin	27,217	2,660	(851)	25,408	10	7		
Distribution costs	(298)	(37)	30	(291)	13	3		
Research and development	(4,334)	150	469	(4,953)	(3)	(13)		
Selling, general and administrative costs	(9,890)	(452)	502	(9,940)	5	(1)		
Other operating income and expense	926	194	(2)	734	26	26		
Operating profit	13,621	2,515	148	10,958	23	24		
Net interest	(736)			(463)				
Profit before tax	12,885			10,495				
Taxation	(3,703)			(3,056)				
Profit for the period	9,182			7,439				
Earnings per share (\$)	6.32			5.10				

AstraZeneca no longer has to pay contingent payments on these products. This payment includes \$1,656 million in respect of payments on account for rights that will crystallise if we exercise future options. If AstraZeneca does not exercise these options certain rights will remain with Merck resulting in a write-off for any rights not acquired. Further details of this matter are included in Note 25 to the Financial Statements from page 166.

#### Inventories

Inventories have increased by \$114 million to \$1,750 million principally due to exchange rate impacts.

#### **Receivables, payables and provisions**

Trade and other receivables increased by \$448 million to \$7,709 million. Exchange rate movements increased receivables by \$220 million. The underlying increase of \$228 million was driven by increased sales in the final quarter and an increase in insurance recoverables.

As of 31 December, 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, 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 may increase over time 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 which we have recognised, will be realisable in full.

Trade and other payables increased by \$1,604 million primarily due to increases in US

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managed market accruals, accruals in respect of intangibles investments made in the fourth quarter and other accruals. Trade and other payables include \$2,618 million in respect of accruals relating to rebates and chargebacks in our US market. These are explained and reconciled fully in the Rebates, chargebacks and returns in the US section from page 45, along with cash discounts and customer returns.

During the year AstraZeneca made a provision of \$636 million in respect of various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices. \$524 million of this provision has been made in respect of the US Attorney's Office investigation into sales and marketing practices involving *Seroquel* with the remainder relating to average wholesale price litigation. Further details on these matters are included in Note 25 to the Financial Statements from page 166.

#### Tax payable and receivable

Net income tax payable has increased by \$885 million to \$2,853 million principally due to tax audit provisions, cash tax timing differences and exchange rate movements. Tax receivable largely comprises tax owing to AstraZeneca from certain governments expected to be received on settlements of transfer pricing audits and disputes (see Note 25 to the Financial Statements from page 166).

#### **Retirement benef t obligations**

Net retirement benefit obligations increased by \$622 million principally as a result of actuarial losses of \$569 million and adverse exchange rate effects of \$215 million. Approximately 97% of the Group's obligations are concentrated in three countries. The following table shows the US dollar effect of a 1% change in the discount rate on the retirement benefit obligations in those countries.

	-1%	+1%
UK (\$m)	1,129	(973)
US (\$m)	256	(225)
Sweden (\$m)	229	(192)
Total (\$m)	1,614	(1,390)

#### **Commitments and contingencies**

The Group has commitments and contingencies which are accounted for in accordance with the accounting policies described in the Financial Statements in the Accounting Policies section from page 128. The Group also has taxation contingencies. These are described in the Taxation section in the Critical accounting policies section from page 48. These matters are explained fully in Note 25 to the Financial Statements from page 166.

#### Net funds/(debt)

	2009	2008	2007
	\$m	\$m	\$m
Net (debt)/funds brought forward at 1 January	(7,174)	(9,112)	6,537
Earnings before interest, tax, depreciation,			
amortisation and impairment	13,630	11,764	9,950
Movement in working capital and provisions	1,329	(210)	(443)
Tax paid	(2,381)	(2,209)	(2,563)
Interest paid	(639)	(690)	(335)
Other non-cash movements	(200)	87	901
Net cash available from operating activities	11,739	8,742	7,510
Purchase of intangibles (net)	(355)	(2,944)	(549)
Other capital expenditure (net)	(824)	(1,057)	(1,076)
Acquisitions	-	-	(14,891)
Investments	(1,179)	(4,001)	(16,516)
Dividends	(2,977)	(2,739)	(2,641)
Net share issues/(re-purchases)	135	(451)	(3,952)
Distributions	(2,842)	(3,190)	(6,593)
Other movements	(9)	387	(50)
Net funds/(debt) carried forward at 31 December	535	(7,174)	(9,112)
Comprised of:			
Cash & short term investments	11,598	4,674	6,044
Loans and borrowings	(11,063)	(11,848)	(15,156)

#### **Cash flow**

Cash generated from operating activities was \$11,739 million in the year, compared with \$8,742 million in 2008. The increase of \$2,997 million was principally driven by an increase in operating profit before depreciation, amortisation and impairment costs of \$1,866 million, offset by a decrease in non-cash items of \$287 million, which includes fair value adjustments. An improvement in working capital flows, including short-term provisions of \$1,539 million, which also contributed significantly to this increase, arose principally from an increase in returns and chargebacks provisions and the legal provisions made in the year.

Net cash outflows from investing activities were \$2,476 million in the year compared with \$3,896 million in 2008. The movement of \$1,420 million is due primarily to the payment of \$2,630 million to Merck in 2008 as part of the partial retirement, and the proceeds from the disposal of the Abraxane<sup>™</sup> co-promotion rights of \$269 million received in 2009, countered by an increase in the purchase of short term investments and fixed deposits of \$1,372 million.

Cash distributions to shareholders, through dividend payments, were \$2,977 million.

Gross debt (including loans, short-term borrowings and overdrafts) was \$11,063 million as at 31 December (2008: \$11,848 million). Of this debt, \$1,926 million is due within one year (2008: \$993 million), which we currently anticipate repaying from current cash balances and short term investments of approximately \$11.6 billion and business cash flows, without the need to re-finance. Net funds of \$535 million have improved by \$7,709 million from net debt of \$7,174 million at 31 December 2008.

We continue to believe that, although our future operating cash flows are subject to a number of uncertainties, as specified in the Business background and major events affecting 2009 section from page 37, our cash and funding resources will be sufficient to meet our forecast requirements for the foreseeable future, including developing and launching new products, externalisation, our ongoing capital programme, our restructuring programme, debt servicing and repayment, options arising under the Merck exit arrangements and shareholder distributions.

#### **Restructuring and synergy costs**

Driving increased productivity from investments in R&D is a key to portfolio renewal and value creation. Further to this objective, AstraZeneca will undertake additional restructuring within the R&D function. These plans include a reduction in the number of disease area targets within our core therapeutic areas, some consolidation of our activities onto a smaller R&D site footprint, and other efficiency measures, subject to consultations with work councils, trades unions and other employee representatives and in accordance with local employment laws.

The next phase of restructuring which includes the completion of the previous programmes announced in 2007, will also include some additional initiatives in supply chain and in SG&A in addition to the R&D initiatives described above.

#### **Dividend for 2009**

	\$	Pence	SEK	Payment date
First interim dividend	0.59	36.0	4.41	14.09.09
Second interim dividend	1.71	105.4	12.43	15.03.10
Total	2.30	141.4	16.84	

#### Summary of shareholder distributions

	Shares		Dividend	Dividend	Shareholder
	re-purchased	Cost	per share	cost	distributions
	(million)	\$m	\$	\$m	\$m
2000	9.4	352	0.7	1,236	1,588
2001	23.5	1,080	0.7	1,225	2,305
2002	28.3	1,190	0.7	1,206	2,396
2003	27.2	1,154	0.795	1,350	2,504
2004	50.1	2,212	0.94	1,555	3,767
2005	67.7	3,001	1.3	2,068	5,069
2006	72.2	4,147	1.72	2,649	6,796
2007	79.9	4,170	1.87	2,740	6,910
2008	13.6	610	2.05	2,971	3,581
2009	-	-	2.30	3,3361	3,336
Total	371.9	17,916	13.075	20,336	38,252

<sup>1</sup>Total dividend cost estimated based upon number of shares in issue at 31 December 2009.

#### Capitalisation and shareholder return

All data in this section is on a Reported basis.

#### Capitalisation

The total number of shares in issue at 31 December was 1,451 million. 3.5 million shares were issued in consideration of share option plans and employee share plans for a total of \$135 million. Shareholders' equity increased by a net \$4,748 million to \$20,660 million at the year end. Minority interests increased to \$161 million (2008: \$148 million).

#### **Dividend and share re-purchases**

In recognition of the Group's strong balance sheet, sustainable significant cash flow and the Board's confidence in the strategic direction and long-term prospects for the business, the Board has adopted a progressive dividend policy, intending to maintain or grow the dividend each year.

In addition the Board has announced a share re-purchase programme.

#### **Future prospects**

AstraZeneca is a focused, integrated, innovation-driven, global biopharmaceutical business. AstraZeneca will be selective about those areas of the industry it chooses to compete in, targeting those product categories where medical innovation or brand equity continues to command a premium in the marketplace. AstraZeneca believes the best way to capture value within this industry is to span the full value chain of discovery, development and commercialisation. AstraZeneca believes its technology base will continue to deliver innovative products that patients will need and for which payers will see value. AstraZeneca believes that its ability to meet the health needs of patients

and healthcare systems in both developed and emerging markets is a core capability.

AstraZeneca believes that pursuit of this strategy will continue to build a pipeline of new medicines that will meet the needs of patients and provide attractive returns for shareholders.

The next five years will be challenging for the industry and for AstraZeneca, as its revenue base transitions through a period of exclusivity losses and new product launches. AstraZeneca believes it would be helpful for investors to understand AstraZeneca's high-level planning assumptions for revenue evolution, margin structure, cash flow and business reinvestment that will guide its management of the business over the next five years.

For the period 2010 to 2014, AstraZeneca has made certain assumptions for the industry environment. AstraZeneca assumes that the global pharmaceutical industry can grow at least in line with real GDP over the planning horizon. Downward pressure on revenue from government interventions in the marketplace. including certain proposals associated with efforts to enact US healthcare reform, remain a continuing feature of the challenging market environment. However, for the planning period, AstraZeneca assumes no further 'step-change' in the evolution of these pressures. As for assumptions specific to the Group, AstraZeneca assumes that there will be no material mergers, acquisitions or disposals. In addition, our plans assume no premature loss of exclusivity for key AstraZeneca products. It is also assumed that exchange rates for our principal currencies will not differ materially from the average rates that prevailed during January 2010.

It is expected that a significant portion of current base revenue will be affected by the loss of market exclusivity on a number of products. Revenue in 2010, for example, will be affected by the expected loss of market exclusivity for *Arimidex* and for *Pulmicort Respules* in the US. AstraZeneca aims to grow market share for key franchises that retain exclusivity, and plans to sustain double-digit growth rates in its Emerging Markets business, supported by the selective addition of branded generics to the portfolio.

### Results of operations – summary analysis of year to 31 December 2008

In 2008 sales increased by 7% on a Reported basis and by 3% on a CER basis compared to 2007. Exchange rate movements benefited Reported sales by 4%. More details on our sales performance by Therapy Area are given in the Therapy Area Review from page 55 in the Performance 2008 sections.

Core gross margin of 80.4% in 2008 was 0.8% higher than 2007 at CER (Reported: 79.1%; 0.8% higher). Principal drivers were lower payments to Merck (1.0%), continued efficiency gains and mix factors (1.2%), partially offset by higher royalty payments (0.6%) and intangible asset impairments and other provisions (0.8%).

Core R&D costs of \$4,953 million were down 1% at CER in 2008 compared to 2007 (Reported: 0%). The inclusion of a full year of MedImmune expense was offset by improved productivity and efficiency, restructuring benefits, portfolio changes and lower charges relating to intangible asset impairments charged to Core R&D expense.

In 2008, Core SG&A costs of \$9,940 million were up 3% at CER (Reported: 4%) due chiefly to the inclusion of a full year of MedImmune costs, increased investment in Emerging Markets and some higher legal expenses.

Core other income of \$734 million was \$6 million higher in 2008 compared to 2007 (Reported: decreased \$204 million) with MedImmune's licensing and royalty income streams offset by expected lower one-time gains and royalty income.

Impairment charges relating to intangible fixed assets totalled \$631 million in 2008. Charges totalling \$407 million, including impairments in respect of *Ethyol* and HPV cervical cancer vaccines, were excluded from Core operating profit in 2008. Charges totalling \$224 million, including \$115 million in respect of *Pulmicort Respules*, were included in Core operating profit.

#### Sales by Therapy Area (2008 and 2007)

		2008		2007	2008 compared to	
	Reported \$m		Growth due to change effects \$m	Reported \$m	CER growth %	Reported growth %
Cardiovascular	6,963	29	248	6,686		4
Gastrointestinal	6,344	(275)	176	6,443	(4)	(2)
Infection and other <sup>1</sup>	2,451	706	31	1,714	41	43
Neuroscience	5,837	346	151	5,340	6	9
Oncology	4,954	(109)	244	4,819	(2)	3
Respiratory & Inflammation	4,128	278	139	3,711	7	11
Other businesses	924	54	24	846	6	9
Total	31,601	1,029	1,013	29,559	3	7

<sup>1</sup> Includes Synagis and FluMist which were acquired in June 2007.

#### Operating prof t (2008 and 2007)

			2008	2007	Perce	ntage of sales	2008 com	pared to 2007
	Reported \$m		rowth due to nange effects \$m	Reported \$m	Reported 2008 %	Reported 2007 %	CER growth %	Reported growth %
Sales	31,601	1,029	1,013	29,559			3	7
Cost of sales	(6,598)	38	(217)	(6,419)	(20.9)	(21.7)	(1)	3
Gross profit	25,003	1,067	796	23,140	79.1	78.3	5	8
Distribution costs	(291)	(39)	(4)	(248)	(0.9)	(0.8)	16	17
Research and development	(5,179)	(88)	71	(5,162)	(16.4)	(17.5)	2	-
Selling, general and administrative costs	(10,913)	(433)	(116)	(10,364)	(34.6)	(35.1)	4	5
Other operating income and expense	524	(188)	(16)	728	1.7	2.5	(26)	(28)
Operating profit	9,144	319	731	8,094	28.9	27.4	4	13
Net finance expense	(463)			(111)				
Profit before tax	8,681			7,983				
Taxation	(2,551)			(2,356)				
Profit for the period	6,130			5,627				
Earnings per share (\$)	4.20			3.74				

Growth rates on line items below operating profit, where meaningful, are given elsewhere in this Annual Report.

In 2008, Core operating profit was up 9% at CER from 2007 (Reported: 13%). CER Core operating margin increased by 1.6% to 34.7% of sales as improvements in gross margin were offset by higher SG&A costs. Reported operating profits, at 28.9%, increased by 1.5% compared with 2007 as a result of improvements in gross margin and R&D efficiencies which more than offset a modest increase in SG&A costs.

Net finance expense was \$463 million in 2008 compared to \$111 million for 2007.

In 2008, the increase in interest expense was driven by additional borrowings arising as a result of the acquisition of MedImmune in 2007. Our exposure to interest costs was reduced in 2008, from the closing position in 2007, as we moved debt used to finance the purchase of MedImmune from short-term, higher interest rate commercial paper, to longer-term debt financing at lower interest rates. The 2008 net finance expense benefited from a net fair value gain of \$130 million relating to two long-term bonds due to widening credit spreads.

In 2008, the effective tax rate was 29.4% (2007: 29.5%).

In 2008, Core EPS were \$5.10, an increase of 8% at CER on 2007, as the increase in Core operating profit and the benefit of a lower number of shares outstanding was partially offset by increased net finance expense. Reported EPS increased by 12% to \$4.20.

Profit for the period totalled \$6,130 million. Adverse exchange rate movements arising on consolidation of \$1,336 million and actuarial losses in the year of \$1,232 million resulted in a total comprehensive income for the year of \$4,224 million.

### Financial position, including cash flow and liquidity – 2008

In 2008, total net assets increased by \$1,145 million to \$16,060 million. The increase due to Group profit of \$6,101 million was offset by dividends of \$2,767 million and net share re-purchases of \$451 million. Exchange rate movements arising on consolidation and actuarial losses also reduced net assets during 2008.

In March 2008, AstraZeneca paid \$2.6 billion to Merck. This payment resulted in AstraZeneca acquiring Merck's interests in certain AstraZeneca products including *Pulmicort, Rhinocort, Symbicort* and *Toprol-XL* and has been included in intangible assets as explained below.

#### Property, plant and equipment

In 2008, property, plant and equipment fell by \$1,255 million to \$7,043 million primarily due to depreciation and impairments of \$1,182 million and exchange rate movements of \$1,131 million offset by additions of \$1,113 million.

#### Goodwill and intangible assets

In 2008, goodwill and intangible assets increased by \$846 million to \$22,197 million.

The main components within goodwill are the amounts capitalised on the acquisition of MedImmune of \$8,757 million and on the restructuring of our US joint venture with Merck in 1998. No significant amounts were capitalised within goodwill in 2008. The total goodwill balance reduced by \$10 million in 2008 due to exchange rate movements. Intangible assets increased by \$856 million to \$12,323 million in 2008. Additions totalled \$2,941 million, amortisation was \$807 million and impairments totalled \$631 million. Exchange rate movements in 2008 reduced intangible assets by \$603 million.

Additions to intangible assets in 2008 included a payment made to Merck under pre-existing arrangements under which Merck's interests in our products in the US will be terminated (subject to the exercise of certain options). \$994 million of this payment relates to certain AstraZeneca products, including Pulmicort, Rhinocort, Symbicort and Toprol-XL. As a result of the payment AstraZeneca no longer has to pay contingent payments on these products to Merck and has obtained the ability to fully exploit these products and to fully exploit other opportunities in the Respiratory Therapy Area that AstraZeneca was previously prevented from doing by Merck's interests in these products. The remainder of the payment (\$1,656 million) represents payments on account for the product rights that will crystallise if we exercise options in 2010.

In March 2008, a \$257 million intangible asset impairment charge was taken as a result of the entry of generic Ethyol, a product capitalised on the acquisition of MedImmune, into the US market. The settlement of the Pulmicort Respules patent litigation triggered an impairment of \$115 million. The remaining impairments for 2008 resulted from the termination of projects in development and a charge for \$91 million relating to the reassessment of the licensing income expected to be generated by the HPV cervical cancer vaccine. Reported performance for 2008 included impairments in respect of Ethyol, HPV cervical cancer vaccine and other projects in development (principally the return of rights to Infinity Pharmaceuticals) which management believed were not part of Core performance for 2008. As a result, management adjusted for impairments totalling \$407 million in presenting Core performance.

#### Inventories

Inventories decreased in 2008 by \$483 million to \$1,636 million due to exchange rate movements of \$298 million along with an underlying reduction in inventory of \$185 million.

#### **Receivables, payables and provisions**

Trade and other receivables increased by \$593 million to \$7,261 million in 2008. Exchange rate movements reduced receivables by \$429 million. The underlying increase of \$1,022 million was driven by increased sales in Emerging Markets, the extension of major credit terms in the UK and increased insurance recoverables. In 2008, trade and other payables increased by \$130 million, or \$675 million after removing the impacts of exchange rate movements, primarily due to increases in US managed market accruals. Trade payables include \$2,136 million in respect of accruals relating to rebates and reductions in our US market.

Provisions in 2008 increased by \$122 million driven mainly by increases in specific insurance and long-term provisions.

#### Tax payable and receivable

Net income tax payable in 2008 increased by \$667 million to \$1,968 million, principally due to tax audit provisions and cash tax timing differences. Net deferred tax liabilities decreased mainly as a result of the impact of actuarial losses suffered in the year, the amortisation and impairment of MedImmune intangible assets, and exchange rate benefits.

#### **Retirement benef t obligations**

Net retirement benefit obligations in 2008 increased by \$734 million principally as a result of actuarial losses of \$1,232 million offset by exchange rate benefits of \$434 million. During 2008, approximately 95% of the Group's obligations were concentrated in three countries.

#### **Cash flow**

Cash generated from operating activities was \$8,742 million in 2008 compared with \$7,510 million in 2007. The increase of \$1,232 million was principally driven by an increase in operating profit before depreciation, amortisation and impairment costs of \$1,814 million, a decrease in tax payments of \$354 million and lower working capital outflows of \$233 million, offset by an increase in interest payments of \$355 million and a decrease in non-cash items of \$814 million, which includes movements on provisions.

Net cash outflows from investing activities were \$3,896 million in 2008 compared with \$14,887 million in 2007.

In 2008, cash distributions to shareholders were \$3,349 million through dividend payments of \$2,739 million and share re-purchases of \$610 million.

During 2008 we issued a further €500 million, 5.625% 18-month bond as part of our re-financing programme, the proceeds of which were used to re-finance maturing commercial paper.

Gross debt (including loans, short-term borrowings and overdrafts) was \$11,848 million at 31 December 2008 (2007: \$15,156 million). Of this debt, \$993 million was due within one year. Net debt of \$7,174 million decreased in 2008 by \$1,938 million from 31 December 2007.

### Investments, divestments and capital expenditure

The major product acquisitions in 2008 reflected our ongoing commitment to strengthening the product pipeline.

In 2007 AstraZeneca acquired MedImmune. On the acquisition of MedImmune, the purchase price for outstanding shares of \$13.9 billion was allocated between intangible assets of \$8.1 billion (including assets in respect of Synagis and motavizumab RSV franchise, FluMist, Ethyol and products in development), goodwill of \$8.8 billion and net liabilities of \$3.0 billion. This allocation, based on strict accounting requirements, does not allow for the separate recognition of valuable elements such as buyer-specific synergies, potential additional indications for identified products or the premium attributable to a well-established, highly-regarded business in the innovative biologics market. Such elements are instead subsumed within goodwill, which is not amortised. Further details of this acquisition are included in Note 22 to the Financial Statements from page 154.

#### Financial risk management Financial risk management policies Insurance

Our risk management processes are described in the Managing risk section from page 79. These processes enable us to identify risks that can be partly or entirely mitigated through the use of insurance. We negotiate best available premium rates with insurance providers on the basis of our extensive risk management procedures. In the current insurance market, the level of cover is decreasing whilst premium rates are increasing. Rather than simply paying higher premiums for lower cover, we focus our insurance resources on the most critical areas, or where there is a legal requirement, and where we can get best value for money. Risks to which we pay particular attention include business interruption, Directors' and Officers' liability and property damage. Recently, insurance for product liability has not been available on commercially acceptable terms and the Group has not held product liability insurance since February 2006.

#### Taxation

Tax risk management forms an integrated part of the Group risk management processes. Our tax strategy is to manage tax risks and tax costs in a manner consistent with shareholders' best long-term interests, taking into account both economic and reputational factors. We draw a distinction between tax

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planning using artificial structures and optimising tax treatment of business transactions, and we engage only in the latter.

#### Treasury

The principal financial risks to which the Group is exposed are those arising from liquidity, interest rate, foreign currency and credit. The Group has a centralised treasury function to manage these risks in accordance with Board-approved policies. Specifically, liquidity risk is managed through maintaining access to a number of sources of funding to meet anticipated funding requirements, including committed bank facilities and cash resources. Interest rate risk is managed through maintaining a debt portfolio that is weighted towards fixed rates of interest. Accordingly the Group's net interest charge is not significantly affected by movements in floating rates of interest. We do not currently hedge the impact on earnings and cash flow of changes in exchange rates, with the exception of the currency exposure that arises between the booking and settlement dates on non-local currency purchases and sales by subsidiaries and the external dividend, along with certain non-US dollar debt. Credit risk is managed through setting and monitoring credit limits appropriate for the assessed risk of the counterparty.

Our capital and risk management objectives and policies are described in further detail in Note 15 to the Financial Statements from page 144 and in the Managing risk section from page 79.

Sensitivity analysis of the Group's exposure to exchange rate and interest rate movements is detailed in Note 16 to the Financial Statements from page 146.

### Critical accounting policies and estimates

Our Financial Statements are prepared in accordance with IFRS as adopted by the EU (adopted IFRS) and as issued by the IASB, and the accounting policies employed are set out in the Accounting Policies section in the Financial Statements from page 128. In applying these policies, we make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. The actual outcome could differ from those estimates. Some of these policies require a high level of judgement because the areas are especially subjective or complex. We believe that the most critical accounting policies and significant areas of judgement and estimation are in:

- > Revenue recognition
- > Research and development
- > Goodwill and intangible assets
- > Litigation
- > Post-retirement benefits
- > Taxation
- > Segmental reporting.

#### **Revenue recognition**

Revenue is recorded at the invoiced amount (excluding inter-company sales and value added taxes) less movements in estimated accruals for rebates and chargebacks given to managed-care and other customers and product returns - a particular feature in the US. The impact in the rest of the world is not significant. It is the Group's policy to offer a credit note for all returns and to destroy all returned stock in all markets. Cash discounts for prompt payment are also deducted from sales. Revenue is recognised at the point of delivery, which is usually when title passes to the customer either on shipment or on receipt of goods by the customer depending on local trading terms. Income from royalties and from disposals of intellectual property, brands and product lines is included in other operating income.

#### Rebates, chargebacks and returns in the US

At the time of invoicing sales in the US, rebates and chargebacks that we expect to pay, in as little time as two weeks or as much as eight months, are estimated. These rebates typically arise from sales contracts with third party managed-care organisations, hospitals, long-term care facilities, group purchasing organisations and various federal or state programmes (Medicaid 'best price' contracts, supplemental rebates etc) and can be classified as follows:

- > Chargebacks, where we enter into arrangements under which certain parties, typically hospitals, the Department of Veterans Affairs and the Department of Defense, are able to buy products from wholesalers at the lower prices we have contracted with them. The chargeback is the difference between the price we invoice to the wholesaler and the contracted price charged by the wholesaler. Chargebacks are paid directly to the wholesalers.
- > Regulatory, including Medicaid and other federal and state programmes, where we pay rebates based on the specific terms of agreements in individual states, which include product usage and information on best prices and average market prices benchmarks.

> Contractual, under which entities such as third party managed-care organisations, long-term care facilities and group purchasing organisations are entitled to rebates depending on specified performance provisions, which vary from contract to contract.

The effects of these deductions on our US pharmaceuticals turnover are set out below.

Accrual assumptions are built up on a product-by-product and customer-bycustomer basis, taking into account specific contract provisions coupled with expected performance, and are then aggregated into a weighted average rebate accrual rate for each of our products. Accrual rates are reviewed and adjusted on a monthly basis. There may be further adjustments when actual rebates are invoiced based on utilisation information submitted to us (in the case of contractual rebates) and claims/invoices are received (in the case of regulatory rebates and chargebacks). We believe that we have been reasonable in our estimates for future rebates using a similar methodology to that of previous years. Inevitably, however, such estimates involve judgements on aggregate future sales levels, segment mix and the customer's contractual performance.

Cash discounts are offered to customers to encourage prompt payment. Accruals are calculated based on historical experience and are adjusted to reflect actual experience.

Industry practice in the US allows wholesalers and pharmacies to return unused stocks within six months of, and up to 12 months after, shelf-life expiry. The customer is credited for the returned product by the issuance of a credit note. Returned product is not exchanged for product from inventory and once a return claim has been determined to be valid and a credit note has been issued to the customer, the returned goods are destroyed and not resold. At the point of sale in the US, we estimate the quantity and value of goods which may ultimately be returned. Our returns accruals in the US are based on actual experience. Our estimate is based on the preceding 12 months for established products together with market-related information, such as estimated stock levels at wholesalers and competitor activity, which we receive via third-party information services. For newly launched products, we use rates based on our experience with similar products or a pre-determined percentage.

#### **Gross to net sales**

	2009 \$m	2008 \$m	2007 \$m	2006 \$m
Gross sales	22,641	20,029	18,456	16,577
Chargebacks	(1,841)	(1,726)	(1,130)	(975)
Regulatory – US government and state programmes	(1,357)	(1,005)	(732)	(532)
Contractual – Managed-care and group purchasing organisation rebates	(4,753)	(3,658)	(3,179)	(2,413)
Cash and other discounts	(428)	(390)	(356)	(329)
Customer returns	(187)	(48)	(18)	(46)
Other	(196)	(167)	(145)	(256)
Net sales	13,879	13,035	12,896	12,026

#### **Movement in provisions**

	Brought forward at 1 January 2009 \$m	Provision for current year \$m	Adjustment in respect of prior years \$m	Returns and payments \$m	Carried forward at 31 December 2009 \$m
Chargebacks	359	1,947	(106)	(1,804)	396
Regulatory – US government and state programmes	520	1,373	(16)	(1,102)	775
Contractual – Managed-care and group purchasing organisation rebates	1,084	4,732	20	(4,389)	1,447
Cash and other discounts	39	428	-	(426)	40
Customer returns	77	194	(2)	(93)	177
Other	57	198	(2)	(194)	59
Total	2,136	8,871	(106)	(8,009)	2,895
			Adjustment		Carried forward

				Adjustment		Carried forward
		Brought forward	Provision for	in respect	Returns	at 31 December
		at 1 January 2008	current year	of prior years	and payments	2008
		\$m	\$m	\$m	\$m	\$m
Chargebacks		186	1,745	(19)	(1,553)	359
Regulatory – US government and state programmes		428	997	8	(913)	520
Contractual – Managed-care and group purchasing organisation rebates		900	3,622	36	(3,474)	1,084
Cash and other discounts		38	390	_	(389)	39
Customer returns		85	48	_	(56)	77
Other		53	167	_	(163)	57
Total		1,690	6,969	25	(6,548)	2,136
		Additions in		Adjustment		Carried forward
	Brought forward	respect of	Provision for	in respect	Returns	at 31 December
	at 1 January 2007	MedImmune	current year	of prior years	and payments	2007
	\$m	\$m	\$m	\$m	\$m	\$m
Chargebacks	92	2	1,115	15	(1,038)	186
Regulatory – US government and state programmes	314	69	769	(37)	(687)	428
Contractual – Managed-care and group purchasing organisation rebates	635	5	3,100	79	(2,919)	900
Cash and other discounts	29	1	356	_	(348)	38
Customer returns	160	1	19	(1)	(94)	85
Other	47	_	153	_	(147)	53
Total	1,277	78	5,512	56	(5,233)	1,690

For products facing generic competition (such as Ethyol and Toprol-XL in the US) our experience is that we usually lose the ability to estimate the levels of returns from wholesalers with the same degree of precision that we can for products still subject to patent protection. This is because we have limited or no insight into a number of areas - the actual timing of the launch of a generic competitor following regulatory approval of the generic product (for example, a generic manufacturer may or may not have produced adequate pre-launch inventory), the pricing and marketing strategy of the competitor, the take-up of the generic and (in cases where a generic manufacturer has approval to launch just one dose size in a market of several dose sizes) the likely level of switching from one dose to another. Under our accounting policy, revenue is recognised only when the amount of the revenue can be measured reliably. Our approach in meeting this condition for products facing generic competition will vary from product to product depending on the specific circumstances.

The movements on US pharmaceuticals revenue accruals are set out above.

The adjustments in respect of prior years benefited Reported US pharmaceuticals turnover by 0.24% in 2007, and decreased turnover by 1% in 2008.

We have distribution service agreements with major wholesaler buyers, which serve to reduce the speculative purchasing behaviour of the wholesalers and reduce short-term fluctuations in the level of inventory they hold. We do not offer any incentives to encourage wholesaler speculative buying and attempt, where possible, to restrict shipments to underlying demand when such speculation occurs.

#### Royalty income

Royalty income is recorded under other operating income in the Financial Statements. Royalties tend to be linked to levels of sales or production by a third party. At the time of preparing the Financial Statements, we may have to estimate the third party's sales or production when arriving at the royalty income to be included. These estimates, which may differ from actual sales or production, do not result in a material impact on Reported other operating income.

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#### Sales of intangible assets

A consequence of charging all internal R&D expenditure to the income statement in the year in which it is incurred (which is normal practice in the pharmaceutical industry) is that we own valuable intangible assets which are not recorded on the balance sheet. We also own acquired intangible assets which are included on the balance sheet. As a consequence of regular reviews of product strategy, from time to time we sell such assets and generate income. Sales of product lines are often accompanied by an agreement on our part to continue manufacturing the relevant product for a reasonable period (often about two years) whilst the purchaser constructs its own manufacturing facilities. The contracts typically involve the receipt of an upfront payment, which the contract attributes to the sale of the intangible assets, and ongoing receipts, which the contract attributes to the sale of the product we manufacture. In cases where the transaction has two or more components, we account for the delivered item (for example, the transfer of title to the intangible asset) as a separate unit of accounting and record revenue on delivery of that component provided that we can make a reasonable estimate of the fair value of the undelivered component. Where the fair market value of the undelivered component (for example, a manufacturing agreement) exceeds the contracted price for that component we defer an appropriate element of the upfront consideration and amortise this over the performance period. However, where the fair market value of the undelivered component is equal to or lower than the contracted price for that component we treat the whole of the upfront amount as being attributable to the delivered intangible assets and recognise that part of the revenue upon delivery. No element of the contracted revenue related to the undelivered component is allocated to the sale of the intangible asset. This is because the contracted revenue relating to the undelivered component is contingent on future events (such as sales) and so cannot be anticipated.

#### **Research and Development**

Our business is underpinned by our marketed products and development portfolio. The R&D expenditure on internal activities to generate these products is generally charged to the income statement in the year that it is incurred. Purchases of intellectual property and product rights to supplement our R&D portfolio are capitalised as intangible assets. Such intangible assets are amortised from the launch of the underlying products and are tested for impairment both before and after launch. This policy is in line with practice adopted by major pharmaceutical companies.

### Impairment testing of goodwill and intangible assets

We have significant investments in goodwill and intangible assets as a result of acquisitions of businesses and purchases of assets, such as product development and marketing rights.

For the purpose of impairment testing of goodwill, the Group is regarded as a single cash-generating unit.

The recoverable amount is based on value in use, using discounted risk-adjusted projections of the Group's pre-tax cash flows over 10 years, a period reflecting the average patent-protected lives of our current products. The projections include assumptions about product launches, competition from rival products and pricing policy as well as the possibility of generics entering the market. In setting these assumptions we consider our past experience, external sources of information (including information on expected increases and ageing of the populations in Established Markets and the expanding patient population in newer markets), our knowledge of competitor activity and our assessment of future changes in the pharmaceutical industry. The 10-year period is covered by internal budgets and forecasts. Given that internal budgets and forecasts are prepared for all projections, no general growth rates are used to extrapolate internal budgets and forecasts for the purposes of determining value in use.

In arriving at value in use, we disaggregate our projected pre-tax cash flows into groups reflecting similar risks and tax effects. For each group of cash flows we use an appropriate discount rate reflecting those risks and tax effects. In arriving at the appropriate discount rate for each group of cash flows, we adjust AstraZeneca's post-tax weighted average cost of capital (7.6% for 2009) to reflect the impact of risks and tax effects. The weighted average pre-tax discount rate we used was approximately 14%.

As a cross-check, we compare our market capitalisation to the book value of our net assets and this indicates significant surplus at 31 December.

No goodwill impairment was identified.

The Group has also performed sensitivity analysis calculations on the projections used and discount rate applied. The Directors have concluded that, given the significant headroom that exists, and the results of the sensitivity analysis performed, there is no significant risk that reasonable changes in key assumptions will cause the carrying value of goodwill to exceed its value in use. Impairment reviews have been carried out on all intangible assets that are in development (and not being amortised), all major intangible assets acquired during the year, all intangible assets that have had indications of impairment during the year and all intangible assets recognised on the acquisition of MedImmune. Sales forecasts and specific allocated costs (which have both been subject to appropriate senior management sign-off) are discounted using AstraZeneca's risk-adjusted pre-tax weighted average cost of capital.

The majority of our investments in intangible assets and goodwill arose from the restructuring of the joint venture with Merck in 1998 and 2008, the acquisition of MedImmune in 2007 and the payment to partially retire Merck's interests in our products in the US in 2008, and we are satisfied that the carrying values are fully justified by estimated future cash flows.

#### Litigation

In the normal course of business, contingent liabilities may arise from product-specific and general legal proceedings, from guarantees or from environmental liabilities connected with our current or former sites. Where we believe that potential liabilities have a less than 50% probability of crystallising or are very difficult to quantify reliably, we treat them as contingent liabilities. These are not provided for but are disclosed in Note 25 to the Financial Statements from page 166.

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 other similar forms of relief), or where a loss is probable and we are able to make a reasonable estimate of the loss, we indicate the loss absorbed or the amount of the provision accrued.

AstraZeneca is defending its interests in various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices and in respect of which AstraZeneca has made an aggregate provision of \$636 million in the year. \$524 million of this provision has been made in respect of the US Attorney's Office's investigation into sales and marketing practices involving Seroquel, with the remainder relating to average wholesale price litigation pending in the US federal court. The current status of these matters is described more fully in Note 25 to the Financial Statements from page 166. This provision constitutes our best estimate at this time of the losses expected for these matters.

Where it is considered that the Group is more likely than not to prevail, legal costs involved in defending the claim are charged to profit as they are incurred. Where it is considered that the Group has a valid contract which provides the right to reimbursement (from insurance or otherwise) of legal costs and/or all or part of any loss incurred or for which a provision has been established, we consider recovery to be virtually certain and the best estimate of the amount expected to be received is recognised as an asset.

At 31 December legal defence costs of approximately \$656 million have been incurred in connection with Seroquel-related product liability claims. The first \$39 million is not covered by insurance. At 31 December 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 above the \$521 million recorded as an insurance receivable 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.

Assessments as to whether or not to recognise provisions or assets and of the amounts concerned usually involve a series of complex judgements about future events and can rely heavily on estimates and assumptions. AstraZeneca believes that the provisions recorded are adequate based on currently available information and that the insurance recoveries recorded will be received. However, given the inherent uncertainties involved in assessing the outcomes of these cases and in estimating the amount of the potential losses and the associated insurance recoveries, we could in future periods incur judgments or insurance settlements that could have a material adverse effect on our results in any particular period.

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.

Although there can be no assurance regarding the outcome of legal proceedings, we do not currently expect them to have a material adverse effect on our financial position, but they could significantly affect our Reported financial results in any particular period.

#### Post-retirement benef ts

We offer post-retirement benefit plans which cover many of our employees around the world. In keeping with local terms and conditions, most of these plans are 'defined contribution' in nature, where the resulting income statement charge is fixed at a set level or is a set percentage of employees' pay. However, several plans, mainly in the UK (which has by far the largest single scheme), the US and Sweden, are defined benefit plans where benefits are based on employees' length of service and final salary (typically averaged over one, three or five years). The UK and US defined benefit schemes were closed to new entrants in 2000. All new employees in these countries are offered defined contribution schemes.

In applying IAS 19 'Employee Benefits', we recognise all actuarial gains and losses immediately through reserves. This methodology results in a less volatile income statement charge than under the alternative approach of recognising actuarial gains and losses over time. Investment decisions in respect of defined benefit schemes are based on underlying actuarial and economic circumstances with the intention of ensuring that the schemes have sufficient assets to meet liabilities as they fall due, rather than meeting accounting requirements. The trustees follow a strategy of awarding mandates to specialist, active investment managers, which results in a broad diversification of investment styles and asset classes. The investment approach is intended to produce less volatility in the plan asset returns.

In assessing the discount rate applied to the obligations, we have used rates on AA corporate bonds with durations corresponding to the maturities of those obligations.

In all cases, the pension costs recorded in the Financial Statements are assessed in accordance with the advice of independent qualified actuaries but require the exercise of significant judgement in relation to assumptions for future salary and pension increases, long-term price inflation and investment returns.

#### Taxation

Accruals for tax contingencies require management to make judgements and estimates in relation to tax audit issues and exposures. Amounts accrued are based on management's interpretation of countryspecific tax law and the likelihood of settlement. Tax benefits are not recognised unless the tax positions are probable of being sustained. Once considered to be probable, management reviews each material tax benefit to assess whether a provision should be taken against full recognition of the benefit on the basis of potential settlement through negotiation and/or litigation. All such provisions are included in creditors due within one year. Any recorded exposure to interest on tax liabilities is provided for in the tax charge.

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, which is 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.

Included in the total net accrual are amounts in respect of the following transfer pricing arrangements:

- > 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 operation 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.
- > AstraZeneca has applied for an advance pricing agreement in relation to intra-group transactions between the UK and the US which is being progressed through competent authority proceedings under the relevant double tax treaty.

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. 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

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#### Payments due by period

	Less than 1 year \$m	1-3 years \$m	3-5 years \$m	Over 5 years \$m	Total \$m
Bank loans and other borrowings	2,512	2,769	834	12,209	18,324
Operating leases	132	128	80	131	471
Contracted capital expenditure	739	-	-	-	739
Total	3,383	2,897	914	12,340	19,534

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.

#### Segmental reporting

During the year AstraZeneca 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 biopharmaceuticals 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 the SET is principally driven by the management of the commercial operations, R&D and manufacturing and supply. The SET also includes Finance, Human Resources and General Counsel representation.

All significant operating decisions are taken by the SET. While members of the SET have responsibility for implementation of decisions in their respective areas, operating decisionmaking is at SET-level as a whole. Where necessary, decisions 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's 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 R&D resources are allocated between activities on merit. based on overall therapeutic considerations and strategy under the aegis of the Group's R&D 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 Group plc, have been integrated into the existing management structure of AstraZeneca both for allocation of resources and for the purposes of assessment and monitoring of performance. As such, although biologics is a relatively new technological area for the Group, it does not operate as a separate operating segment.

#### Off-balance sheet transaction and commitments

We have no off-balance sheet arrangements and our derivative activities are nonspeculative. The table above sets out our minimum contractual obligations at the year end.

### Other accounting information New accounting standards

New IFRS which have been issued (both adopted and not yet adopted) are discussed in the Accounting Policies section in the Financial Statements from page 128.

#### Sarbanes-Oxley Act section 404

As a consequence of our listing on the NYSE, AstraZeneca is required to comply with those provisions of the Sarbanes-Oxley Act applicable to foreign issuers. Section 404 of the Sarbanes-Oxley Act requires companies annually to assess and make public statements about the quality and effectiveness of their internal control over financial reporting.

Our approach to the assessment has been to select key transaction and financial reporting processes in our largest operating units and a number of specialist areas, such as financial consolidation and reporting, treasury operations and taxation, so that, in aggregate, we have covered a significant proportion of each of the key line items in our Financial Statements. Each of these operating units and specialist areas has ensured that its relevant processes and controls are documented to appropriate standards, taking into account, in particular, the guidance provided by the SEC. We have also reviewed the structure and operation of our 'entity level' control environment. This refers to the overarching control environment, including structure of reviews, checks and balances that are essential to the management of a wellcontrolled business.

The Directors have concluded that our internal control over financial reporting is effective at 31 December and the assessment is set out in the Directors' Responsibilities for, and Report on, Internal Control over Financial Reporting section in the Financial Statements on page 122. KPMG has audited the effectiveness of our internal control over financial reporting and, as noted in the Auditor's Report on the Financial Statements and on Internal Control over Financial Reporting (Sarbanes-Oxley Act Section 404) on page 123, their report is unqualified.

## **Geographical Review**

#### 2009 in brief

- > Significant growth continues to be delivered by key products: Arimidex (7%), Crestor (29%), Seroquel (12%) and Symbicort (23%). Nexium growth of 9% outside the US.
- > Despite a continually challenging environment, including pressure from generic medicines, combined sales of Arimidex, Crestor, Nexium, Seroquel and Symbicort were up 10% in the US to 66% of our total US sales.
- In North America, despite several key mergers (Merck/Schering-Plough, Pfizer/Wyeth), AstraZeneca maintained its position as the second largest pharmaceutical company in Canada. In the US, AstraZeneca is now the third largest pharmaceutical company. In the US, AstraZeneca grew its audited sales faster than any other pharmaceutical company in the top 10.
- > Solid sales performance outside the US, up 6%.
- > Strong brand performance in our Western Europe markets but intense competition and governmental controls over healthcare expenditure.
- > Emerging Markets delivered strong sales growth, up 12% with Emerging Europe sales up 7% and Emerging Asia Pacific sales (including China) up 15%.
- > Live attenuated H1N1 influenza (swine flu) vaccine approved. AstraZeneca contracted with the US Department of Health and Human Services to supply 42 million doses of live attenuated H1N1 influenza vaccine at \$389 million.
- > For the first time, the seasonal influenza vaccine, FluMist, sold out of its approximately 10 million dose supply.

For more information regarding our products see the Therapy Area Review from page 55. Details of material legal proceedings can be found in Note 25 to the Financial Statements from page 166 and details of relevant risks are set out in the Principal risks and uncertainties section from page 80.

See the market definitions table on page 206 for information on AstraZeneca's market definitions.

### North America

Sales in the US increased 9% to \$14,778 million, benefiting from the 10% growth of our leading brands. Combined sales of those brands, namely Arimidex, Crestor, Nexium, Seroquel (all formulations) and Symbicort, were up 10% to \$9,717 million (2008: \$8,803 million) and sales of Toprol-XL and its authorised generic increased as a result of supply issues facing its generic competitors. AstraZeneca is currently the third largest pharmaceutical company in the US, with a 6% share of US prescription pharmaceutical sales. Sales for Aptium Oncology, Inc. fell by 1% to \$393 million (2008: \$395 million) and sales for Astra Tech AB rose by 4% to \$83 million (2008: \$80 million).

Seroquel maintained its strong position as the number one prescribed atypical anti-psychotic on the market, with sales up 13% to \$3,416 million (2008: \$3,015 million). Seroquel (all formulations) posted total prescription growth of 2% with an increase of 408,000 prescriptions, driven by strong Seroquel XR prescription growth of 195%. At the end of 2009, Seroquel XR accounted for 11.1% of the Seroquel total prescription volume in the US, up from 3.4% at the end of 2008.

Throughout 2009, *Nexium* continued to lead the branded proton pump inhibitor (PPI) market for new prescriptions, total prescriptions and total capsules dispensed. Generic lansoprazole and Prevacid OTC 24 Hour were introduced in November, leaving *Nexium* as the only branded product with significant market share in the PPI class. In the face of continuing generic, OTC and pricing pressures, *Nexium* sales were down 9% to \$2,835 million in 2009 (2008: \$3,101 million).

*Crestor* achieved sales of \$2,100 million (2008: \$1,678 million) and a total prescription growth of 22.8%. For the second year in a row *Crestor* was the only branded statin to grow market share despite pressure from generic medicines. In fact, in 2009, *Crestor*'s total prescription growth of 22.8% significantly outpaced the market by 17.5% and that of total generic statins by 3.3%. We continue to see increased interest in the clinical profile of *Crestor* from physicians following receipt of the atherosclerosis indication. *Crestor* is the fastest growing branded statin prescribed by cardiologists and internists. In June, AstraZeneca and Abbott submitted an NDA for *Certriad* for the treatment of mixed dyslipidaemia. AstraZeneca and Abbott have also entered into an agreement under which AstraZeneca obtained the non-exclusive right to co-promote Trilipix<sup>™</sup>, alongside Abbott in the US (excluding Puerto Rico), from June. This is the second co-promotion agreement between AstraZeneca and Abbott. In 2008, the companies announced a non-exclusive agreement for Abbott to co-promote *Crestor* alongside AstraZeneca in the US (excluding Puerto Rico).

Onglyza<sup>™</sup> was launched in August, the first launch in the collaboration with BMS. Execution of the Onglyza<sup>™</sup> launch strategy remains on-target and the number of physicians prescribing the product is growing. Brand awareness is increasing and is in line with expectations.

Sales for *Toprol-XL* and the authorised generic, which is marketed and distributed by Par Pharmaceutical Companies, Inc. increased 227% to \$964 million (2008: \$295 million) following the withdrawal from the market of two other generic metoprolol succinate products in early 2009. AstraZeneca worked diligently following these withdrawals to ensure an adequate supply of *Toprol-XL* and the authorised generic. In September, Watson Pharmaceuticals Inc. received approval for 25mg and 50mg strengths of metoprolol succinate. We expect further generic competition in 2010.

Arimidex continued to perform well with sales up 16% to \$878 million (2008: \$754 million) for the full year. Arimidex continues to be the market leader in new prescriptions in hormonal treatments for post-menopausal women with hormone receptor positive breast cancer in the US.

Patent protection in the US for the *Casodex* advanced prostate cancer indication expired in April 2009. In July, multiple generic formulations of *Casodex* were approved by the FDA and entered the market. As a result, 2009 sales of *Casodex* declined 49% to \$148 million (2008: \$292 million).

Sales for *Pulmicort Respules* were down 21% to \$692 million (2008: \$874 million) as a result of the 'at risk' launch of generic budesonide inhalation suspension by Teva in November 2008. On 25 November 2008, the parties settled the ensuing litigation and in accordance with the settlement agreement, Teva commenced sales of its generic product under an exclusive licence from AstraZeneca on 15 December 2009.

#### **Our financial performance**

			2009			2008	2007	2009 comp	ared to 2008	2008 comp	ared to 2007
	Sales \$m		Growth due to exchange effect \$m	Sales \$m	CER growth \$m	Growth due to exchange effect \$m	Sales \$m	CER growth %	Reported growth %	CER growth %	Reported growth %
US	14,778	1,268	-	13,510	142	2	13,366	9	9	1	1
Canada	1,203	37	(109)	1,275	95	35	1,145	3	(6)	8	11
North America	15,981	1,305	(109)	14,785	237	37	14,511	9	8	2	2
Western Europe	9,277	257	(723)	9,743	55	573	9,115	3	(5)	1	7
Japan	2,341	142	242	1,957	73	223	1,661	7	20	4	18
Australasia	853	98	(88)	843	107	21	715	12	1	15	18
Other Established Markets	12,471	497	(569)	12,543	235	817	11,491	4	(1)	2	9
Emerging Europe	1,091	87	(211)	1,215	102	85	1,028	7	(10)	10	18
China	811	168	16	627	136	54	437	27	29	31	43
Emerging Asia Pacific	780	52	(74)	802	72	(19)	749	6	(3)	10	7
Other Emerging	1,670	208	(167)	1,629	247	39	1,343	13	3	18	21
Emerging Markets	4,352	515	(436)	4,273	557	159	3,557	12	2	16	20
Total Sales	32,804	2,317	(1,114)	31,601	1,029	1,013	29,559	7	4	3	7

Symbicort pMDI continued to deliver steady growth in the US with sales up 91% to \$488 million (2008: \$255 million). It surpassed a 15% total prescription share and a 17% new prescription share of the inhaled corticosteroid/long-acting beta-agonist market. Symbicort pMDI is now prescribed to 26% of all patients who are new to combination therapy. In February 2009, it was approved for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

Synagis is the only FDA-approved MAb to help protect high-risk babies against severe respiratory syncytial virus (RSV). In 2009, sales in the US were \$782 million (2008: \$923 million). Sales in the 2009-2010 RSV season started slower than anticipated due to payer pressure as a result of the introduction of more restrictive guidelines regarding the use and dosing of *Synagis* by the American Academy of Pediatrics and the adoption of these guidelines.

AstraZeneca's monovalent H1N1 influenza (swine flu) vaccine, which is made using the same technology and process as AstraZeneca's seasonal influenza vaccine, *FluMist*, was approved by the FDA in September for the same patient population as *FluMist* (patients two to 49 years of age). AstraZeneca began shipping product to the US Department of Health and Human Services (HHS) in September. All sales in the US were through the HHS and totalled \$389 million.

AstraZeneca has a number of new drug application submissions under review by the regulatory authorities in the US and the EU, including: Crestor (for a new indication, as an sNDA based on the results of the JUPITER study), Vimovo, Certriad, motavizumab and Symbicort pMDI as an sNDA for paediatric use as well as sNDAs for Seroquel XR for generalised anxiety disorder (acute, maintenance and use in elderly), and for the use of Seroquel XR as monotherapy for the treatment of patients with major depressive disorder (acute, maintenance and use in elderly). Further information about the status of these submissions and others is contained in the Therapy Area Review from page 55.

Currently, there is no direct government control of prices for commercial prescription drug sales in the US. However, some publicly funded programmes, such as Medicaid and TRICARE (Department of Veterans Affairs), have statutorily mandated rebates and discounts that have the effect of price controls for these programmes. Additionally, pressure on pricing, availability and utilisation of prescription drugs for both commercial and public payers continues to increase, driven by, among other things, an increased focus on generic alternatives. Primary drivers of increased generic use are budgetary policies within healthcare systems and providers, including the use of 'generics only' formularies, and increases in patient co-insurance or co-payments. In 2009, 75% of the prescriptions dispensed in the US were generic. Despite these price pressures and a challenging economic environment, AstraZeneca increased net product sales in 2009 by 9% and IMS Health audited sales for the US market show that AstraZeneca

was the fastest growing branded company in the top 10. While it is unlikely that there will be widespread adoption of a broad national price-control scheme in the near future, there will continue to be increased attention to pharmaceutical prices and their impact on healthcare costs for the foreseeable future.

In 2010, we anticipate there will be continued focus on health reform that may result in the implementation of changes in legislation and regulation. AstraZeneca believes that every American should have affordable health insurance and prescription drug coverage. In reviewing different health reform proposals that Congress is considering, AstraZeneca will ask whether any particular provision:

- > Promotes market competition that leads to improved health outcomes
- Ensures patient safety is maintained or enhanced
- > Expands coverage for the uninsured
- > Fosters and rewards innovation
- > Provides protection for intellectual property.

For further discussion of the proposed US healthcare reforms, see the Competition, price controls and price reductions section on page 83.

In its fourth year of operation, the Medicare Part D prescription drug programme maintained high levels of enrolment and beneficiary satisfaction. It also achieved prescription volume growth similar to that of other mature markets and provided access to our medicines for a large segment of the patient population. Overall access for AstraZeneca's products in key accounts was maintained or improved in 2009. We continue our long-standing commitment to educating Medicare beneficiaries and supporting healthcare professionals in all aspects of Medicare Part D through our partnership with the National Council on Aging. This includes a consumer website, My Medicare Matters, which was revised this year to provide detailed, yet easy-tounderstand information about Medicare services including Part D for people with commonly diagnosed diseases among the elderly, starting with diabetes, cancer and Alzheimer's disease and related dementias. Funding from AstraZeneca also supports MyMedicareCommunity.org, an on-line community for healthcare professionals and grass roots organisations serving people with Medicare.

Additionally, through the AZ&Me Prescription Savings Programme, AstraZeneca provides prescription access to financially needy Medicare Part D beneficiaries. AstraZeneca has been providing patient assistance to the uninsured for 30 years. Last year, we provided more than \$750 million in savings to approximately 505,000 people without drug coverage (approximately 3.8 million prescriptions).

#### Canada

Despite the entry of generic forms of Seroquel IR in late 2008, total product sales in Canada increased by 3% to \$1,203 million (2008: \$1,275 million) and we remain the second largest brand name pharmaceutical company in Canada. Combined sales of Crestor, Nexium, Symbicort and Atacand were up 18% to \$872 million (2008: \$805 million) with Crestor and Nexium among the top 10 prescription products in Canada by sales. Sales of *Seroquel* were down 68% to \$48 million (2008: \$160 million) as a result of generic entry. Crestor maintained its number two ranking in the statin market and was the fastest-growing product in both new and total prescription segments (25.5% and 27.6% growth, respectively). Crestor is also the second largest pharmaceutical product in Canada by sales.

AstraZeneca received a number of important regulatory approvals from Health Canada in 2009, including regulatory approval for Onglyza<sup>™</sup> for the treatment of Type 2 diabetes, *Symbicort Turbuhaler* for the treatment of chronic obstructive pulmonary disease and *Seroquel XR* for the treatment of major depressive disorder. In addition, new tablet strengths (32/12.5mg and 32/25mg) were approved for *Atacand Plus*.

Key organisational efficiencies were obtained through structural changes, as well as the move to regional shared service models and common North American technology platforms.

A recent study, 'The Rx&D International Report on Access to Medicines, 2008-2009' by George Wyatt, highlights that only 55% of innovative medicines receive approval from Canada's Health Technology Assessment appraisal system compared to an international average of 73%. The Patented Medicine Prices Review Board (PMPRB) has the role of ensuring that prices charged by manufacturers for patented medicines are not excessive. Recent PMPRB guideline changes to be introduced in 2010 have secured a competitive pricing environment for the Canadian pharmaceutical industry.

The provinces have adopted different approaches to pharmaceutical funding, from one end of the continuum in Quebec, with more open access, to more restricted access in British Columbia. Ontario, Alberta and British Columbia have all undertaken reviews of their drug reimbursement system, resulting in the introduction of product listing agreements, the reduction of generic prices and changes to the role of pharmacists. The trend in Canada indicates provinces will continue to introduce policy changes that drive cost savings, while providing reasonable patient access to innovative medicines.

#### **Rest of World**

Sales in the Rest of World performed strongly in 2009, up 6% (flat as reported) to \$16,823 million (2008: \$16,816 million), despite the world economic crisis. Key products (*Arimidex, Crestor, Nexium, Seroquel* and *Symbicort*) delivered a strong performance, up 15% (+8% reported) with sales of \$7,977 million (2008: \$7,413 million). China, Emerging Asia Pacific and Other Emerging markets delivered particularly strong sales, up 14% (+7% reported) with sales of \$3,261 million (2008: \$3,058 million).

#### **Other Established Markets**

Sales in Other Established Markets increased by 4% (-1% reported). The key products driving sales growth in 2009 were *Crestor*, *Symbicort*, *Nexium* and *Seroquel*.

#### Western Europe

In our Western Europe markets, we saw good growth of 3% (-5% reported). The weakness of the pound sterling in comparison to the euro resulted in a significant change in the pattern of export trade within the EU with strong sales in the UK (up 27%, +6% reported) more than offsetting sales declines in Italy (down 3%, -9% reported), Spain (down 6%, -11% reported), and the Nordics (ie Sweden, Finland, Denmark and Norway) (down 5%, -16% reported).

Within our Western Europe markets, *Crestor* has delivered a strong financial performance and has outperformed the market with strong double-digit growth. Likewise, *Seroquel* has outperformed the market by two times with the successful launch of *Seroquel XR* and the bipolar indication driving performance. *Symbicort* has defended its market position and *Nexium* has moved from second to first place in its class. *Arimidex* has maintained its position as the leading aromatase inhibitor. Sales of *Casodex* continue to decline following patent expiries in 2008.

Sales in our Western Europe markets continued to be impacted by government initiatives to contain drug expenditures and by generic erosion of those of our products which have lost patent protection and Regulatory Exclusivity.

We have continued with our programme of resource management in our Western Europe markets and have reduced our cost base by 5% and headcount by over 600 during 2009.

Overall our sales in France were up 2% (-4% reported) to \$1,849 million (2008: \$1,922 million). The strong performance of *Crestor* and *Nexium*, which gained significant market share from competitors, was offset by the continuing impact of patent expiry for *Casodex*.

In Germany, sales were up 3% (-2% reported) to \$1,278 million (2008: \$1,307 million) with good growth in *Atacand, Symbicort* and *Seroquel* offsetting the continued declines in *Nexium*, resulting from government restrictions to access, and *Casodex* following patent expiry.

Reviews

As a result of the weak pound sterling and its impact on export sales through parallel trade, in the UK sales were up 27% (+6% reported) to \$1,082 million (2008: \$1,020 million) driven by *Crestor* (up 62%, +35% reported), *Seroquel* (up 64%, +35% reported), *Symbicort* (up 42%, +18% reported) and *Nexium* (up 95%, +59% reported).

In Italy, overall sales declined by 3% (-9% reported) to \$1,199 million (2008: \$1,323 million) as a result of reference pricing and *Casodex* patent expiry. However, *Crestor* performed well, increasing its sales by 8% (+3% reported) and *Seroquel* showed strong growth, increasing sales by 36% (+28% reported).

In Spain, sales were down 6% (-11% reported) to \$768 million (2008: \$863 million) due to *Seroquel* (down 17%, -21% reported), *Symbicort* (down 3%, -9% reported) and *Arimidex* (down 30%, -33% reported). However, *Nexium* performed well with sales up 15% (+9% reported).

Most governments in Europe intervene directly to control the price and reimbursement of medicines. The decision-making power of prescribers in Europe has been eroded in favour of a diverse range of payers. While the systems to control pharmaceutical spending vary, they have all had a noticeable negative impact on the uptake and availability of innovative medicines. Several governments have imposed price reductions and increased the use of generic medicines as part of healthcare expenditure control. Several countries are applying strict tests of cost-effectiveness to medicines, which has reduced access for European patients to medicines in areas of high unmet medical need. These and other measures all contribute to an increasingly difficult environment for branded pharmaceuticals in Europe.

#### Japan

In Japan, strong volume gains of 8.3% increased overall sales by 7% (+20% reported) to \$2,341 million (2008: \$1,957 million) and allowed us to maintain our twelfth place position in the market. This was achieved despite a decline of 5% (+6% reported) of *Casodex*, our largest product in Japan, following the launch of generic competitors in May 2009. The key drivers of growth were the continued success of *Crestor* (up 58%, +76% reported), the continued growth of *Losec* (up 8%, +20% reported) and the increased penetration of *Seroquel* (up 25%, +39% reported).

In addition, future growth prospects received a boost in 2009 with the approval of *Symbicort Turbuhaler* for the Japanese market. *Symbicort Turbuhaler* was launched in January 2010 into an asthma market where the proportion of patients treated by inhaled corticosteroids is growing but lags behind other major markets by five to 10 years. *Symbicort Turbuhaler* is being promoted in Japan by both AstraZeneca and Astellas.

In Japan there is formal central government control of prices by the Ministry of Health, Labour and Welfare (MHLW) and the pricing and reimbursement system has been stable in recent years. Regular price revisions are imposed in April every other year that reduce the reimbursement price of almost all products. Accordingly, prices were not revised in 2009, but will be in 2010. At the same time, it is expected that in April 2010, a new pricing rule will be adopted on a trial basis to reward the development of innovative new products. Under this rule, new products with a below industry-average doctor margin will be subject to either a zero or a significantly reduced price revision, as long as the manufacturer has demonstrated appropriate progress in developing unapproved products and indications requested by the government. The long-term objective of the Japanese government is to raise generic volume share from 20.9% in 2008 to 30% by 2012; recent reforms have supported this goal by making the substitution of a generic product for a branded product easier.

#### Australasia

In Australia and New Zealand, we delivered a strong sales performance with sales up 12% (+1% reported) to \$853 million (2008: \$843 million), driven mainly by sales growth for *Crestor, Atacand, Nexium, Seroquel* and *Symbicort.* These five brands grew by 26% (+14% reported). *Crestor*'s performance in Australia has been particularly strong, gaining over 6% volume market share in the year.

#### **Emerging Markets**

In the Emerging Markets, sales increased by 12% (+2% reported) to \$4,352 million (2008: \$4,273 million), accounting for nearly 49% of total sales growth outside the US. Sales in Emerging Europe were up 7% (-10% reported) to \$1,091 million (2008: \$1,215 million). Sales in China (excluding Hong Kong) increased by 27% (+29% reported) to \$811 million (2008: \$627 million).

In many of the larger markets, such as Brazil and Mexico, patients tend to pay directly for prescription medicines and consequently these markets are at less risk of direct government interventions on pricing and reimbursement. In other markets such as South Korea, Taiwan and Turkey where governments do pay for medicines, we are seeing measures to reduce the cost of prescriptions in line with the systems in Europe, Canada and Australia.

#### **Emerging Europe**

As part of our ongoing growth strategy, we have significantly increased our presence in the Russian market and sales have grown by 23% (-2% reported) to \$180 million (2008: \$184 million). The strongest performance has been seen in the cardiovascular (up 61%, +26% reported) and respiratory (up 33%, +6% reported) Therapy Areas.

In Romania, AstraZeneca has increased its market share to 3.3% in a very dynamic prescription market environment. Sales have increased by 51% (+29% reported) to \$92 million (2008: \$71 million), driven primarily by *Crestor* (up 54%, +29% reported) and *Nexium* (up 59%, +36% reported).

In late 2009 the government in Turkey imposed unprecedented levels of price reductions on the pharmaceutical industry. As a result our full-year growth was limited to 6%.

Ukraine, Kazakhstan, Belarus and Georgia have been particularly challenged by the financial crisis, most notably in Ukraine, although the pharmaceutical sector has been less affected than others by the GDP decline.

#### China

In China, in line with our growth and expansion strategy of the past five years, we have continued to build our presence and sales (excluding Hong Kong) were up 27% (+29% reported) to \$811 million (2008: \$627 million). We are the second largest multinational pharmaceutical company in the prescription market in China (including Hong Kong) with a growth rate for prescription sales of 29%. Our investment in China increased with further growth in the number of sales representatives, and continued to support our innovation discovery research centre in Shanghai and our several external collaborations. In November, the third edition of China's National Reimbursable Drugs List (NRDL) was published by the Ministry of Human Resources and Social Security (MHRSS), five years after the publication of the second edition in 2005. 131 new 'western' medicines were added to the list, representing a 13% increase. For AstraZeneca *Crestor, Nexium i.v., Symbicort* and *Seloken XR* were included on the list for the first time whilst previous restrictions that applied to *Arimidex, Casodex* and *Zoladex* were removed. Based on the current guidelines issued by MHRSS, we expect the new list to be operational at the provincial and hospital level in the second half of 2010.

In August, China's National Essential Drug System (NEDL) was officially launched. This formulary lists 307 essential drugs (205 chemical and biologics and 102 formulated traditional Chinese medicines) which should be used in all government owned healthcare institutions. *Seloken* and *Losec* MUPS are listed in the NEDL. The Chinese Government has a target that by the end of 2009, 30% of basic healthcare institutions (ie community health centres and rural hospitals) will stock all drugs listed in the NEDL.

#### **Emerging Asia Pacific**

In Emerging Asia Pacific, overall sales were up 6% (-3% reported) to \$780 million (2008: \$802 million) with double-digit growth in India, Malaysia and Vietnam and a more subdued performance in Thailand, the Philippines and Singapore due to the more pronounced impact of the economic crisis and government interventions in these countries.

#### **Other Emerging markets**

#### Latin America

During 2009, GDP growth in Latin America slowed significantly to -2.1% from 4.2% in 2008, as a result of the global financial crisis. The pharmaceutical market in Latin America grew by 12% compared to 2008 and AstraZeneca's sales grew 8% (-4% reported) to \$1,118 million (2008: \$1,159 million), mainly driven by Brazil, Argentina and Venezuela. As a result, our market share grew to 2.4% (2008: 2.3%) in the prescription market, improving our position again from eleventh last year to tenth this year in the regional competitor rankings. Atacand, Crestor, Nexium, Seroquel and Symbicort showed strong performance, with overall sales up 17% (+5% reported) to \$544 million (2008: \$516 million). Nexium is our number one prescription product in Latin America, with sales up 4% (-5% reported) to \$175 million (2008: \$185 million), and is ranked fourth in the top 20 products of the Latin American prescription market. Crestor is our second largest prescription product, with overall sales up 27% (+14% reported) to \$146 million (2008: \$128 million), and is now number seven in the top 20 Latin American prescription products.

Brazil, Mexico and Venezuela are our three largest markets in the region, with sales up 18% (+4% reported) to \$457 million (2008: \$440 million), down 9% (-26% reported) to \$261 million (2008: \$353 million) and up 15% (+15% reported) to \$163 million (2008: \$142 million), respectively. Mexico in particular has been heavily impacted by the global financial crisis as a result of its reliance on the US economy.

#### Middle East and Africa (MEA)

During 2009, MEA has achieved strong growth essentially driven by Maghreb and Egypt. Our largest three markets in the region are now South Africa, the Gulf States and Saudi Arabia.

Sales force expansion in MEA over the past few years has directly contributed to this strong performance in the region, with *Crestor*, *Symbicort* and *Seroquel* demonstrating growth. Overall, AstraZeneca's sales in MEA are growing twice as fast as the pharmaceutical market in MEA.

\$m

## **Therapy Area Review**

This section contains further information about the Therapy Areas in which our efforts are focused: Cardiovascular, Gastrointestinal, Infection, Neuroscience, Oncology, and Respiratory & Inflammation.

We describe the business environment, trends and other factors that have influenced our decision to focus on diseases in these six areas, our strategic objectives for each and our progress towards achieving these objectives. We include information about our marketed medicines and how they are designed to make a meaningful difference for patients, together with an overview of performance during the year. We also report in detail on the potential new products and product life-cycle developments in our pipeline that reflect our commitment to maintaining a flow of innovation that adds value for our shareholders and society.

For a list of all our potential new products and product life-cycle developments see the Development Pipeline table from page 196.

Many of our products are subject to litigation. Detailed information about material legal proceedings can be found in Note 25 to the Financial Statements from page 166. Details of relevant risks are set out in the Principal risks and uncertainties section from page 80. Projects in Phase III

34 Projects in Phase II

44 Projects in Phase I

**43** Projects in pre-clinical

Sales	by	Therapy Area	

Cardiovascular (+25%)

2009	8,376
	6,963
2007	6,686

#### Gastrointestinal (-2%)

2009	6,011
2008	6,344
2007	6,443

Infection and other<sup>1</sup> (+10%)

2009	2,631
2008	2,451
2007	1,714

Neuroscience (+10%)

2009	6,237
2008	5,837
2007	5,340

#### Oncology (-7%)

2009	4,518
2008	4,954
2007	4,819

#### **Respiratory & Inflammation** (+6%)

2009 🚦	4,132
2008	4,128
2007	3,711

<sup>1</sup> Includes *Synagis* and *FluMist* which were acquired in June 2007.

### Cardiovascular

#### In brief

- > Onglyza<sup>™</sup> has been launched in the US, Canada, Mexico, Germany, the UK and Denmark and has been approved in Argentina, Brazil, India and all other EU countries.
- > Crestor sales up 29% to \$4.5 billion. Crestor approval has broadened to every EU country with launches in Germany and Spain in 2009.
- > Crestor was approved in the US for the treatment of paediatric patients from 10 to 17 years of age with heterozygous familial hypercholesterolemia based on the PLUTO study. This study fulfilled our paediatric exclusivity obligations, which resulted in Paediatric Exclusivity being granted in July, which will provide an additional six months of exclusivity to market Crestor in the US.
- > Crestor filings were submitted in the US and the EU as well as other markets seeking an outcomes indication and labelling based on the JUPITER study which demonstrated a significant reduction in major cardiovascular (CV) events (44% compared to placebo) in men (over 50) and women (over 60) with elevated high-sensitivity C-reactive protein but low/normal cholesterol levels.
- > The parties concluded discovery in the Crestor consolidated ANDA patent litigations filed in the US District Court for the District of Delaware. The actions involve eight generic drug manufacturers challenging the patent covering the active ingredient for Crestor. The Court decided numerous pre-trial motions, including a denial of AstraZeneca's and the licensor's (Shionogi) motion for summary judgment in respect of alleged inequitable conduct. The Court amended the pre-trial schedule, re-setting the beginning trial date to 22 February 2010.
- In Canada, previously reported Patented Medicines (Notice of Compliance) Regulations proceedings in respect of *Crestor* continued and others were commenced in response to Notices of Allegation from further generic manufacturers.
- > Atacand sales up 5% to \$1.4 billion.
- > Toprol-XL US sales up 227% for the full year.
- > MAA filed for *Brilinta/Brilique* (ticagrelor) in October and an NDA in November.
- > In December, AstraZeneca and BMS submitted an NDA for the once-daily fixed-dose combination of Onglyza<sup>™</sup> (saxagliptin) and metformin.
- > US submission for Certriad, a fixed-dose combination of Crestor (rosuvastatin calcium) and Abbott's Trilipix<sup>™</sup> (fenofibric acid), for the treatment of mixed dyslipidaemia.
- > An NDA for Axanum, a single capsule of Nexium and aspirin, was filed in April.

#### **Our marketed products**

*Crestor*<sup>1</sup> (rosuvastatin calcium) is a statin for the treatment of dyslipidaemia and hypercholesterolemia, and to slow the progression of atherosclerosis.

*Atacand*<sup>2</sup> (candesartan cilexetii) is an angiotensin II antagonist for the 1st line treatment of hypertension and symptomatic heart failure.

**Seloken/Toprol-XL** (metoprolol succinate) is a beta-blocker once-daily tablet for 24-hour control of hypertension and for use in heart failure and angina.

**Tenormin** (atenolol) is a cardioselective beta-blocker for hypertension, angina pectoris and other CV disorders.

**Zestril**<sup>3</sup> (lisinopril dihydrate) is an ACE inhibitor used for the treatment of a wide range of CV diseases, including hypertension.

*Plendil* (felodipine) is a calcium antagonist for the treatment of hypertension and angina.

**Onglyza**<sup>™4</sup> (saxagliptin) is a dipeptidyl peptidase IV inhibitor for the treatment of Type 2 diabetes.

- <sup>1</sup>Licensed from Shionogi & Co. Ltd.
- <sup>2</sup> Licensed from Takeda Chemicals Industries Ltd.
- <sup>3</sup>Licensed from Merck & Co., Inc.
- <sup>4</sup>Co-developed and co-commercialised with Bristol-Myers Squibb Company.

#### **Our strategic objectives**

An estimated 17.5 million people died from cardiovascular (CV) disease in 2005, 7.6 million due to heart attacks, despite improvements in the quality of diagnosis and treatment. Direct and indirect costs of treating coronary heart disease were estimated to be €192 billion in Europe in 2008<sup>1</sup> and \$313 billion in the US in 2009<sup>2</sup>.

Backed by over 40 years' experience, AstraZeneca is a world leader in CV medicines. We aim to build on our strong position, focusing on the growth areas of atherosclerosis (hardening of the arteries), thrombosis (blood clotting), diabetes and atrial fibrillation.

### Hypertension, atherosclerosis and dyslipidaemia

High blood pressure (hypertension) and abnormal levels of blood cholesterol (dyslipidaemia) damage the arterial wall and thereby lead to atherosclerosis. CV events driven by atherosclerotic disease remain the leading cause of death in the western world. Lipid-modifying therapy, primarily statins, is a cornerstone for the treatment of atherosclerosis. Within the lipid-modifying market, generics are taking a significant share of the market and it is anticipated that generic atorvastatin (Lipitor<sup>™</sup>) will be available late in 2011.

#### Our focus

#### Our key marketed products

Since its launch in 2003, our statin, *Crestor*, has continued to gain market share, based on its differentiated profile in managing cholesterol levels and its unique recent label indication for treating atherosclerosis. *Crestor* approval has broadened to every EU country with launches in Germany and Spain in 2009.

Fewer than half of the people thought to have high levels of low-density lipoprotein cholesterol (LDL-C) 'bad cholesterol' get diagnosed and treated and, of those people, only about half reach their physician's recommended cholesterol target using existing treatments. Crestor is the most effective statin in lowering LDL-C and the majority of patients reach their LDL-C goals using the usual 10mg starting dose. Crestor also produces an increase in high-density lipoprotein cholesterol (HDL-C) 'good cholesterol', across a range of doses. At its usual 10mg starting dose, Crestor has been shown, versus placebo, to reduce LDL-C by up to 52% and raise HDL-C by up to 14%, with eight out of 10 patients reaching their lipid goals.

In December, the FDA approved *Crestor* for use as an adjunct to diet for slowing the progression of atherosclerosis in patients with elevated cholesterol. *Crestor* is the only statin with an atherosclerosis indication in the US which is not limited by disease severity or restricted to patients with coronary heart disease.

Atacand, first launched in 1997, is approved for the treatment of hypertension in over 100 countries and for symptomatic heart failure in 70 countries. Atacand is an angiotensin II antagonist, and this class of medicine is the fastest-growing segment of the global hypertension market. Atacand Plus (candesartan cilexetil/hydrochlorothiazide) is a fixed-dose combination of Atacand and the diuretic hydrochlorothiazide, indicated for the treatment of hypertension in patients who require more than one hypertensive therapy. Atacand Plus is approved in 88 countries. In 2008, AstraZeneca sought approval in Europe and other markets for two additional dose strengths of Atacand Plus. In 2009, the new strengths of Atacand Plus (32mg/12.5mg and 32mg/25mg) were approved in Canada, Australia, Sweden and nine other markets. Further approvals and launches are anticipated in 2010.

<sup>&</sup>lt;sup>1</sup>European cardiovascular disease statistics, 2008 edition, Steven Allender *et al*, British Foundation Health Promotion Research Group.

<sup>&</sup>lt;sup>2</sup>National Heart, Lung, and Blood Institute. Fact Book, Fiscal Year 2008, hlbi.nih.gov/about/factbook/ FactBookFinal.pdf.

#### **Our financial performance**

	2009			2008			2007	2009 compared to 2008		2008 compared to 2007	
	Sales	CER to growth	rowth due exchange effect	Sales	CER growth	Growth due to exchange effect	Sales	CER growth	Reported growth	CER growth	Reported growth
Ostation /Teanst V/1	\$m	\$m	\$m	\$m	\$m	\$m	\$m	%	%	%	<u>%</u>
Seloken/Toprol-XL <sup>1</sup>	1,443	677	(41)	807	(667)	36	1,438	84	79	(46)	(44)
Crestor	4,502	1,048	(143)	3,597	714	87	2,796	29	25	26	29
Atacand	1,436	67	(102)	1,471	123	61	1,287	5	(2)	10	14
Plendil	241	(20)	(7)	268	(18)	15	271	(7)	(10)	(7)	(1)
Tenormin	296	(15)	(2)	313	(17)	22	308	(5)	(5)	(6)	2
Zestril	184	(40)	(12)	236	(72)	13	295	(17)	(22)	(24)	(20)
Onglyza™	11	11	-	-	-	_	-	n/m	n/m	n/m	n/m
Other	263	9	(17)	271	(34)	14	291	3	(3)	(12)	(7)
Total	8,376	1,737	(324)	6,963	29	248	6,686	25	20	-	4

<sup>1</sup> Includes sales of the authorised generic of *Toprol-XL* to Par Pharmaceutical Companies, Inc.

\$bn





A High blood pressure	51.1
B Abnormal levels of blood cholesterol	35.4
C Diabetes	28.5
D Thrombosis	23.0
E Other	21.7

### CV is the single largest therapy area in the global healthcare market with a worldwide market value of \$160 billion.

CV disease remains the greatest risk to life for adults, accounting for 17 million deaths worldwide each year. In the US, 23 million people suffer from diabetes and two in five people with diabetes still have poor lipid profiles, one in three have poor blood pressure control and one in five have poor glucose control.

# **160bn**

CV is the single largest therapy area in the global healthcare market. Worldwide market value of \$160 billion Following an sNDA submission in April 2009, the FDA has approved *Atacand* for the treatment of hypertension in children one to 17 years of age. This sNDA submission has also resulted in the granting of an additional six-month period of exclusivity to market *Atacand* in the US.

### Clinical studies of our key marketed products

GALAXY, our long-term global clinical research programme for *Crestor*, which investigates links between optimal lipid control, atherosclerosis and CV morbidity and mortality, has completed a number of studies involving over 65,000 patients in over 55 countries. Some of the studies undertaken as part of the GALAXY programme are referred to below, namely the JUPITER, PLUTO, AURORA, SATURN and PLANETS I and II studies.

Regulatory submissions for *Crestor* based on the JUPITER study results, details of which were included in our 2008 Annual Report and Form 20-F Information, are under review in the US and the EU as well as in other markets with approvals in Malaysia and Colombia. The JUPITER study was the subject of an FDA Advisory Committee in December with the Committee voting positively on the benefit/risk profile demonstrated in the study. A decision by the FDA on the submission is expected in the first quarter of 2010.

The PLUTO study evaluated the efficacy and safety of *Crestor* in patients 10 to 17 years of age with heterozygous familial hypercholesterolemia. Completion of the PLUTO study fulfilled our paediatric exclusivity requirements in the US and resulted in an additional six-month period of exclusivity to market *Crestor* in the US being granted in July. In October, a successful paediatric registration for *Crestor* was achieved. The AURORA study, published in April 2009, evaluated the effects of *Crestor* 10mg and placebo on survival and major CV events in patients with end-stage renal disease on chronic hemodialysis and demonstrated that *Crestor* had no positive impact on such patients. The findings of the AURORA study are consistent with other previously published results with other statins and suggest that the CV disease present in chronic hemodialysis patients is different from other clinical settings and is not positively impacted by statin treatment.

Ongoing studies of *Crestor* include the SATURN study and the PLANETS I and II studies. The SATURN study, which is designed to measure the impact of *Crestor* 40mg and atorvastatin (Lipitor<sup>™</sup>) 80mg on the progression of atherosclerosis in high-risk patients, is expected to report in 2011. The PLANETS I and II studies, which are designed to compare the efficacy and safety of *Crestor* 10mg and 40mg to atorvastatin (Lipitor<sup>™</sup>) 80mg in patients with proteinuric renal disease in diabetics and nondiabetics, respectively, are expected to report in the first half of 2010.

#### In the pipeline

We continue the search for the next major therapy to reduce atherosclerotic risk. In collaboration with Abbott, we are developing an investigational compound, *Certriad*, a fixed-dose combination of the active ingredients in *Crestor* (rosuvastatin calcium) and Abbott's Trilipix<sup>™</sup> (fenofibric acid). An NDA submission in respect of *Certriad* for the treatment of mixed dyslipidaemia was announced jointly by both companies in June. Certriad is a potential new approach to help patients with mixed dyslipidaemia achieve their treatment goals using a single capsule, which targets all three major blood lipids: LDL-C, HDL-C and triglycerides. Study results presented in 2008 showed that this combination provides greater benefit across multiple lipid parameters than the individual monotherapies, with significantly improved HDL-C and triglycerides compared to *Crestor* therapy alone, and significantly improved LDL-C compared to Trilipix<sup>™</sup> alone.

In 2009, AstraZeneca and the University of Virginia entered into a strategic research collaboration to enhance development of new treatments primarily for coronary artery disease with a secondary focus on peripheral vascular disease. The collaborative pre-clinical research projects will focus on identifying disease mechanisms and biological targets that have the potential to be starting points for successful and commercially viable treatments for these diseases, both major causes of CV morbidity and mortality worldwide.

#### **Diabetes**

The number of people affected by Type 2 diabetes continues to grow, predominantly driven by obesity. Type 2 diabetes is a chronic progressive disease and patients often require multiple medications to control their condition. There are a number of established oral generic and branded classes, such as sulfonylureas and thiazolidinediones; however, newer classes such as oral dipeptidyl peptidase IV inhibitors are entering the market successfully by offering effective blood sugar control and improved tolerability. Several new classes of drugs are in development in this area. CV safety has been given particular emphasis in recent regulatory reviews and guidance documents provided by the FDA. Additional patient safety requirements for new medicines can also be anticipated from other regulatory authorities.

#### **Our focus**

#### Our key marketed products

The collaboration on a worldwide basis<sup>1</sup> between AstraZeneca and BMS to develop and commercialise two compounds discovered by BMS (Onglyza<sup>™</sup> (saxagliptin) and dapagliflozin) for the treatment of Type 2 diabetes continues to make good progress.

During 2009, Onglyza<sup>™</sup> was launched in the US, Canada, Mexico, Germany, the UK and Denmark and was approved in Argentina, Brazil, India and the EU. A large worldwide study assessing CV events will be conducted as a US post-marketing requirement.

#### In the pipeline

In December, AstraZeneca and BMS submitted an NDA for the once-daily fixed-dose combination of Onglyza<sup>™</sup> (saxagliptin) and metformin.

Dapagliflozin is a potential oral anti-diabetic, which belongs to the novel class of sodiumglucose co-transporter 2 inhibitors. It is designed to be used both as monotherapy and in combination with other therapies for Type 2 diabetes. Early Phase III data demonstrate that, when compared to a placebo, 24 weeks' treatment with dapagliflozin improved blood glucose parameters, resulted in weight loss and was well tolerated in patients with Type 2 diabetes. The extensive Phase III programme is ongoing.

Our activities in the glucokinase activator (GKA) area continued during 2009, and Phase II studies for AZD1656 are ongoing. The GKA mechanism of action induces insulin release from the pancreas and reduces glucose output from the liver, with marked blood glucose reducing effects in situations of hyperglycaemia.

During 2009, we also progressed our AZD4017, AZD8329 and AZD7867 projects into early clinical testing. These potential medicines aim to increase insulin sensitivity and thereby induce better glycaemic control with beneficial effects on body weight and blood lipids.

In December, AstraZeneca concluded an agreement with Biovitrum AB (publ) (Biovitrum) for the acquisition of all Biovitrum's rights to its leptin modulator programme aimed at treating obesity. The leptin modulator programme is currently in pre-clinical development.

#### Acute coronary syndromes

Acute coronary syndromes (ACS) is an umbrella term for sudden chest pain and other symptoms due to insufficient blood supply (ischaemia) to the heart muscles. ACS is the acute culmination of ischemic heart disease, the leading cause of death worldwide (WHO 2008). There remains a significant need to improve outcomes and reduce the costs of treating ACS.

#### Our focus

#### In the pipeline

*Brilinta/Brilique* (ticagrelor) is the first reversibly binding, oral, adenosine diphosphate receptor antagonist being developed to reduce the risk of blood clots and thrombotic events in patients diagnosed with ACS. In August, AstraZeneca announced results from the Phase III study, PLATO, a head-to-head 18,624 patient outcomes study of ticagrelor plus aspirin versus the active comparator, clopidogrel (Plavix<sup>™</sup>/Iscover<sup>™</sup>), plus aspirin. The PLATO study was designed to establish whether ticagrelor could achieve meaningful CV and safety endpoints in ACS patients. The PLATO study included all the major ACS patient types (unstable angina, ST segment elevation myocardial infarction and non-ST segment elevation myocardial infarction) and followed patients who underwent invasive procedures (eg stent placement or surgery) or were managed with prescription medication.

The data from the PLATO study suggests that ticagrelor has achieved greater efficacy in the primary endpoint, reduction of CV events (CV death, heart attack, stroke), over clopidogrel without an increase in major bleeding. This efficacy endpoint was driven by a statistically significant reduction in both CV deaths and heart attacks with no difference in strokes. Ticagrelor is the first investigational antiplatelet that has demonstrated a reduction in CV death versus clopidogrel in patients with ACS. The reduction in the risk of CV events with ticagrelor occurred early and this benefit increased over time compared to clopidogrel.

The PLATO trial design prospectively identified 66 subgroups. The findings from 62 of the 66 subgroups were consistent with the results of the overall study population. Given the large number of subgroups evaluated, the four inconsistent findings may have been due to chance. One of the four subgroups showed a difference in efficacy results between patients in North America and those enrolled elsewhere. Alongside explanation by the play of chance, this raised questions of whether geographic differences between populations of patients or practice patterns influenced the effects of the randomised treatments. While no definitive explanation has been found to date, further analyses suggest a possible association between aspirin dose and the primary efficacy results, such that reduced efficacy was observed with ticagrelor and increasing aspirin doses. AstraZeneca and the PLATO investigators are continuing to explore these and other hypotheses, as well as other follow-on analyses of the PLATO trial data set, and plan to publish in due course.

AstraZeneca filed an MAA for ticagrelor in October and an NDA in November.

Axanum is a single capsule of aspirin (acetylsalicylic acid (ASA)) (75-325mg) and *Nexium*. Low-dose ASA (75-325mg) is the mainstay therapy for patients who are at high

<sup>1</sup>The collaboration for saxagliptin excludes Japan.

risk of having a CV event such as a heart attack or stroke. Patients report that low-dose ASA treatment can cause gastrointestinal (GI) problems and up to 30% of patients with upper GI problems (ie complications and symptoms) caused by the use of low-dose ASA discontinue or take deliberate breaks from their low-dose ASA treatment due to GI problems, which leaves them without adequate CV protection and puts them at greater risk of having a CV event. The risk of a CV event increases as early as 10 days from the discontinuation of the treatment.

An NDA in respect of *Axanum* was submitted to the FDA in April 2009 for risk reduction of peptic ulcers associated with low-dose ASA (75-325mg) therapy in patients at risk. The proposed labelling also includes the approved low-dose ASA indications. The submission was based on the results of the OBERON and ASTERIX studies evaluating the safety and efficacy of *Nexium* in reducing the risk of gastric and/or duodenal ulcers in patients taking low-dose ASA (75-325mg) continuously during the studies, which is defined as at least five days per week.

The data from the recent OBERON study, a double-blind, randomised, prospective analysis of 2,426 patients taking low-dose ASA (75-325mg), revealed that each of *Nexium* 20mg and 40mg reduced the cumulative proportion of patients with peptic ulcers after 26 weeks of treatment by 80-85% compared to placebo. Upper GI symptoms were assessed showing that the proportion of patients treated with *Nexium* with upper GI symptoms was significantly lower than in the placebo arm.

The ASTERIX study was a randomised, double-blind, placebo-controlled, study in 991 patients. Patients were randomised to treatment with either once-daily *Nexium* 20mg or placebo for six months while continuing to take their low-dose ASA therapy. After six months, *Nexium* was shown to reduce the risk of developing an ulcer by 70%.

#### **Atrial fibrillation**

Atrial fibrillation (AF) is the most common cardiac arrhythmia. Rhythm-control therapy to control the symptoms of AF is dominated by generic amiodarone, which is effective at maintaining patients in normal heart rhythm but very poorly tolerated. AF is associated with an increased risk of cerebral embolism resulting in stroke and disability. To reduce the risk of such AF-related complications, anti-coagulation with vitamin K antagonists can be used. New anti-coagulation therapies with improved convenience are emerging.

#### Our focus

#### In the pipeline

For the control of heart rhythm in AF, our focus is on atrial-specific agents as a way to reduce the risk of pro-arrhythmic effects. Our first compound in this area is in pre-clinical development. During 2009, the development of AZD1305, a combined ion-channel blocker which was in Phase II concept testing, was discontinued due to an emerging unfavourable benefit/risk profile.

Our oral, direct thrombin inhibitor (AZD0837) is ready to be taken into Phase III testing for the prevention of strokes and other embolic events in AF patients, using a once-daily extended release formulation that provides a sustained anti-coagulation effect throughout the dosing interval. AstraZeneca is considering the potential for AZD0837 in a number of indications as well as evaluating potential collaborations with third parties for its future development.

#### Litigation

Detailed information about material legal proceedings relating to our CV products can be found in Note 25 to the Financial Statements from page 166.

#### Financial performance 2009/2008 Performance 2009

#### Reported performance

CV sales were up 20% as reported to \$8,376 million (2008: \$6,963 million). Strong growth from *Crestor*, driven by the promotion of the atherosclerosis indication, and substantially increased sales of *Toprol-XL* and the authorised generic version of the drug in the US were the major contributors to growth in CV sales.

#### Performance – CER growth rates CV sales were up 25% from 2008 at CER.

Crestor sales increased by 29% to \$4,502 million. US sales for Crestor for the full year increased by 25% to \$2,100 million. The total prescription share of Crestor in the US statin market increased to 11.3% in December 2009 from 9.9% in December 2008, and it was the only branded statin to gain market share. Crestor sales outside the US were up 33% for the full year to \$2,402 million, over half of global sales for the product. Sales of Crestor were up 24% in our Western Europe markets to \$968 million and 58% in Japan, driving sales growth in Other Established Markets and Canada up 33% in total. Sales of Crestor in Emerging Markets increased by 32%.

Sales of *Seloken/Toprol-XL* and its authorised generic increased by 84% to \$1,443 million in 2009, as a result of increased sales of *Toprol-XL* and its authorised generic in the US. Sales in the US increased by 227% to \$964 million following the withdrawal from the market of two other generic metoprolol succinate products in early 2009. However, we expect further generic competition in 2010.

Sales of *Atacand* in the US for the full year were unchanged from 2008 at \$263 million, and account for 18% of global *Atacand* sales. *Atacand* sales outside the US were up 5% to \$1,173 million, with a 3% increase in Other Established Markets and Canada and a 13% increase in Emerging Markets.

Alliance revenue from the Onglyza<sup>™</sup> collaboration with BMS totalled \$11 million in 2009.

#### Performance 2008 Reported performance

CV sales were up 4% as reported to \$6,963 million (2007: \$6,686 million). Strong growth from *Crestor*, fuelled by the promotion of the atherosclerosis indication, and increased sales of *Atacand* offset the continuing significant declines in *Seloken/Toprol-XL*.

#### Performance - CER growth rates

CV sales were unchanged from 2007 at CER. *Crestor* sales increased by 26% to \$3,597 million. US sales for *Crestor* for the full year increased by 18% to \$1,678 million. *Crestor* total prescription share in the US statin market increased to 9.9% in December 2008 from 8.6% in December 2007, and was the only branded statin to gain market share. *Crestor* sales outside the US were up 34% for the full year to \$1,919 million, over half of global sales for the product. Sales of *Crestor* were up 16% in our Western Europe markets to \$836 million and 93% in Japan. Sales of *Crestor* in Emerging Markets increased by 41%.

Sales of *Toprol-XL* and authorised generic sales of the drug in the US were down 70% for the full year to \$295 million. For the full year, *Seloken* sales outside the US were up 1% to \$512 million.

US sales for *Atacand* for the full year increased 1% to \$262 million. *Atacand* sales outside the US were up 12% to \$1,209 million, a 10% increase in Other Established Markets and Canada, and an 18% increase in Emerging Markets.

### Gastrointestinal

#### In brief

- > Sales of Nexium \$5 billion, down 1%.
- > Nexium oral and intravenous was approved in the EU and other markets for the short-term maintenance of haemostasis and prevention of re-bleeding in patients following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.
- > An sNDA for Nexium was submitted for risk reduction of peptic ulcers associated with low-dose acetylsalicylic acid therapy in patients at risk.
- > Losec/Prilosec sales \$946 million, declining in the EU and the US due to continuing generic erosion. Overall sales down 10%; Japan sales increased 8%; China sales increased 21%.
- > A Danish court issued an injunction against sales of generic esomeprazole magnesium by Sandoz A/S (Sandoz). The injunction prohibits Sandoz from selling, offering for sale or marketing the pharmaceutical products 'Esomeprazole Sandoz' and other pharmaceutical products containing esomeprazole magnesium with an optical purity of equal or greater to 99.8% enantionmeric excess in Denmark.
- > AstraZeneca filed applications in Austria 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 initiated legal proceedings in Portugal to suspend approvals for Sandoz's generic esomeprazole. In October the court granted AstraZeneca a preliminary injunction against Sandoz, suspending the efficacy of the marketing and price approvals for Sandoz's generic esomeprazole. The decision has been appealed by the Portuguese authorities.
- In January 2010, AstraZeneca settled US Nexium patent litigation against Teva Pharmaceuticals Ltd (Teva Pharma) and affiliates. AstraZeneca has granted Teva Pharma a licence to enter the US market with its generic esomeprazole, subject to regulatory approval, on 27 May 2014, or earlier in certain circumstances. Teva Pharma conceded validity/enforceability of all patents in Teva Pharma's US Nexium patent litigations and that Teva Pharma's proposed generic esomeprazole would infringe six US Nexium patents.
- > Patent litigation continuing in the US against other generic manufacturers following an ANDA relating to Nexium.
- In Canada, Patented Medicines (Notice of Compliance) Regulations proceedings involving Apotex relating to *Nexium* continued. A hearing is scheduled to commence on 31 May 2010.

#### **Our marketed products**

**Nexium** (esomeprazole) is the first proton pump inhibitor (PPI) for the treatment of acid-related diseases to offer clinical improvements over other PPIs and other treatments.

*Losec/Prilosec* (omeprazole) is used for the short-term and long-term treatment of acid-related diseases.

*Entocort* (budesonide) is a locally acting corticosteroid for the treatment of inflammatory bowel disease.

#### **Our strategic objectives**

We aim to maintain our strong position in gastrointestinal (GI) treatments by continuing to focus on PPIs. New *Nexium* line extensions include prevention of re-bleeding in patients with peptic ulcer bleeding and prevention of low-dose aspirin associated peptic ulcers. Our R&D is focused on finding new, innovative ways for treating acid-related disease.

#### **Our focus**

#### Our key marketed products

Nexium is marketed in approximately 100 countries and is available in oral (tablet/ capsules and oral suspension) and intravenous (i.v.) dosage forms for the treatment of acid-related diseases. Nexium is an effective short-term and long-term therapy for patients with gastro-oesophageal reflux disease (GERD). Nexium is also approved for the treatment of GERD in children one to 17 years of age. For the treatment of active peptic ulcer disease, seven-day Nexium triple therapy (in combination with two antibiotics for the eradication of H.pylori) heals most patients without the need for follow-up anti-secretory therapy. In Europe and other markets. Nexium is approved for the healing and prevention of ulcers associated with NSAID therapy, including cyclooxygenase 2 selective inhibitors. In the US, Nexium is approved for reducing the risk of gastric ulcers associated with continuous NSAID therapy in patients at risk of developing gastric ulcers. Nexium is also approved in the US, the EU, Canada and Australia for the treatment of patients with the rare gastric disorder, Zollinger-Ellison syndrome. Following treatment with Nexium i.v., oral Nexium is approved in the FU and other markets for the maintenance of haemostasis and prevention of re-bleeding of gastric or duodenal ulcers.

Nexium i.v., which is used when oral administration is not suitable for the treatment of GERD and upper GI side effects induced by NSAIDs, is approved in 86 countries including the US and all EU countries. Nexium i.v. is also approved in the EU and other markets for the short-term maintenance of haemostasis and prevention of re-bleeding in patients following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers. *Losec/Prilosec* was first launched in 1988 and is approved for the treatment of GERD. We continue to maintain certain patent property covering *Losec/Prilosec*.

Losec/Prilosec is available both as a prescription-only medication and, in some countries, as an OTC medication where it offers consumers a more effective self-medication option for the treatment of heartburn compared to antacids and H2 receptor antagonists. In 2009, an agreement to license rights for *Losec* for OTC use to Bayer Consumer Care AG was announced. This agreement will extend the number of markets in which *Losec* is available as an OTC product.

In November, the FDA issued a Public Health Advisory to consumers and Information for Healthcare Professionals about the label update to Plavix<sup>™</sup> (clopidogrel) about interactions with Prilosec and Prilosec OTC and potentially with other medicines that inhibit the CYP2C19 enzyme, including Nexium. AstraZeneca has full confidence in the overall benefit/risk and safety profile of Losec/Prilosec and Nexium. We will continue to evaluate thoroughly the safety and effectiveness of Losec/Prilosec and Nexium in accordance with AstraZeneca's procedures. AstraZeneca is involved in ongoing dialogue with the FDA, the EMEA and the CHMP about any pharmacological interaction and its clinical relevance.

*Entocort* is approved for the treatment of two types of inflammatory bowel disease. *Entocort* capsules are approved for use both as an acute treatment of and for maintenance of remission for mild to moderate Crohn's disease. *Entocort* enema is approved in some markets for the treatment of ulcerative colitis. *Entocort* has better tolerability compared to other corticosteroids in the treatment of both conditions. In Crohn's disease, *Entocort* also has greater efficacy than aminosalicylic acid medicines.

#### Clinical studies of key marketed products

Data from the LOTUS study (a multinational, randomised study of 554 patients) in which *Nexium* was compared to surgery for the management of GERD has now reported five years of follow-up. The results show that both therapies are very effective, with proportions of patients still in remission above 90% and with both therapies being well tolerated. The paediatric GERD programme in the youngest age group of zero to one year of age has been completed and submissions to regulatory authorities have commenced.

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#### **Our financial performance**

	2009			2008		2007	2009 compared to 2008		2008 compared to 2007		
	Sales	Growth due         Growth due           CER to exchange         CER         to exchange           growth         effect         Sales         growth         effect         Sales	CER growth	Reported growth	CER growth	Reported growth					
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	%	%	%	%
Nexium	4,959	(73)	(168)	5,200	(121)	105	5,216	(1)	(5)	(2)	-
Losec/Prilosec	946	(105)	(4)	1,055	(156)	68	1,143	(10)	(10)	(14)	(8)
Other	106	21	(4)	89	2	3	84	24	19	2	6
Total	6,011	(157)	(176)	6,344	(275)	176	6,443	(2)	(5)	(4)	(2)

### Therapy area world market (MAT/Q3/09)



The GI world market is valued at \$39 billion, with the PPI market accounting for \$26 billion. In the West (ie Europe and North America) between 10-20% of adults suffer from GERD. The prevalence of GERD in Asia is lower, but increasing. Despite effective PPI treatments, around 40% of patients do not achieve full relief from symptoms.

## **39bn**

The GI world market is valued at \$39 billion, with the proton pump inhibitor market accounting for \$26 billion AstraZeneca conducted two studies, OBERON and ASTERIX, to evaluate the safety and efficacy of *Nexium* in the prevention of gastric and/or duodenal ulcers in patients who take low-dose aspirin (acetylsalicylic acid (ASA)) (75-325mg) continuously during the studies, which is defined as at least five days per week. The results of these studies are described in more detail in the Cardiovascular section from page 56. In April 2009, AstraZeneca submitted an sNDA for the low-dose ASA (75-325mg) indication for *Nexium* and an NDA for the new product *Axanum* based upon the findings in these studies.

#### In the pipeline

Our research activities focus on reflux inhibitors and hypersensitivity therapy. Our lead compound, lesogaberan (AZD3355), is undergoing clinical studies in Phase II. Follow-up compounds are in different stages up to Phase II testing.

#### Litigation

Detailed information about material legal proceedings relating to our GI products can be found in Note 25 to the Financial Statements from page 166.

#### Financial performance 2009/2008 Performance 2009 Reported performance

Gl sales for 2009 were down 5% on a reported basis to \$6,011 million from \$6,344 million in 2008.

#### Performance - CER growth rates

GI sales fell by 2% at CER.

Global Nexium sales were down 1% to \$4,959 million from \$5,200 million the previous year. The decline was driven by the decrease in the US of 9% to \$2,835 million, however this was largely mitigated by sales outside the US increasing by 9% to \$2,124 million. In the US, dispensed retail tablet volumes decreased by less than 1% despite increased generic and OTC competition. In respect of Nexium, there was growth in Canada (11%), Western Europe (7%) and Emerging Markets (15%). For the full year, sales of *Losec/Prilosec* fell 10% to \$946 million. *Prilosec* sales in the US were down 63% as a result of continued generic erosion. Outside the US, *Losec* sales were flat, despite increases in China (21%) and Japan (8%).

#### Performance 2008

#### Reported performance

GI sales for 2008 were down 2% on a reported basis to \$6,344 million from \$6,443 million in 2007.

#### Performance - CER growth rates

GI sales fell by 4% at CER. Growth in Canada (9%), Japan (5%) and Emerging Markets (20%) more than offset the 5% decline in sales in our Western Europe markets.

Nexium sales were down 2%, excluding the effects of exchange, to \$5,200 million from \$5,216 million the previous year. The decline was driven by the decrease in the US of 8% to \$3,101 million, however, this was largely mitigated by sales outside the US increasing by 9% to \$2,099 million. In the US, dispensed retail tablet volumes increased (2%) and Nexium was the only major PPI brand to do so in 2008.

For the full year, sales of *Losec/Prilosec* fell 14% to \$1,055 million. *Prilosec* sales in the US were down 25% as a result of generic competition for the 40mg dosage form in the second half of the year. Outside the US, *Losec* sales declined by 11%, despite increases in China (19%) and Japan (5%).

### Infection

#### In brief

- > Synagis sales of \$1.1 billion; in the US \$782 million.
- > Merrem/Meronem sales of \$872 million, up 5%.
- > H1N1 influenza (swine flu) vaccine successfully developed and delivered to the US Department of Health and Human Services (HHS) (sales \$389 million).
- > *FluMist* sales of \$145 million.
- > Filed formal regulatory reply to the motavizumab Complete Response Letter.
- > In-licence of ceftaroline from Forest outside the US, Canada and Japan.
- > Acquired the infection research company Novexel (completion of the acquisition is subject to the expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act).
- > Expanded collaboration with Forest to include two antibiotic development programmes: ceftazidime/NXL-104 (CAZ104) and ceftaroline/ NXL-104 (CEF104).

#### Our marketed products

Synagis (palivizumab) is a humanised MAb used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in paediatric patients at high risk of acquiring RSV disease.

*Merrem/Meronem*<sup>1</sup> (meropenem) is a carbapenem anti-bacterial used for the treatment of serious infections in hospitalised patients.

FluMist (influenza virus vaccine live, intranasal) is a live, attenuated, trivalent influenza virus vaccine approved for active immunisation of people two to 49 years of age against influenza disease caused by influenza virus subtypes A and B contained in the vaccine.

H1N1 influenza (swine flu) vaccine was successfully developed and delivered to the HHS and is indicated for the active immunisation of individuals two to 49 years of age against influenza caused by pandemic H1N1 virus.

Cubicin<sup>™2</sup> (daptomycin) is a cyclic lipopeptide anti-bacterial used for the treatment of serious infections in hospitalised patients.

<sup>1</sup> Licensed from Dainippon Sumitomo Pharma Co., Ltd. <sup>2</sup> Licensed from Cubist Pharmaceuticals, Inc.

#### **Our strategic objectives**

We aim to build a leading franchise in the treatment of infectious diseases through continued commercialisation of brands such as *Synagis*, *Merrem* and *FluMist*, effective use of our structural and genomic-based discovery technologies and antibody platforms, and continued research into novel approaches in areas of unmet medical need.

#### **Resistant bacterial infections**

World demand for antibiotics remains high due to escalating resistance and the increased risk of serious infections in both immunosuppressed patients and ageing populations. Many bacterial infections currently have few satisfactory treatment options prompting demand for new and better therapies. The in-licensing from Forest of ceftaroline, ceftazidime/NXL-104 (CAZ104) and ceftaroline/NXL-104 (CEF104) adds to the strong AstraZeneca portfolio and reinforces our commitment to treating resistant bacterial infections.

#### **Our focus**

#### Our key marketed products

Merrem/Meronem is the leading carbapenem anti-bacterial and has a growing share of the intravenous antibiotic market because of its activity against bacteria resistant to many other agents. Cubicin<sup>™</sup> is used for the treatment of serious Gram-positive infections in hospitalised patients and is sold by AstraZeneca in selected territories in Asia and the Middle East.

#### In the pipeline

During 2009, we licensed ceftaroline from Forest and will be responsible for its registration and marketing outside the US, Canada and Japan. Four Phase III studies have been completed for ceftaroline, with NDA filings made in December and MAA filings anticipated in 2010. Ceftaroline has demonstrated activity against a number of infections and multi-drug resistant pathogens, including MRSA.

In December we acquired Novexel (completion of the acquisition is subject to the expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act), a private infection research company in France, and we will collaborate with Forest on the future co-development and commercialisation of two antibiotic development programmes, CAZ104 and CEF104. CAZ104 is a combination of NXL-104 and ceftazidime, a third generation cephalosporin to which resistance has emerged. It is expected to move into Phase III development in late 2010 for serious infections requiring intensive care unit stays such as intra-abdominal, urinary tract and hospital acquired pneumonia. CEF104 is a combination of NXL-104 and ceftaroline, which is expected to move into Phase II development in late 2010 in indications where a mixed Gram-negative and Gram-positive profile can be of use, such as skin and diabetic foot infections.

To meet the high and growing need for new and better therapies for resistant bacterial infections we have also built an anti-bacterials discovery capability that places AstraZeneca among the industry leaders with the capability to create novel mechanism anti-bacterials. Out of this work, a candidate anti-bacterial drug, AZD9742, with a novel mechanism of action entered Phase I testing late in 2009.

#### **Respiratory syncytial virus**

Approximately half of all infants are infected with respiratory syncytial virus (RSV) during the first year of life and nearly all children in the US have been infected by the time they reach their second birthday. Unlike other viral infections, there is no complete and durable immunity created by RSV, so repeated infection is likely and common. Premature babies (earlier than 36 weeks gestational age, especially those less than 32 weeks) and babies with chronic lung disease or congenital heart disease are at an even greater risk of contracting severe RSV disease than full-term babies.

#### **Our focus**

#### Our key marketed products

Synagis is used for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of the disease. It was the first MAb approved in the US for an infectious disease and since its launch in 1998 it has become the standard of care for RSV prevention. *Synagis* remains the only immunoprophylaxis in the marketplace indicated for the prevention of RSV in paediatric patients at high risk of RSV. *Synagis* is administered by intra-muscular injection.

#### In the pipeline

We filed a biological licence application with the FDA for an improved anti-RSV MAb, motavizumab, and received a Complete Response Letter in 2008. We filed a formal regulatory reply to the Complete Response Letter in December 2009. We do not believe that further clinical studies will be required by the FDA for marketing approval.

In addition, an intranasal vaccine is being developed for the prevention of lower respiratory tract illness caused by RSV and parainfluenza virus-3 (PIV3) in infants. There are two RSV vaccine programmes: MEDI-559 and MEDI-534. We are conducting several

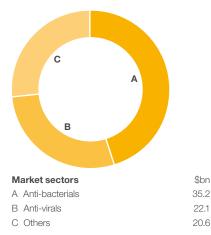
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#### **Our financial performance**

	2009			2008			2007	2009 compared to 2008		2008 compared to 2007	
	Sales \$m		rowth due exchange effect \$m	Sales \$m	CER growth \$m	Growth due to exchange effect \$m	Sales \$m	CER growth %	Reported growth %	CER growth %	Reported growth %
Merrem	872	44	(69)	897	97	27	773	5	(3)	13	16
Synagis <sup>1</sup>	1,082	(148)	-	1,230	612	-	618	(12)	(12)	n/m	n/m
FluMist <sup>1</sup>	145	41	-	104	51	-	53	39	39	n/m	n/m
H1N1 influenza vaccine	389	389	-	_	-	-	-	n/m	n/m	n/m	n/m
Other	143	(69)	(8)	220	(54)	4	270	(31)	(35)	(20)	(19)
Total	2,631	257	(77)	2,451	706	31	1,714	10	7	41	43

<sup>1</sup>Acquired in June 2007.

### Therapy area world market (MAT/Q3/09)



The world infection market is valued at \$78 billion, with anti-bacterials accounting for approximately 45% and anti-virals for 28%. World demand for antibiotics remains high, due to escalating resistance and the increased risk of serious infections in both immunosuppressed patients and ageing populations. Approximately half of all infants are infected with RSV during the first year of life. Seasonal influenza results in three to five million cases of severe illness and up to a half a million deaths globally each year.

# **78bn**

The world infection market is valued at \$78 billion, with anti-bacterials accounting for approximately 45% and anti-virals for 28% Phase I and Phase I/II studies for these vaccines, both alone and in collaboration with the US National Institute of Allergy and Infectious Diseases.

#### Influenza virus

Influenza is the most common vaccinepreventable disease in the developed world. According to WHO estimates, seasonal influenza results in three to five million cases of severe illness and up to half a million deaths globally each year, primarily among the elderly. Rates of infection are highest among children, with school-aged children significantly contributing to the spread of the disease. Influenza also has socio-economic consequences related to both direct and indirect healthcare costs, including hospitalisations, work absence and loss of work productivity when either a caregiver or child is sick with influenza.

#### Our focus

#### Our key marketed products

FluMist is the first live, attenuated nasally delivered vaccine approved in the US for the prevention of disease caused by influenza virus subtypes A and B in eligible children and adults, two to 49 years of age. Beginning in the 2009/2010 season, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices in the US voted to expand recommendations for routine seasonal influenza vaccination to include all school-age children up to 18 years of age. In 2009, FluMist was approved for marketing in South Korea. Hong Kong and Israel. Applications are under review in Canada, Mexico and the EU. The total product supply of approximately 10 million seasonal FluMist doses sold out in 2009.

In response to the novel H1N1 influenza (swine flu) pandemic need in 2009, the US Department of Health and Human Services (HHS) awarded AstraZeneca a contract to develop and manufacture 42 million doses of influenza A (H1N1) 2009 monovalent vaccine. The total contract value is approximately \$389 million. The monovalent H1N1 influenza vaccine, which is made using the same technology and process as *FluMist*, was approved by the FDA in September for the same patient population as *FluMist*. AstraZeneca began shipping product to the HHS in September.

#### In the pipeline

We continually strive to seek ways to improve our influenza vaccine. Each year we conduct clinical studies enabling us to develop and release a new vaccine for that year's influenza virus. In addition, we are investigating the potential of a quadravalent live attenuated influenza vaccine and have two studies for this underway.

#### **Hepatitis C virus**

Hepatitis C virus (HCV) infects an estimated 170 million people worldwide and the current market for HCV therapy exceeds \$2 billion annually. However, therapy for the strains that predominate in the US and Western Europe requires 12 months' treatment and produces a durable cure in only 50% of patients. Key opinion leaders expect the current standard of treatment (interferon plus ribavirin) to change to a form of combination therapy involving one or more new mechanism of action direct-acting anti-virals and there are several small and large pharmaceutical companies with varying HCV pipelines focused on such therapies. A future paradigm of combinations of anti-virals as standard care offers the opportunity for several new therapies to be widely used.

#### Our focus

#### In the pipeline

Projects in development include AZD7295, a novel HCV compound, currently in Phase II.

#### Sepsis

Sepsis is a life-threatening condition resulting from uncontrolled severe infections, which affects an estimated three million people a year worldwide. Few industry pipelines are focused on the development of products specifically for registration for the treatment of sepsis or septic shock.

#### **Our focus**

#### In the pipeline

The development programme for CytoFab<sup>™</sup>, an anti-TNF  $\alpha$  polyclonal antibody, our potential treatment for severe sepsis licensed from Protherics Inc. (now part of the BTG plc group), continues in Phase II development. CytoFab<sup>™</sup> has the potential to be one of a limited number of medicines specifically developed for patients with severe sepsis.

#### **Tuberculosis**

Tuberculosis (TB) remains a worldwide threat and is newly diagnosed in over eight million people worldwide every year. It is one of the greatest causes of death from infectious disease in the developing world.

#### **Our focus**

As part of our commitment to make a contribution to improving health in the developing world, we are working to find a new, improved treatment for TB. We have a dedicated research facility in Bangalore, India that is focused on finding a treatment for TB that will act on drug-resistant strains, simplify the treatment regime (current regimes are complex and lengthy, meaning many patients give up before the infection is fully treated) and will be compatible with HIV/AIDS therapies (TB and HIV/AIDS form a lethal combination, each speeding the other's progress). Over 80 scientists in Bangalore are working closely with our infection research centre in Boston, US as well as with academic leaders in the field, and they have full access to all AstraZeneca's platform technologies, such as 'high throughput screening' and compound libraries. It is a complex area of research but a candidate drug, AZD5847, entered Phase I studies late in 2009.

#### Litigation

Detailed information about material legal proceedings relating to our Infection products can be found in Note 25 to the Financial Statements from page 166.

#### Financial performance 2009/2008 Performance 2009 Reported performance

Total Infection sales increased on a reported basis by 7% to \$2,631 million. H1N1 influenza vaccine sales were \$389 million.

#### Performance - CER growth rates

Infection sales were up 10% at CER. This was driven by sales of \$389 million for the H1N1 influenza vaccine to the US government and continued growth in *Merrem/Meronem* (5%) and *FluMist* (39%), which more than offset the 12% decline in *Synagis* sales.

Worldwide sales of *Synagis* in the fourth quarter were \$401 million, a 21% decrease from the same period in 2008, driven by a decrease of 31% of US *Synagis* sales for the fourth quarter. This decline in the US is a result of the adoption of new guidelines published by the American Academy of Pediatrics restricting the usage of *Synagis* at the start of the 2009/2010 RSV season.

FluMist sales were \$145 million for the full year.

#### Performance 2008 Reported performance

Total Infection sales increased on a reported basis by 43% to \$2,451 million as a full year of *Synagis* and *FluMist* sales were taken in the Group for the first time, and *Merrem/Meronem* sales enjoyed another year of good growth.

#### Performance – CER growth rates

Infection sales were up 41% at CER.

For the full year, *Synagis* sales were \$1,230 million. *Synagis* sales in 2007 were \$618 million, but this only reflected sales since the acquisition of MedImmune in June 2007. Worldwide sales of *Synagis* in the fourth quarter were \$506 million, a 5% increase over the same period in 2007 when the product was included in sales.

*FluMist* sales were \$104 million for the full year. In contrast to 2008, all of 2007's *FluMist* sales of \$53 million were realised in the fourth quarter as a result of the timing of regulatory approvals for the new formulation and expanded label.

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### **Neuroscience**

#### In brief

- > Total Seroquel sales up 12% to \$4.9 billion.
- > Seroquel has been granted Paediatric Exclusivity in the US as a result of studies conducted in children and adolescents, which will provide an additional six months of exclusivity to market Seroquel in the US.
- In December, the FDA approved Seroquel XR as an adjunctive treatment to anti-depressants in adults with major depressive disorder (MDD). AstraZeneca also received a Complete Response Letter for its Seroquel XR submission for MDD as acute and maintenance monotherapy in adults and for acute therapy in the elderly.
- In September, Seroquel XR and Seroquel were approved under the European Mutual Recognition Procedure for the prevention of recurrence in bipolar disorder.
- In December, the FDA approved Seroquel for the treatment of schizophrenia in adolescents 13 to 17 years of age as monotherapy, and for the acute treatment of manic episodes associated with bipolar I disorder in children and adolescents 10 to 17 years of age, both as monotherapy and as an adjunct to lithium or divalproex.
- > The EU submission for Seroquel XR for the treatment of MDD received a negative opinion in May but has been referred to the CHMP and the outcome is anticipated in the first quarter of 2010.
- > Seroquel XR submissions for generalised anxiety disorder (GAD) received a Complete Response Letter from the FDA in February 2009 (adult population) and in September (elderly population).
- > Global development and licence agreement with Targacept for Targacept's late-stage compound TC-5214.
- > In-licence of NKTR-118 and NKTR-119 from Nektar.
- > AstraZeneca established several neuroscience research collaborations in 2009, amongst which is a collaboration with Jubilant in the areas of chemical lead generation and lead optimisation to support our efforts in analgesia and neurology.
- > The US Court of Appeals affirmed a Summary Judgment Motion granted to AstraZeneca in the patent infringement actions commenced against two generic drug manufacturers in the US following the filing of ANDAs relating to Seroquel.
- > Three consolidated ANDA patent infringement lawsuits, previously filed in the US against Handa, Accord and Biovail, proceed in discovery. The three ANDAs seek approval to market generic copies of *Seroquel XR* before the expiry of its patents.
- > Personal injury actions in the US and Canada involving Seroquel are being defended vigorously, with successful results to date in the US.
- > Agreement in principle reached with the US Attorney's Office to settle claims relating to Seroquel sales and marketing practices and to make a payment of \$524 million (including interest). Final settlement is subject to negotiation of a civil settlement agreement and a corporate integrity agreement. Other litigation and government investigations regarding sales and marketing practices are being defended vigorously.

#### **Our marketed products**

Seroquel (quetiapine fumarate) is an atypical anti-psychotic drug approved for the treatment of schizophrenia and bipolar disorder (mania, depression and maintenance). Seroquel XR (an extended release formulation of quetiapine fumarate) is generally approved for the treatment of schizophrenia, bipolar disorder and in some territories for MDD and GAD. Approved use for Seroquel and Seroquel XR varies based on territory.

*Zomig* (zolmitriptan) is used for the treatment of migraines with or without aura.

*Diprivan* (propofol) is an intravenous general anaesthetic used in the induction and maintenance of anaesthesia, light sedation for diagnostic procedures and for intensive care sedation.

Naropin (ropivacaine) is a long-acting local anaesthetic, replacing the previous standard treatment of bupivacaine.

*Xylocaine* (lidocaine) is a widely used short-acting local anaesthetic.

**EMLA** (lidocaine + prilocaine) is a local anaesthetic for topical application.

#### Our strategic objectives

Disorders of the central nervous system (CNS) represent the number one disease burden today in high-income countries<sup>1</sup>. In many other world regions, including Asia, the prevalence of CNS disorders is expected to grow substantially<sup>2</sup> as the standard of living increases. We aim to strengthen our position in neuroscience through further growth of *Seroquel* and *Seroquel XR* and by the successful introduction of a range of new medicines aimed at significant medical need in psychiatry, analgesia (pain control) and cognition, including Alzheimer's disease and attention deficit hyperactivity disorder.

#### **Psychiatry**

Most branded schizophrenia products will face generic competition in the period 2012 to 2015, with major current atypical anti-psychotic patents expiring by 2018. Future demand will be for products with significantly improved efficacy and tolerability. The depression and anxiety markets are currently dominated by generic selective serotonin re-uptake inhibitors and serotonin norepinephrine re-uptake inhibitors. As growth in the US slows, the Japanese and other Asian markets continue to expand due to increased diagnosis and use of pharmacological treatments in response to both targeted government programmes and wider acceptance of pharmacological treatments. Generic growth is anticipated over the next five years as patents expire, which will make market entry for new innovative products more difficult in the medium and longer term.

It will be increasingly important to develop new medicines addressing the needs of specific patient segments, and to work closely with the specialists in the medical community and the public health sector to address the growing burden of psychiatric disease on society.

#### Our focus

#### Our key marketed products

Seroquel is a leading atypical anti-psychotic treatment for schizophrenia and bipolar disorder. Seroquel remains the most commonly prescribed atypical anti-psychotic treatment in the US, where it is the only atypical anti-psychotic approved as monotherapy treatment for both bipolar depression and bipolar mania as well as the leading atypical brand globally by sales value.

First launched in 1997, *Seroquel* is now approved in 94 countries. *Seroquel XR*, an extended release formulation that offers patients and doctors a once-daily treatment, was launched in the US for the treatment of schizophrenia in 2007 and is now approved in 63 countries for schizophrenia, 38 countries for bipolar mania, 37 countries for bipolar depression and eight countries, including the US, for bipolar maintenance, in three markets for major depressive disorder (MDD), and in one market for generalised anxiety disorder (GAD).

In January 2009, the FDA granted a six-month Paediatric Exclusivity to *Seroquel* for its licensed indications, based on studies that we conducted in adolescents with schizophrenia, and in children and adolescents with bipolar mania. The six-month Paediatric Exclusivity will extend the exclusivity to market *Seroquel* in the US to March 2012.

In September, Seroquel and Seroquel XR were approved in the EU for the prevention of recurrence of bipolar disorder in patients whose manic, mixed or depressive episode has responded to treatment with Seroquel or Seroquel XR. Following this new indication, Seroquel and Seroquel XR are the only agents approved in the EU to treat all phases of bipolar disorder, acute depressive episodes, acute manic episodes and maintenance treatment to prevent recurrence of any mood event in bipolar disorder.

In 2008, regulatory submissions were made for the use of *Seroquel XR* in MDD and GAD. In December 2008, the FDA approved *Seroquel XR* as an adjunctive treatment to anti-depressants in adults with MDD. The FDA also issued Complete Response Letters in December 2009 for the monotherapy submissions as acute and maintenance therapy in adults and acute therapy in the elderly. The MDD application in the EU was rejected in May and AstraZeneca has now

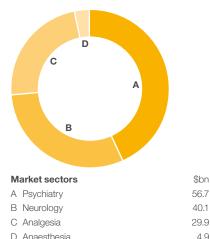
<sup>&</sup>lt;sup>1</sup>WHO ranking 2008, disease burden measured by disability adjusted life years.

<sup>&</sup>lt;sup>2</sup> Brookmeyer R *et al*, Alzheimer's & Dementia 2007; Arthritis Foundation, American Chronic Pain Foundation, Reforming Chinese Healthcare through Public-Private Partnership, Swiss Re May 2007.

#### **Our financial performance**

		2009				2008			2009 compared to 2008		2008 compared to 2007	
		Growth due CER to exchange				Growth due CER to exchange			Reported	CER	Reported	
	Sales \$m	growth \$m	effect \$m	Sales \$m	growth \$m	effect \$m	Sales \$m	growth %	growth %	growth %	growth %	
Seroquel	4,866	521	(107)	4,452	346	79	4,027	12	9	9	11	
Diprivan	290	18	(6)	278	(3)	18	263	6	4	(1)	6	
Zomig	434	2	(16)	448	(3)	17	434	-	(3)	(1)	3	
Local anaesthetics	599	27	(33)	605	13	35	557	4	(1)	2	9	
Other	48	(2)	(4)	54	(7)	2	59	(4)	(11)	(12)	(8)	
Total	6,237	566	(166)	5,837	346	151	5,340	10	7	6	9	

### Therapy area world market (MAT/Q3/09)



#### The neuroscience world market totals \$132 billion. The medical need in neuroscience is significant.

Depression and anxiety disorders remain under-diagnosed and under-treated, with 15% of the population suffering from major depression at least once in their lives. Schizophrenia affects around 1% of the adult population, and 17 million people suffer from bipolar disorder across the major markets. Chronic pain is the most common reason for seeking medical care. Alzheimer's disease affects approximately 24 million people worldwide (predicted to reach 40 million by 2020) and current therapy does not significantly change the course of this progressive neuro-degenerative disorder.

# 132bn

The neuroscience world market totals \$132 billion

referred the application to the CHMP, with the outcome anticipated in early 2010.

Complete Response Letters for the Seroquel *XR* GAD submission were received from the FDA in February 2009 (adult population) and September (elderly population). The application was considered unfavourably by an FDA Advisory Committee in April 2009; dialogue with the FDA remains ongoing.

In December, the FDA approved *Seroquel* for the treatment of schizophrenia in adolescents 13 to 17 years of age as monotherapy, and for the acute treatment of manic episodes associated with bipolar disorder in children and adolescents 10 to 17 years of age, both as monotherapy and as an adjunct to lithium or divalproex.

#### In the pipeline

AstraZeneca and Targacept have entered into a strategic collaboration and licence agreement for the global development and commercialisation of Targacept's late-stage compound, TC-5214. TC-5214 is being developed as an adjunct to anti-depressant therapy in adults with MDD who do not respond adequately to 1st line anti-depressant treatment. TC-5214, which recently completed a Phase IIb study, is a nicotinic ion channel blocker that is thought to treat depression by modulating the activity of various neuronal nicotinic receptor subtypes. AstraZeneca and Targacept will jointly design a global Phase III clinical programme, anticipated to begin in mid-2010, with the goal of filing an NDA in 2012.

We have progressed AZD8418 into Phase I and AZD8529 into Phase II for the treatment of schizophrenia. AZD7268 entered into Phase II for the treatment of depression and anxiety. Development of AZD7325 was discontinued.

In 2009, AstraZeneca entered into a number of research collaborations, including those mentioned below. AstraZeneca has entered into a research collaboration with Jubilant in the area of new chemical lead generation and optimisation effectiveness to support our efforts in analgesia and neurology. AstraZeneca has also entered into a collaboration with PsychoGenics, Inc. to support behaviour profiling of new medicines across several disease areas. Furthermore, AstraZeneca has entered into a research agreement with Duke University to identify novel strategies and targets for better treatment of bipolar disorder using optogenetics.

### Analgesia and anaesthesia (pain control)

Major unmet need remains for improvements in both efficacy and tolerability in the neuropathic pain market, including addressing the needs of specific patient segments such as those with debilitating conditions, for example mechanical hypersensitivity. It is believed that advances in the understanding of the mechanisms which lead to neuropathic pain will allow for improved patient segmentation and, potentially, this could increase the success rate of research in this condition.

The osteoarthritis (OA) market is steadily growing, due to ageing populations and novel agents entering the market. However, the established use of branded generic treatment makes market entry more difficult. Biologics are an emerging treatment option for OA, and this is an area in which we have an active interest through our biologics activities.

#### Our focus

#### Our key marketed products

In 2009, *Zomig* nasal spray was approved for the acute treatment of migraine attacks in adolescents (12 to 17 years of age) in 14 member states in the EU.

*Diprivan* is the world's best-selling intravenous general anaesthetic. A complete changeover to *Diprivan* EDTA, a microbial-resistant formulation, will be effective from 2010.

*EMLA* submissions/approvals of patch presentation have continued, particularly in Europe. In Japan, *EMLA* is out-licensed to Sato Pharmaceuticals Co., Ltd. which expects to file a Japanese new drug application for *EMLA* cream in 2010.

#### In the pipeline

Vimovo (PN400) is a fixed-dose combination tablet of enteric-coated naproxen and immediate release esomeprazole which uses proprietary technology licensed from Pozen Inc. through a collaboration established in August 2006. It is being developed for the relief of signs and symptoms of OA, rheumatoid arthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric ulcers. Risk factors for the NSAID-associated gastric ulcers include age, a documented history of gastric ulcers, or concomitant use of low-dose aspirin. OA is the most common form of arthritis and the most common cause of chronic pain, affecting nearly 151 million individuals worldwide. The PN400 Phase III studies demonstrated that patients at risk of developing NSAID-associated gastric ulcers taking PN400 experienced significantly fewer endoscopically confirmed gastric ulcers compared with patients taking enteric-coated naproxen (500mg) alone. An NDA was filed in June. The FDA has confirmed that the proposed trade name for PN400, Vimovo, is acceptable and that it will be re-reviewed 90 days prior to the approval of the NDA. A regulatory filing in the EU was submitted in October.

In September, AstraZeneca licensed two potential products, NKTR-118 and NKTR-119, from Nektar. NKTR-118, an oral peripherallyacting opioid antagonist, is in clinical development for the treatment of opioid induced constipation (OIC), which is the key gastrointestinal (GI) side effect of opioid treatment for pain, for which there are limited therapeutic treatment options. Data from a Phase II study demonstrated that oral NKTR-118 improved lower GI dysfunction by increasing the frequency of bowel movements in patients with OIC, while simultaneously preserving opioid-mediated pain relief. NKTR-119 is an earlier-stage programme that combines NKTR-118 with an opioid, with the goal of treating pain without the side effect of constipation traditionally associated with opioid therapy.

AZD2423 has progressed into Phase I studies and AZD2066 has entered into Phase II studies for the treatment of neuropathic (caused by nerve damage) pain. AZD3043, a short-acting anaesthetic, has entered Phase I studies. Additionally, we have extended our research collaboration with the University of Heidelberg to further understanding of the pathophysiology of chronic pain conditions.

#### Cognition

Alzheimer's disease (AD) remains one of the largest areas of unmet medical need and also one of high risk for neuroscience product development, due in part to the challenges of establishing efficacy in clinical studies. Current treatments, which physicians consider inadequate, target the symptoms, not the underlying cause, of the disease. Growth in this area is strong (20% to 40% across the world) but all existing marketed treatments will face patent expiry by 2015. Disease modification, delivered through biologics and/or small molecule treatments, is clearly the hope for AD patients. Along with better diagnostics, it is expected to allow for earlier intervention and better clinical outcomes, but the first wave of disease modifiers is still several years away.

Attention deficit hyperactivity disorder (ADHD) affects 22 million children worldwide<sup>3</sup> (plus another several million adults). While there are a number of treatments available today, which work well for many of these young patients, they also carry certain risks because a great majority of them are psycho-stimulants (mostly amphetamines and methylphenidate). We continue to work on treatment options that would offer strong efficacy without the challenges that current treatments bring. We also hope to offer new options to adult ADHD patients, many of whom remain undiagnosed or untreated today.

#### Our focus

In the pipeline

The current portfolio of potential medicines in this area includes six development programmes, of which three are in clinical evaluation in AD, ADHD and cognitive disorders in schizophrenia (CDS). In addition to developing molecules for cognitive disorders, we continue to progress one development phase molecule for the treatment of other neurodegenerative diseases.

Through our collaboration with the Karolinska Institute in Sweden, the Banner Alzheimer's Institute in Phoenix, Arizona and others, our R&D capabilities in positron emission tomography (PET) imaging of the human brain continue to progress. AstraZeneca's amyloid PET ligands may enable us to detect AD early and to assess drug effects in AD. We have discovered and taken into patient studies two C-11 amyloid PET ligands, which are being developed as research biomarkers. Additionally, a collaboration with the Mental Health Research Institute in Australia has been initiated to develop new ways of identifying AD patients at early stages of the disease.

Compounds in clinical evaluation include products deriving from our relationship with Targacept (AZD3480, TC-5619 and AZD1446). AZD3480, a neuronal nicotinic receptor agent, is currently in Phase II clinical testing in ADHD. In 2009, Targacept announced top-line results from a Phase IIa ADHD study in which the primary outcome measure was met. TC-5619 has entered a Phase IIa study in CDS. AZD1446 has entered Phase IIa studies in ADHD and AD.

#### Litigation

Detailed information about material legal proceedings in respect of our Neuroscience products can be found in Note 25 to the Financial Statements from page 166.

#### Financial performance 2009/2008 Performance 2009

#### Reported performance

Neuroscience sales on a reported basis grew by 7% to \$6,237 million in 2009 from \$5,837 million in 2008.

#### Performance - CER growth rates

Neuroscience sales grew by 10% to \$6,237 million from \$5,837 million last year.

US sales for *Seroquel* (all formulations) for the full year were \$3,416 million, 13% ahead of last year. *Seroquel* (all formulations) remains the market leader in the US anti-psychotic market, with a total prescription share of 31.3% in December 2009.

For the full year, *Seroquel* (all formulations) sales outside the US increased by 8% to \$1,450 million. In the Rest of World (ie excluding the US and Canada) value and volume growth for *Seroquel* were well ahead of the atypical anti-psychotic market.

Sales of *Zomig* for the full year were down 3% in the US to \$182 million. Sales outside the US were up 3% to \$252 million.

#### Performance 2008

#### Reported performance

Neuroscience sales grew by 9% in 2008, up to \$5,837 million from \$5,340 million in 2007. All geographic areas experienced growth and *Seroquel* (all formulations) grew strongly by 11%.

#### Performance – CER growth rates

Neuroscience sales grew by 6% to \$5,837 million from \$5,340 million in 2007.

US sales for Seroquel (all formulations) for the full year were \$3,015 million. For the full year, Seroquel (all formulations) sales outside the US increased by 8% to \$1,437 million. In the Rest of World (ie excluding the US and Canada) value and volume growth for Seroquel were well ahead of the atypical anti-psychotic market in all regions.

Sales of *Zomig* for the full year were up 6% in the US to \$187 million. Sales outside the US were down 5% to \$261 million.

<sup>3</sup> Decision Resources 2008.

### Oncology

#### In brief

- > Arimidex sales up 7% to \$1.9 billion and continues to be the leading branded hormonal therapy for early breast cancer in the US, Japan, Spain, the UK and France.
- > Zoladex sales \$1.1 billion, flat from the previous year.
- > Casodex sales \$0.8 billion, down 34%, following expiry of patents in all major territories.
- > Iressa was approved in the EU for the treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of the epidermal growth factor receptortyrosine kinase (EGFR-TK).
- > Faslodex 500mg has been shown to be more efficacious than Faslodex 250mg at treating breast cancer and regulatory submissions to change the dose have been made in the EU and the US, together with the first filing in Japan.
- > Withdrawal of the US and the EU regulatory submissions for Zactima in NSCLC in October but clinical studies continue in a number of other types of cancer.
- > Registration studies ongoing for *Recentin* in first line colorectal cancer and recurrent glioblastoma multiforme and NSCLC.
- > Registration studies ongoing for zibotentan (ZD4054) in castrate resistant prostate cancer.
- > Olaparib (AZD2281) is in ongoing Phase II studies for the treatment of certain types of breast and ovarian cancer. Olaparib will progress to Phase III development in breast cancer with genetic DNA repair deficits.
- > Teva Parenteral Medicines (Teva Par) has challenged our patents for Faslodex. In January 2010, AstraZeneca filed a patent infringement action against Teva Par in the US District Court for the District of Delaware.

#### **Our marketed products**

Arimidex (anastrozole) is an aromatase inhibitor for the treatment of early breast cancer.

Zoladex (goserelin acetate implant), in one- and three-month depots, is a luteinising hormone-releasing hormone agonist for the treatment of prostate cancer, breast cancer and certain benign gynaecological disorders.

*Casodex* (bicalutamide) is an anti-androgen therapy for the treatment of prostate cancer.

*Iressa* (gefitinib) is an EGFR-TK inhibitor that acts to block signals for cancer cell growth and survival in NSCLC.

*Faslodex* (fulvestrant) is an injectable oestrogen receptor antagonist for the treatment of breast cancer.

*Nolvadex* (tamoxifen citrate) remains a widely prescribed breast cancer treatment outside the US.

#### **Our strategic objectives**

We aim to build on our position as a world leader in cancer treatment through continued sales of *Arimidex*, the launch of a more efficacious dose of *Faslodex* (*Faslodex* 500mg), the growth of *Iressa* and the successful introduction of novel therapeutic approaches currently in development, including both small molecule drugs and biologics, targeted at defined patient populations with high unmet medical need.

#### Cancer Our focus

#### Our key marketed products

Arimidex continues to be the leading branded hormonal therapy for patients with early breast cancer in the US, Japan, Spain, the UK and France, and is also approved in a number of markets in Europe for a switch indication for patients who have already received two to three years of tamoxifen. This success is largely based on the extensive long-term efficacy and safety results of the ATAC study, which showed Arimidex to be significantly superior to tamoxifen at preventing breast cancer recurrence during and beyond the five-year treatment course. Breast cancer recurrence is defined as loco-regional recurrence, distant recurrence or contra-lateral breast cancer.

Faslodex 250mg is now approved in 70 markets and offers an additional hormonal therapy option for patients with hormonereceptor positive advanced breast cancer, delaying the need for cytotoxic chemotherapy. It is a once-monthly injection approved for the 2nd line treatment of hormone-receptor positive advanced breast cancer in post-menopausal women.

*Casodex* is used as a 50mg tablet for the treatment of advanced prostate cancer, and as a 150mg tablet for the treatment of locally advanced prostate cancer.

Zoladex, a luteinising hormone-releasing hormone (LHRH) agonist, is approved in 120 countries. It is approved for the treatment of prostate cancer, breast cancer and certain benign gynaecological disorders. In non-metastatic prostate cancer, *Zoladex* has been shown to improve overall survival, both when used in addition to radical prostatectomy and when used in addition to radiotherapy. The 10-year follow-up results of a study for the European Organisation for Research and Treatment of Cancer confirmed the long-term survival benefits of *Zoladex* when used as adjuvant to radiotherapy in patients with locally advanced prostate cancer. In breast cancer, *Zoladex* is widely approved for use in advanced breast cancer in premenopausal women. In a number of countries, *Zoladex* is also approved for the adjuvant treatment of early stage pre-menopausal breast cancer as an alternative to and/or in addition to chemotherapy. *Zoladex* offers proven survival benefits for breast cancer patients with a favourable tolerability profile.

Competition in the LHRH agonist market is expected to increase in Europe during 2010, with the anticipated launches of generic goserelin. This follows the launch of generic goserelin (one-month depot) in Germany and the UK in 2009.

Iressa is approved in 66 countries and is the leading epidermal growth factor receptor-tyrosine kinase (EGFR-TK) inhibitor in Japan and the Asia Pacific region where it is marketed for pre-treated advanced non-small cell lung cancer (NSCLC). Based on data from the Phase III INTEREST study, which compared Iressa with docetaxel in pre-treated NSCLC, and the Phase III IPASS study, which compared Iressa with doublet chemotherapy (carboplatin/paclitaxel) in 1st line NSCLC patients, a marketing authorisation for Iressa for the treatment of EGFR mutationpositive advanced NSCLC patients (all lines of therapy) was granted by the EMEA in June, followed by the European launch in July. AstraZeneca is consulting with other regulatory authorities regarding the data from the IPASS study and is progressing submissions worldwide.

We have various distribution and marketing arrangements for branded *Ethyol.* In the US, Ben Venue Laboratories, Inc. is authorised to distribute *Ethyol.* Outside the US, our two main distribution partners are Pinnacle Biologics, Inc. for our Western Europe markets, Turkey and Israel, and Scherico Ltd for various other countries.

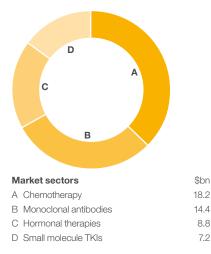
#### In the pipeline

Zactima (vandetanib) is a potential new oral anti-cancer therapy, which has a unique anti-cancer profile through two clinically proven mechanisms. It blocks the development of a tumour's blood supply (anti-angiogenesis) and blocks the growth and survival of the tumour itself (anti-EGFR). Vandetanib also inhibits RET (rearranged during transfection)-kinase activity, an important growth driver in certain types of thyroid cancer. In June, AstraZeneca made submissions to the FDA and the EMEA for the use of vandetanib 100mg in combination with chemotherapy in patients with advanced NSCLC. In October, these submissions were

#### **Our financial performance**

		2009			2008			2009 compared to 2008		2008 compared to 2007	
			Growth due to exchange		CER	Growth due to exchange		CER	Reported	CER	Reported
	Sales \$m	growth \$m	effect \$m	Sales \$m	growth \$m	effect \$m	Sales \$m	growth %	growth %	growth %	growth %
Casodex	844	(424)	10	1,258	(161)	84	1,335	(34)	(33)	(12)	(6)
Arimidex	1,921	129	(65)	1,857	69	58	1,730	7	3	4	7
Zoladex	1,086	-	(52)	1,138	(31)	65	1,104	-	(5)	(3)	3
Iressa	297	20	12	265	8	19	238	8	12	3	11
Faslodex	262	26	(13)	249	25	10	214	10	5	12	16
Nolvadex	88	-	3	85	(5)	7	83	-	4	(6)	2
Abraxane™	_	(64)	-	64	2	-	62	(100)	(100)	3	3
Ethyol	15	(13)	-	28	(15)	-	43	(46)	(46)	n/m	n/m
Other	5	(4)	(1)	10	(1)	1	10	(40)	(50)	(10)	_
Total	4,518	(330)	(106)	4,954	(109)	244	4,819	(7)	(9)	(2)	3

### Therapy area world market (MAT/Q3/09)



The world market value for cancer therapies is \$49 billion and continues to grow.

An increasing number of large research-based pharmaceutical and biotech companies have a stated ambition to build their business in oncology. For several years there has been a substantial increase in cancer-based clinical study activity. According to IMS data, value growth in oncology will continue at double digit compound annual growth rates and is, therefore, well above the growth rates of other therapy areas.

## **49bn**

#### The world market value for cancer therapies is \$49 billion and continues to grow

withdrawn. The decision to withdraw these submissions was based on an updated analysis that demonstrated no overall survival advantage when vandetanib was added to chemotherapy as well as preliminary feedback from regulatory authorities that the submissions based on progression-free survival as the primary endpoint might not be sufficient for approval.

The ZEPHYR study of vandetanib 300mg monotherapy versus placebo in patients who have previously progressed on EGFR-TK inhibitor treatment did not meet its primary endpoint of overall survival. This completes the Phase III development of vandetanib. AstraZeneca has no current plans to make regulatory submissions in respect of vandetanib for the treatment of NSCLC.

The ZETA study met its primary endpoint, showing that vandetanib 300mg significantly extends progression-free survival in patients with advanced medullary thyroid cancer. The safety profile of vandetanib in the ZETA study was manageable, which is similar to the findings of other studies. Medullary thyroid cancer is a rare cancer with no currently approved treatment. AstraZeneca will be discussing the data from the ZETA study with regulatory authorities.

Results from the CONFIRM study demonstrate that *Faslodex* 500mg offers a superior benefit/risk profile to *Faslodex* 250mg for the treatment of breast cancer. This data has formed the basis of regulatory submissions across the globe.

Recentin (cediranib) is a highly potent anti-angiogenic agent that inhibits all three vascular endothelial growth factor receptors and is suitable for once-daily oral dosing. It is currently in Phase III development in first line colorectal cancer (CRC) and recurrent glioblastoma (rGBM). Patient recruitment for the HORIZON CRC programme completed last year and the Phase III REGAL study in rGBM comparing *Recentin* monotherapy versus lomustine +/-*Recentin* finished enrolling patients in the third quarter of 2009. Recruitment in the BR29 study investigating *Recentin* at 20mg plus carboplatin/paclitaxel versus carboplatin/ paclitaxel alone in NSCLC is ongoing. The initial read-outs for Phase III of the HORIZON and REGAL studies are expected in the first half of 2010.

Encouraging Phase II data for *Recentin* in renal cancer, prostate cancer, alveolar soft part sarcoma, NSCLC and rGBM were also presented in 2009.

Zibotentan (ZD4054) is an oral once-daily potent and specific endothelin A-receptor antagonist. Data from Phase II studies suggested that in men with metastatic castrate resistant prostate cancer (CRPC), zibotentan 10mg demonstrated a promising survival benefit and a generally well-tolerated side effect profile. Zibotentan 10mg is now in Phase III development. The Phase III ENTHUSE studies are investigating efficacy in metastatic CRPC, both as monotherapy and in combination with docetaxel, and in non-metastatic CRPC.

Olaparib (AZD2281) is an oral poly-ADPribose-polymerase inhibitor, a new class of drug which potentially offers an innovative therapeutic approach to treating cancers by targeting a weakness in DNA repair inherent in many tumour cells. Olaparib is currently being evaluated in Phase II studies for the treatment of certain types of breast and ovarian cancer. The initial Phase III programme which is planned to start in mid 2010 focuses on breast cancer with genetic DNA repair deficits. Our early oncology pipeline includes a range of novel compounds that target signalling pathways believed to be pivotal in cancer cell growth, tumour invasion, DNA repair mechanisms and survival. Phase II data from AZD6244, a potent MEK (mitogen-activated protein kinase 1) inhibitor licensed from Array, showed biological activity in lung cancer and melanoma. In June, a deal was signed with Merck relating to a combination of AstraZeneca's AZD6244 and Merck's MK-2206, AZD6244 has been shown to affect MEK, an important signal that promotes cancer cell growth and survival; while Merck's MK-2206 is a novel AKT kinase inhibitor, which acts on a complementary signalling pathway in cancer cells. By using a combination of both of these compounds, the aim is to explore the potential effect of blocking multiple points along a signalling pathway thereby preventing tumour growth.

In December, AstraZeneca entered into a master collaboration agreement with Dako to develop companion diagnostic tests for selected cancer treatments. This agreement forms part of AstraZeneca's personalised healthcare strategy, and will have benefits for more than 10 of AstraZeneca's oncology drug projects in early development.

AZD8055, AZD8931, AZD1480 and AZD4547 are all undergoing Phase I studies. AZD1152, an aurora kinase inhibitor, has shown activity in acute myelogenous leukaemia and will complete Phase II studies in mid-2010. We are also developing potential new cancer treatments using biological approaches with highly defined molecular targets for patient populations with unmet medical need and currently have four Phase I studies ongoing with biologics.

Our early biologics pipeline consists of MAbs directed against processes central to tumour progression. We are also developing MAbs that enhance the ability of a patient's own immune system to kill cancer cells.

CAT-8015 is a biologic being investigated for the treatment of blood-based malignancies, including lymphoma and leukaemia. It targets a common protein receptor found on the majority of β-cell cancers. In 2009, Phase I development for CAT-8015 continued to move forward in β-cell lymphoma and leukaemia. In 2009, three additional oncology antibody programmes entered into Phase I studies targeting a variety of advanced solid tumours using different pathways such as insulin-like growth factors and specific cell surface receptors.

In 2009, AstraZeneca discontinued its development of blinatumomab (MT-103/ MEDI-538) in the US and returned the North American licence rights for blinatumomab to Micromet, Inc.

In 2009, AstraZeneca entered into a research collaboration with the Institute of Cancer Research (UK) and Cancer Research Technology Limited to jointly discover inhibitors of targets on a novel pathway which is thought to be important in a range of tumour types.

#### Litigation

Detailed information about material legal proceedings relating to our Oncology products can be found in Note 25 to the Financial Statements from page 166.

#### Financial performance 2009/2008 Performance 2009

Reported performance Oncology sales decreased by 9% on a reported basis to \$4,518 million down from \$4,954 million in 2008.

#### Performance - CER growth rates

Oncology sales were down 7% at CER. *Arimidex* sales were up 7% to \$1,921 million. In the US, *Arimidex* sales were up 16% to \$878 million. Outside the US, sales were flat at \$1,043 million.

*Casodex* sales decreased by 34% to \$844 million, with sales in the US down by 49% and sales outside the US down by 29% due to continued erosion from generic competition.

*Iressa* sales for the year were up 8% with growth in China (11%), Western Europe (250%) and Japan (10%).

*Faslodex* sales were up 10% with a 5% increase in the US and a 15% increase outside the US.

#### Performance 2008

Reported performance

Oncology sales increased by 3% on a reported basis to \$4,954 million up from \$4,819 million in 2007.

#### Performance – CER growth rates

Oncology sales were down 2% at CER. *Arimidex* sales were up 4% to \$1,857 million. In the US, *Arimidex* sales were up 9% to \$754 million. Outside the US, *Arimidex* sales increased by 1% to \$1,103 million.

*Casodex* sales decreased by 12% to \$1,258 million, with sales in the US down by 2% and sales outside the US down by 15%.

*Iressa* sales for the year were up 3% as growth in Emerging Markets more than offset the 3% decline in sales in Japan.

*Faslodex* sales were up 12% with a 5% increase in the US and an 18% increase outside the US.

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# Respiratory & Inflammation

# In brief

> Total Symbicort sales \$2.3 billion, up 23%.

- > Symbicort pMDI licensed for long-term maintenance treatment of asthma in the US. The chronic obstructive pulmonary disease (COPD) indication was approved by the FDA in February 2009. An additional programme for paediatric asthma indication has been submitted to the FDA and a Complete Response Letter was received in April. AstraZeneca has responded to the Complete Response Letter with a proposed programme to address the FDA questions.
- > Outside the US, Symbicort SMART is now approved for use in managing asthma in 96 countries.
- > Outside the US, Symbicort Turbuhaler is now approved for the treatment of COPD in 96 countries.
- In October, Symbicort Turbuhaler was approved in Japan for the treatment of adult asthma and it was launched in Japan in January 2010. AstraZeneca and Astellas have entered into an agreement for the co-promotion of Symbicort Turbuhaler in Japan.
- > Total Pulmicort sales of \$1,310 million and is now approved in 116 countries.
- > With settlement of AstraZeneca's Pulmicort Respules patent infringement litigation against Teva in November 2008, Teva obtained an exclusive licence to sell generic Pulmicort Respules in the US from 15 December 2009 on payment of royalties to AstraZeneca. Teva launched its licensed product in December. AstraZeneca sales of Pulmicort Respules continue despite Teva's entry.
- > Following FDA approval of Apotex's generic version of *Pulmicort Respules* in March 2009, AstraZeneca obtained a preliminary injunction against Apotex, Inc. and Apotex Corp. (Apotex) preventing an at-risk launch of the product until further order of the Court. Apotex appealed the decision. Other patent infringement litigation in relation to *Pulmicort Respules* against Breath Limited continues.

### **Our marketed products**

Symbicort pMDI (budesonide/formoterol in a pressurised metered-dose inhaler) is used for the maintenance treatment of asthma and COPD in the US.

Symbicort SMART (our Symbicort Maintenance and Reliever Therapy) is approved for maintenance and reliever therapy in persistent asthma.

Symbicort Turbuhaler (budesonide/formoterol in a dry powder inhaler) is a combination of an inhaled corticosteroid and a fast onset, long-acting bronchodilator used for the treatment of asthma and COPD.

*Pulmicort* (budesonide) is a corticosteroid antiinflammatory inhalation drug that helps prevent symptoms and improves the control of asthma.

Pulmicort Respules (budesonide inhalation suspension) is the first nebulised corticosteroid in the US for the treatment of asthma in children as young as 12 months.

*Rhinocort* (budesonide) is a nasal steroid treatment for allergic rhinitis (hay fever), perennial rhinitis and nasal polyps.

Oxis (formoterol) is a fast onset, long-acting betaagonist used for the treatment of asthma and COPD.

*Accolate* (zafirlukast) is an oral leukotriene receptor antagonist used for the treatment of asthma.

### **Our strategic objectives**

We aim to build on our strong position in the respiratory field through the growth of key products, particularly *Symbicort*, with new indications and market launches, including chronic obstructive pulmonary disease (COPD), as well as through developing a strong pipeline of novel small molecule and biologics approaches to COPD and asthma. We aspire to enter the rheumatology market predominantly through our biologics pipeline.

### **COPD** and asthma

According to WHO, COPD is currently the fourth leading cause of death worldwide, with future increases anticipated. Current treatment has recently demonstrated some survival benefit but the prognosis of the COPD patient remains poor. In asthma, morbidity and mortality remain important issues and disease normalisation is not achieved by any treatment.

The typical treatment for both COPD and asthma is a fixed-dose combination of an inhaled corticosteroid (ICS) with a long-acting beta-agonist (LABA) (for example *Symbicort*) or for COPD specifically, an inhaled long-acting muscarinic antagonist (LAMA). Other major asthma treatments include monotherapy ICSs, oral leukotriene receptor antagonists and/ or oral steroids for severe disease and (in combination with antibiotics) for exacerbations. While there are not many significant new treatment modalities on the horizon for asthma and COPD, some pharmaceutical companies have once- and twice-daily ICS/ LABAs in late-stage development and the first regulatory approvals for a new LABA and a novel anti-inflammatory mechanism, an oral phosphodiesterase 4 inhibitor, have been seen this year. Significant new product classes impacting the asthma market are unlikely before 2015. However, specifically for the treatment of COPD, the new product class of fixed combination LABA/LAMA is estimated to impact the market in early 2013. Longer term, novel anti-inflammatory compounds and/or anti-proteases, alone or in combinations of LABAs or LAMAs aimed mainly at the prevention and/or treatment of COPD exacerbations, are likely to appear on the market. Generic ICS/LABA combinations may be available from the early part of this decade.

### Our focus

### Our key marketed products

*Symbicort Turbuhaler* improves symptoms and provides a clinically important improvement in the health of many patients with either asthma or COPD by providing rapid, effective control and effective reduction of exacerbations.

In October, *Symbicort Turbuhaler* was approved in Japan for the treatment of adult asthma and it was launched in Japan in January 2010. AstraZeneca and Astellas have entered into an agreement for the copromotion of *Symbicort Turbuhaler* in Japan.

Symbicort pMDI (pressurised metered dose inhaler) is approved, in the US, for the long-term maintenance treatment of asthma in patients 12 years of age and older and was launched in the US in 2007. The COPD indication was approved and launched in the US in early 2009. In December 2008, the Joint Advisory Committees of the FDA completed a review of the benefits and risks of asthma medications containing LABAs. The Advisory Committees concluded that the benefits of *Symbicort* pMDI outweigh the risks in adult and adolescent asthma patients. However, a final decision has not yet been communicated by the FDA.

An sNDA for *Symbicort* pMDI in paediatric asthma was submitted in 2008. AstraZeneca received a Complete Response Letter in April 2009 for this application and has since submitted a response outlining an additional programme to address the FDA's questions.

# **Our financial performance**

	2009					2008	2007	2009 compared to 2008		2008 compared to 2007	
		Growth due CER to exchange			Growth due CER to exchange			CER	Reported	CER	Reported
	Sales \$m	growth \$m	effect \$m	Sales \$m	growth \$m	effect \$m	Sales \$m	growth %	growth %	growth %	growth %
Pulmicort	1,310	(155)	(30)	1,495	7	34	1,454	(10)	(12)	-	3
Symbicort	2,294	456	(166)	2,004	346	83	1,575	23	14	22	27
Rhinocort	264	(47)	(11)	322	(41)	9	354	(15)	(18)	(12)	(9)
Oxis	63	-	(8)	71	(21)	6	86	-	(11)	(24)	(17)
Accolate	66	(6)	(1)	73	(4)	1	76	(8)	(10)	(5)	(4)
Other	135	(14)	(14)	163	(9)	6	166	(9)	(17)	(5)	(2)
Total	4,132	234	(230)	4,128	278	139	3,711	6	-	7	11





# The prescription respiratory world market value is \$54 billion.

WHO estimates that 300 million people worldwide suffer from asthma and more than 200 million have COPD, which is currently the fourth leading cause of death worldwide with further increases anticipated in future decades.



Symbicort SMART provides increased asthma control and simplifies asthma management through the use of only one inhaler for both maintenance and relief of asthma symptoms. As well as being a cost-effective treatment for many healthcare payers, the Symbicort SMART approach can also result in lower ICS and oral steroid use compared to other treatment options.

*Pulmicort* remains the world's leading inhaled corticosteroid for the treatment of asthma and is available in several forms. Teva now has an exclusive licence to sell generic *Pulmicort Respules* in the US.

*Rhinocort* combines powerful efficacy with rapid onset of action and minimal side effects and is available as a once-daily treatment for allergic rhinitis (hay fever), perennial rhinitis and nasal polyps in the *Rhinocort Aqua* (nasal spray) and the *Turbuhaler* (dry powder inhaler) forms.

*Oxis* is added to the treatment regimen for asthma and COPD when corticosteroid treatment alone is not adequate. *Oxis* is also indicated for symptom relief in COPD.

# Clinical studies of our key marketed products

During 2009, the data from the SUN study, the second pivotal Symbicort pMDI study, was published. This study is part of the COPD NDA submission. The study confirmed the clinical benefits of Symbicort pMDI in moderate and severe COPD patients and showed that Symbicort pMDI 160/4.5 two inhalations twice-daily had a greater improvement in pre-dose forced expiratory volume I tests averaged over the treatment period compared with formoterol and placebo. In addition, several other important clinical studies in COPD were published showing the benefit of early onset effect relieving morning symptoms as well as improved outcomes when added to LAMAs.

Clinical data from the CLIMB study demonstrated that *Symbicort* added to Spiriva<sup>™</sup> (tiotropium) provided greater clinical improvements than tiotropium alone over a 12-week treatment period. Results from the CLIMB study also showed that the occurrence of severe COPD exacerbations was reduced by as much as 62% in patients where *Symbicort* was added to tiotropium compared to patients on tiotropium alone. Furthermore, the CLIMB study showed that patients treated with the *Symbicort*/tiotropium inhaled combination experienced benefits.

# In the pipeline

AZD9668, currently in Phase IIb studies, is an oral inhibitor of neutrophil elastase, an enzyme strongly implicated in the inflammatory process, mucus hypersecretion and matrix degradation that drives the signs and symptoms of and disease progression in COPD.

Alongside this novel approach and building on our capabilities in combinations and device development demonstrated through our experience with Symbicort, we are aiming to improve further the mainstay of treatment for all COPD patients by combining two long-acting bronchodilators, AZD3199 and AZD9164, in one inhaler. The individual compounds are currently in Phase II studies (AZD3199 is in Phase IIb studies). Patients should benefit from improved symptom control, as well as from the reduction in the complications arising from multiple dosing or inhaler devices and the combination supports the recommendations of the international auidelines for the treatment of COPD for maximal bronchodilation as 1st line therapy.

AZD1981, a prostanoid receptor CRTh2 antagonist currently in Phase IIa studies, is a potential new oral small molecule approach to treating uncontrolled asthma. AZD1981 is expected to prevent the recruitment and activation of Th2 cells and eosinophils, which are both increased in asthma. AZD8848 is a novel small molecule toll-like receptor-7 agonist in Phase II studies for the treatment of asthma being developed in collaboration with Dainippon Sumitomo Pharmaceuticals Co. Ltd (Dainippon Sumitomo).

MEDI-563 is an investigational approach that may help treat inadequately controlled asthma by targeting the interleukin-5 (IL-5) receptor, blocking the binding of IL-5 to the receptor and depleting the cells expressing the IL-5 receptor, typically eosinophils, which are thought to play a key role in the pathology of asthma. In addition, two Phase II studies are ongoing to assess the ability of MEDI-563 to reduce the asthmatic relapse rate following an acute care episode, as well as its ability to reduce the rate of asthma exacerbations overall.

In 2009, we initiated a Phase IIb study to determine the chronic dosing of MEDI-528 (an anti-IL-9 MAb) on asthma exacerbations in moderate to severe asthma.

CAT-354 targets interleukine-13, one of the key cytokines implicated in asthma pathogenesis. In 2009, we initiated a Phase IIa study to investigate the potential of a subcutaneous injection form of CAT-354 to treat patients with moderate to severe persistent asthma who are inadequately controlled despite current standard of care.

In addition, the early pipeline for respiratory biologics was bolstered by the entry of three new development programmes targeting COPD, which will likely progress to human studies in late 2010.

The early biologic pipeline has been reshaped to focus more on COPD, looking for novel strategies to inhibit exacerbations in COPD, which include regulation of inflammatory cell migration and activation with MAbs directed to antigens.

Strategic collaboration activity continues to be important to our respiratory pipeline. Our collaboration with Dynavax Technologies Corporation (Dynavax), which began in 2006, continues to pursue opportunities in the field of toll-like receptor-9 with immunostimulatory DNA sequences. Our collaborations with Dainippon Sumitomo (referred to above) and Dynavax both aim to find treatments for the normalisation of disease in asthma and the prevention of exacerbations in COPD. Our 2007 discovery alliance with Argenta Discovery Limited aimed at identifying improved bronchodilators to treat COPD continues and is now entirely focused on the combined anti-muscarinic and beta-2 adrenergic agonists. AstraZeneca continues to develop the LAMA compounds identified in the collaboration.

Our three-year research collaboration with Silence Therapeutics A.G. (Silence), established in 2007, is continuing. In 2008, we entered into a new collaboration with Silence focused on the development of a range of novel approaches for the delivery of siRNA molecules, which allows both Silence and AstraZeneca to commercialise the novel delivery systems which we develop together.

AstraZeneca announced in July that it had terminated the licence agreement with MAP Pharmaceuticals, Inc. (MAP), regarding unit dose budesonide (UDB). UDB, an investigational treatment for paediatric asthma, was the subject of an initial Phase III clinical study conducted by MAP. In February 2009, MAP announced that the study failed to meet its primary endpoints. In light of the clinical study results, AstraZeneca exercised its right to terminate the licence agreement.

# Rheumatology

Rheumatoid arthritis (RA) is currently treated with generic disease-modifying anti-rheumatic agents and, where the relevant criteria are met, biologic disease-modifiers. There remains a need for novel effective treatments since only about a third of patients treated with biologics achieve their treatment goals. The RA therapy market will experience modest annual growth over the 2008-2018 forecast period, as sales increase from \$8.2 billion to \$13.1 billion. In 2008, sales of the biologic tumour necrosis factor (TNF) alpha blockers accounted for 80% of major-market RA sales. Launches of additional TNF blockers are ongoing, and use of other biologic approaches, currently reserved for TNF failures, is expected to increase. Targeted novel oral drugs aimed at patients that currently choose not to take, are ineligible for or do not respond to biologics, are in development to provide anti-TNF-like efficacy with safety benefits and more convenient dosing. (Source: Decision Resources 2009).

Current treatment of systemic lupus erythematosus (SLE) focuses on controlling disease flares, preventing renal failure and suppressing symptoms to an acceptable level while minimising toxicity. Despite considerable recent development activity, no targeted disease-modifying agents have yet been successfully launched for SLE. Most emerging biologic agents will likely be used initially in combination with corticosteroids or immunosuppressants to provide incremental benefit and/or allow reduced doses or numbers of these agents.

# Our focus

#### In the pipeline

In 2009, we invested in several novel multi-functional MAbs in inflammatory and autoimmune conditions.

MEDI-545 is a MAb which targets interferonalpha, which regulates processes involved in autoimmune diseases. In 2009, we completed enrolment for a Phase IIa study in patients with SLE and a Phase I study in patients with active dermatomyositis or polymyositis.

CAM-3001 (licensed from CSL Limited) is a MAb in Phase I development with potential to help patients with RA through targeting the alpha sub-unit of the granulocyte-macrophage colony stimulating factor receptor.

In 2009, we initiated a Phase I study in scleroderma for a MAb, which targets the anti-interferon alpha receptor. We also filed an initial new drug application for a MAb which targets the CD-19 receptor.

AZD9056 and AZD5672, which were in Phase II development, have been terminated. AstraZeneca continues to explore approaches and mechanisms which have the potential to improve therapy and to deliver better outcomes for patients with rheumatological conditions.

### Litigation

Detailed information about material legal proceedings in respect of our Respiratory & Inflammation products can be found in Note 25 to the Financial Statements from page 166.

# Financial performance 2009/2008 Performance 2009

Reported performance Respiratory & Inflammation (R&I) sales were \$4,132 million, almost level with the \$4,128 million in 2008.

Performance - CER growth rates

R&I sales grew by 6% at CER.

Total sales of *Symbicort* grew by 23% to \$2,294 million. In the US, sales of *Symbicort* pMDI were \$488 million, up 91%. This strong growth is lead by physicians' increasing use of *Symbicort* pMDI, particularly in those patients newly starting fixed combination therapy. For these patients, more than one in three prescriptions written by specialists and more than one in four prescriptions written by primary care physicians, is for *Symbicort* pMDI. *Symbicort* (*Turbuhaler* and *SMART*) sales outside the US in the year were \$1,806 million, up 13%.

Total sales for *Pulmicort* were down 10% to \$1,310 million. Total US sales for *Pulmicort* for the full year were down 18% to \$804 million due to generic competition for *Pulmicort Respules*. *Pulmicort Respules* accounted for around 86% of total *Pulmicort* sales in the US. Total sales of *Pulmicort* outside the US were up 4% for the full year to \$506 million.

# Performance 2008

Reported performance

Sales in R&I increased by 11% to \$4,128 million from \$3,711 million in 2007.

Performance - CER growth rates

R&I sales grew by 7% at CER.

Total sales of *Symbicort* grew by 22% to \$2,004 million. In the US, sales of *Symbicort* pMDI were \$255 million. *Symbicort* (*Turbuhaler* and *SMART*) sales outside the US in the year were \$1,749 million, up 9%.

Total Pulmicort sales were flat at \$1,495 million, with US sales up 2% as the generic competition from the Teva product affected quarter four sales. US sales for Pulmicort were down 15% to \$260 million in the fourth quarter of 2008 and Pulmicort Respules sales were down 18% as a result of the 'at risk' launch of generic budesonide inhalation suspension (BIS) on 18 November 2008. The patent litigation between Teva and AstraZeneca was subsequently settled on 25 November 2008. The agreement allows Teva to commence sales of BIS under an exclusive licence from AstraZeneca beginning on 15 December 2009. The agreement also provided that any product already shipped by Teva would remain in the market to be further distributed and dispensed. As a result, Teva products accounted for nearly 15% of total prescriptions for BIS products dispensed during the fourth guarter of 2008, including a 40% share in December 2008. US sales for Pulmicort for the full year were \$982 million. Pulmicort Respules accounted for around 90% of total Pulmicort sales in the US. Total sales of *Pulmicort* outside the US were down 2% for the full year to \$513 million.

# **Other Businesses**

# Astra Tech

Astra Tech AB (Astra Tech) is engaged in the research, development, manufacture and marketing of medical devices and implants for use in healthcare, primarily in urology, surgery and odontology. Astra Tech has two main business divisions: Astra Tech Dental, which is responsible for the odontology area of the business, and Astra Tech Healthcare, which is responsible for the surgery and urology areas of the business. Astra Tech has a leading position in several countries in Europe and is expanding its operations in key markets, particularly in the US, Japan and South East Asia.

All product lines showed continued good sales growth in 2009. The downturn in the world economy has had a dramatic impact on the dental implant market, which is estimated to have declined by 5% during 2009. However, Astra Tech Dental has performed well in this declining market, growing its implant sales and increasing its market share in several key markets. In pursuit of the growth strategy for Astra Tech Dental, the sales and marketing organisation for dental implants was further strengthened and adapted to the prevailing market conditions. The downturn in the world economy has had no significant impact on the market for Astra Tech Healthcare products.

Since Astra Tech's acquisition of Atlantis Components Inc. (Atlantis) in 2007, Astra Tech has introduced the Atlantis product range into most European markets and the market response has been very favourable. The European manufacturing facility for Atlantis products, which Astra Tech opened in late 2008, is now in full operation, meeting an increasing demand from the European market. The acquisition of Atlantis has given Astra Tech a strong platform for development within digital dentistry, offering an important opportunity for continued growth for the dental implants product line. Major investments have been made in new production equipment for the manufacturing of new *LoFric* catheter products, which will be launched early in 2010.

The Astra Tech training and education programme has been further developed and, in combination with its state-of-the-art centre for training and education at its headquarters, advanced international education programmes and seminars are continuously being offered to existing and potential customers. Further investments have been made in R&D, clinical research and new production facilities to strengthen the product portfolio.

#### Aptium Oncology

For more than 25 years, Aptium Oncology, Inc. (Aptium Oncology) has been developing and managing hospital-based outpatient cancer centres in the US. Ownership of Aptium Oncology provides AstraZeneca with a unique window into the provider sector of the US oncology market and, through Aptium Oncology's network of over 175 physicians, access to many opinion leaders in the field of oncology who can help to shape early phase drug development decisions. It is also involved in clinical study delivery for a number of our pipeline products and provides scientific advice and staff training for oncology teams.

In 2009, Aptium Oncology continued to perform well in its cancer centre management business with positive profit and cash flow contributions. As anticipated, in the second half of the year, two of Aptium Oncology's long-term management contracts expired. In both cases, Aptium Oncology successfully established the infrastructure and services to allow the hospitals to manage independently their programmes after 15 and 25 years, respectively.

During 2009, Aptium Oncology continued to refine its business model to adapt to the ever-changing dynamics of the US healthcare industry. Aptium Oncology remains focused on growth and its consultancy business continues to lay the groundwork for new management relationships although, due to the loss of the long-term management contracts referred to above, Aptium Oncology's growth will be from a lower base. Clinical research is an integral part of care delivery at Aptium Oncology's cancer centres and an area of strategic strength for the company. Aptium Oncology's Gastrointestinal Cancer Consortium, established in 2008, has been successful in bringing together eight leading US academic institutions to speed up the process of finding and testing active new compounds for patients with gastrointestinal cancers. In 2010, Aptium Oncology plans to create a similar consortium focused on multiple myeloma.

# Environmental Sustainability

In this section, we describe our commitment in key areas of environmental sustainability – managing our impact on climate change, managing our waste and understanding the potential impact of pharmaceuticals in the environment. More information about our work in these areas and in others, such as resource efficiency, biodiversity and emissions to air and water, can be found on our website, astrazeneca.com/responsibility.

Our current set of five-year targets and objectives takes us to the end of 2010. We are in the process of finalising a new environmental sustainability strategy, including associated targets and objectives, which will drive our continued commitment in this important area.

# **Climate change**

We continue to work hard to manage our impact on climate change without compromising our ability to deliver new medicines that make a difference in important areas of healthcare.

We believe that our primary responsibility is to reduce our carbon footprint by, amongst other things, improving our energy efficiency and pursuing lower-carbon alternatives to fossil fuels. The use of carbon offset or other third party reduction credits to address residual emissions is something we will not consider as an alternative to driving our own efforts to reduce emissions.

In common with most businesses, our emissions arise from the energy we use at our facilities and from the various means of transport we use. Our carbon footprint is also affected by some of our respiratory therapies, specifically our pressurised metered dose inhaler (pMDI) products which rely on propellants such as hydrofluoroalkane, which is a greenhouse gas, to deliver the medicine to the airways. Patients who are unable to use our Turbuhaler dry powder inhaler, which does not require propellants, need these pMDI products. We believe that the expanded treatment choice and potential benefits that they offer outweigh the potential impact on the environment.

We continue to drive the management of our carbon footprint across key areas of business activity. For example, recognising the significant global warming emissions from business road travel for sales and marketing activities, we are maintaining a strong focus in this area. We are working with our fleet management and leasing suppliers to introduce fleet reporting to track the  $CO_2$  emissions of new and existing fleet vehicles and are introducing  $CO_2$  caps on new car acquisitions in our major markets. We also continue to invest in advanced driver training to improve both safety and fuel efficiency associated with driving. Other areas in which we are pursuing further improvement include the implementation of green technology principles in our process design and exploration of the potential for further investment in low carbon and renewable energy options at our sites.

Our current climate change targets, approved by the Board in 2005, aim to ensure that our absolute emissions in 2010 will be no greater than they were at the start of the decade and 55% less than they were in 1990. This requires substantial efforts to be made across our business to produce, by the end of 2010, an absolute reduction of 12% in global warming emissions from all sources other than pMDls, when compared with 2005. We have made good progress in recent years in reducing greenhouse gas emissions and, in 2009, our total emissions from all sources were 9% lower than in 2008. For data on our performance over the last three years see opposite.

Across all our activity, we work with our partners to share learning and foster best practice. We are also increasingly participating in the global debate on what business can do to help mitigate global warming and adapt to the unavoidable consequences of climate change.

# Waste management

The management of waste associated with our activities is another key element of our environmental sustainability strategy. We are working to reduce our total waste index to meet our 2010 improvement target (40% by the end of 2010 from a 2001/2002 reference point).

Our waste is categorised as 'hazardous waste' or 'other waste' according to national legislation, which varies in its definitions. The majority of our hazardous waste consists of solvent and aqueous streams from manufacturing activities. Other waste includes general waste from our facilities around the world.

Our primary objective is waste prevention. Where this is not practical, we focus on waste minimisation and appropriate treatment or disposal to maximise the reuse and recycling of materials, including energy recovery from the incineration of waste streams. Programmes designed to reduce the amount of waste we generate include the continual improvement of existing production processes, minimising

### Greenhouse gas emissions<sup>1, 2</sup>

CO2-equivalents million tonnes

2009	1.12
2008	1.22
2007	1.30

#### Index tonnes/\$m sales

2009	36
2008	40
2007	45

Figures are calculated in line with the Greenhouse Gas (GhG) Protocol guidance (ghgprotocol.org).

#### Waste production<sup>1,3</sup>

Total waste thousand tonnes

2009	50.0
2008	54.1
2007	57.6

#### Index tonnes/\$m sales

2009	1.60
2008	1.79
2007	1.99

<sup>1</sup> Data exclude MedImmune.

<sup>2</sup> The 2008 and 2007 figures have been revised due to improved data capture.

<sup>3</sup> We have replaced the ozone depleting potential (ODP) KPI with waste production as we believe this is now a more meaningful KPI. ODP data continue to be published on our website, astrazeneca.com/responsibility.

the environmental burden of new production processes under development, integration of environmental considerations in purchasing and internal waste awareness programmes. For data on our performance over the last three years see above.

# Pharmaceuticals in the environment

We understand, and take seriously, concerns about the detection of trace amounts of pharmaceutical residues in the environment. We work continuously to improve our understanding of the science and how pharmaceuticals interact with the environment and the risks that they may pose.

The presence of trace amounts of pharmaceuticals in the environment (PIE) resulting from patient excretion is an inevitable result of the way most current medicines work: pharmaceuticals need to be stable enough to have a useful shelf-life and oral dosage forms must be robust enough, in most cases, to pass through the stomach intact.

We are committed to identifying any potential adverse effects on the environment that our medicines might have and responsibly balancing these against the benefits that these medicines bring to patients' lives. We actively engage and partner with other pharmaceutical companies, NGOs, scientists, regulators, patients and prescribers to share learning and experience and to promote responsible management of PIE issues, in line with current scientific knowledge.

# **Dedicated research**

The levels of pharmaceutical residues detected in the environment are generally extremely low and are unlikely to pose a risk to human health. For example, the levels detected in drinking water are so low that, to ingest one single patient dose, someone would have to drink more water than is possible in a lifetime. However, whilst improving all the time, understanding of the potential for long-term effects of PIE, for example to aquatic life, requires further research.

This is an ongoing priority for our scientists at our Environmental Laboratory in Brixham, UK, who are at the forefront of this field of science, working both independently and in collaboration with other companies, leading academics and regulatory bodies to advance PIE-related research. Work at Brixham is focused on improving our understanding of the processes leading to the breakdown and removal of pharmaceutical residues in sewage treatment plants and the wider environment, and improving the predictability of the potential adverse environmental effects through the development of novel ecotoxicological test methodologies.

#### **Product stewardship**

We conduct environmental risk assessments for all our new, and many of our established, products in accordance with applicable regulations. Going beyond the regulatory requirements, we have also reviewed the environmental risk assessments for many of our older established products and, where appropriate, have undertaken additional voluntary testing to refine the assessments.

We have also introduced Environmental Risk Management Plans that will accompany all new medicines throughout their life-cycle. These plans enable all available environmental data to be taken into account at key decision points during drug discovery and development, and to provide early warning of medicines that could pose a potential risk to the environment.

We make environmental risk data for our existing products publicly available via the Swedish Doctors Prescribing Guide website (fass.se), using the voluntary disclosure system introduced by the Swedish Association of the Pharmaceutical Industry. AstraZeneca has a leading role in developing the guidance for this activity.

# In the Global Community

Wherever AstraZeneca is located worldwide, we aim to make a positive contribution to our local communities through sponsorships, charitable donations and other initiatives that help to make a difference. Our activities are focused on bringing sustainable benefit in ways that are consistent with our business of improving health and quality of life, and of promoting the value of science among young people.

In January 2009, we launched a revised and strengthened global Community Support Policy to provide an enhanced platform for capturing, aligning and maximising the benefit of our community support commitments worldwide. Targeted training for all relevant staff is being provided. As well as community support, the policy describes the requirements regarding product donations and support to patient groups and other healthcare organisations.

In 2009, we spent a total of \$882 million (2008: \$718 million) on community sponsorships and charitable donations worldwide, including our product donation and patient assistance programmes which make our medicines available free of charge or at reduced prices. Our expanded patient assistance programmes in the US contributed to a total commitment of \$786 million worth of product donations valued at an average wholesale price (2008: \$646 million). The increase is because more people enrolled in our US AZ&Me patient assistance programme and used more medicines in 2009 due, we believe, to the economic recession. Our community support spend (\$96 million) included a contribution during the year of \$25 million to the AstraZeneca HealthCare Foundation for its cardiovascular programme which is focused on improving cardiovascular health in the US.

We also contribute where possible to disaster relief efforts. During 2009, when typhoons Ketsana and Parma hit the Philippines, causing widespread devastation, we donated medicines to the relief effort and 15 of our employees did voluntary work with the Philippine army, helping over 1,000 flood victims. We responded similarly with donations to the local relief effort when earthquakes hit Indonesia and, when typhoon Morakot struck Taiwan, AstraZeneca Asia Pacific made a \$200,000 donation to the local Red Cross.

At a global level, we also made a further contribution of \$240,000 to the Red Cross Centre in Kuala Lumpur, Malaysia, established in 2006 by the Red Cross with \$700,000 of funding from AstraZeneca. The Centre continues to play an important role in disaster relief in the Asia Pacific region. With prepositioned emergency supplies, the Centre was able to respond quickly to the events in 2009, distributing hygiene kits to thousands of people in need in the affected areas. Our 2009 donation, coupled with one of \$200,000 that we made in 2008, has enabled the Red Cross to maintain appropriate levels of emergency relief stock at the Centre.

In January 2010, following the earthquake in Haiti, we donated medicines and contributed a total of \$500,000 to the British Red Cross Emergency Appeal. We also committed an additional \$500,000 to support a longerterm disaster recovery programme that will give the people of Haiti the help they need to re-build their lives and their communities.

#### In the developing world

Whilst we remain committed to making a contribution to improving healthcare in the developing world, we believe that real progress can only be made through the commitment of all the related stakeholders, including governments, NGOs and the international community, as well as the private sector. Only by working together can sustainable improvements be achieved.

The medicines in our range today are not for the treatment of tuberculosis (TB), HIV/AIDS and malaria, currently the developing world's most significant disease challenges, but we are applying our skills and resources to helping in other ways. Our contribution centres on two main areas of activity – dedicated TB research and working in partnership to help strengthen local health capabilities.

## **Dedicated TB research**

Our dedicated research facility in Bangalore, India is focused on finding a new, improved treatment for TB, which is a major cause of illness and death worldwide, especially in Asia and Africa. AstraZeneca is the only major pharmaceutical company with a research programme in India totally dedicated to TB. Further information can be found in the Therapy Area Review in the Infection section on page 64.

#### Working in partnership

In some parts of the developing world, the availability of medicines is not always the main challenge. Access to healthcare also depends on having a functional healthcare system, trained healthcare workers and effective supply and distribution mechanisms in place to ensure that medicines are used to their full effect as part of overall health management. To help meet these challenges, alongside our ongoing TB research, we partner with NGOs and other organisations working with local communities to strengthen their frameworks for delivering healthcare in TB and other disease areas in a sustainable way.

Key principles for our partnerships are that they lead to positive, measurable outcomes, can be scaled up and potentially replicated to improve outcomes for a greater number, and can deliver a sustainable framework that can ultimately be owned and managed locally, without the need for our support. We also aim to ensure that such partnerships can contribute to our business development, by enabling us to understand better the health needs of, and to build important relationships in, markets of the future.

Our current partnerships are primarily focused on helping hard-hit communities in Asia and Africa to combat TB, which is on the increase in these regions, but we also have some programmes in other disease areas and in other countries.

Our long-standing partnership with the British Red Cross and Red Crescent Societies includes support to community-based programmes in Central Asia that are helping to combat TB and to improve the quality of life of people living with TB and TB/HIV co-infection in the hard-hit areas of Turkmenistan, Kyrgyzstan and Kazakhstan. To date, these programmes have helped over 10,000 people living with TB or TB/HIV to complete their TB treatment, with treatment completion rates reaching 89%, 92% and 73% in Turkmenistan, Kyrgyzstan and Kazakhstan, respectively, Alongside this, the Red Crescent Society has delivered TB awareness campaigns that have reached over two million people in the region. The long-term presence of the Red Crescent Society in Central Asia has enabled the organisation to build effective and far reaching community programmes. These activities continue to contribute to a reduction in TB incidence and mortality in Central Asia.

Our partnership with the African Medical and Research Foundation is focused on developing a model for the integrated management of TB, HIV/AIDS and malaria at both national and local levels in Uganda, where there is a high incidence of all three diseases. This integrated management approach has not been widely addressed previously and we are one of the few organisations involved in such work. A pilot programme is now underway in the high incidence areas of the Luwero and Kiboga districts of central Uganda. Key targets include increasing laboratory diagnostic capacity and improving community-based healthcare management. Progress to date includes the completion and handover to local district management teams of three new laboratories and the establishment of 144 village health teams, with a total of over 750 people trained in health promotion in their local communities.

In Ethiopia, our partnership with Axios is focused on building local capability in managing breast cancer, which is the second most common cancer among young women in that country. The project has focused on strengthening diagnosis and treatment capabilities, including the creation of previously unavailable treatment protocols and standardised reporting guidelines for use across the country. Benefits to the patient have included reduced time between diagnosis and surgery (from 12-18 months in 2006 to three to six months in 2009).

Our support to Voluntary Service Overseas (VSO) includes working in partnership to help them further develop their strategy and framework for delivering their health goals. We also fund VSO volunteers working to build local healthcare capabilities in underserved communities across Africa and Asia. Alongside this, our employees are able to volunteer for placements in appropriate countries to support VSO, drawing on the broad range of skills they can offer in human resources, finance, information technology and communications, as well as health and medicine.

More information about these partnerships and our other activities worldwide is available on our website, astrazeneca.com/responsibility.

### **Engaging at international level**

As part of our focus on TB, we actively engage in international efforts to help in the fight against this devastating disease.

AstraZeneca participates in the Gates Global Health CEO Roundtable, the purpose of which is to bring together the world's leading pharmaceutical companies with the Bill & Melinda Gates Foundation to leverage our respective areas of strength and expertise in the pursuit of global health priorities. We will continue to partner with the Bill & Melinda Gates Foundation on TB in a variety of projects spanning early phase drug discovery through to development of suitable regulatory pathways for new agents.

During 2009, we also continued our involvement with the Stop TB Partnership, which aims to forge a more effective response to TB, and strengthen strategic impact, by engaging a broad range of stakeholders, including the private sector, foundations, academic and research institutions, the media, NGOs and civil society.

AstraZeneca is the only major pharmaceutical company involved in the New Medicines for TB project, begun in 2006. Funded by a grant from the EU Framework VI programme and consisting of around 15 groups of Europe's most prominent scientists and researchers in the field, this consortium seeks to combine academic and pharmaceutical skills to further the discovery of new therapies for TB.

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# **Risk**

In this section we describe our key risk management and assurance mechanisms, and the principal risks and uncertainties which we currently consider to be material to our business in that they may have a significant effect on our financial condition, results of operations and/or reputation. Specific risks and uncertainties are also discussed at various points in this Directors' Report, where relevant.

# Managing risk

As a global, innovation-driven biopharmaceutical company, we face a diverse range of risks and uncertainties that may adversely affect our business. Our approach to risk management is designed to encourage clear decision-making as to which risks we accept and which risks we manage to an acceptable level, in each case informed by an understanding of the commercial, financial, compliance and reputational implications of these risks.

We work continuously to ensure that we have effective risk management processes in place to support the delivery of our strategic objectives, the material needs of our stakeholders and our core values. We monitor our business activities and our external and internal environments for new and emerging risks to ensure that these are proactively managed at the appropriate level as they arise.

The Board believes that the processes and accountabilities which are in place (and described below in further detail) provide it with adequate information on the key risks and uncertainties facing the business. Further information about the risks and uncertainties facing the business are set out in the Principal risks and uncertainties section from page 80.

#### **Embedded in business processes**

We strive to ensure sound risk management is embedded within our business and performance management processes.

Annually, the Group develops a long-term business plan to support the delivery of its strategy. Each area for which a SET member is responsible (SET function) is required to provide a comprehensive assessment of its risks as part of the annual business planning process. The CEO and the CFO undertake quarterly business reviews (QBRs) in respect of each SET function at which the key risks relating to the relevant SET function are reviewed. Underpinning this review, the managers of the key areas within each SET function are required, prior to the QBRs, to provide quarterly updates on their key risks which are then consolidated into the relevant SET function list of key risks for review at the QBRs. The top 10 risks of each SET function are then aggregated into a Group risk register. The purpose of the risk review is threefold: (i) to identify and measure risks; (ii) to define and review plans to mitigate risks we do not wish to take; and (iii) to define and review plans to manage those risks we do wish to take. A risk management standard, guidelines and supporting tools are in place to support the managers in the effective identification, management, mitigation and reporting of risks.

Our approach to risk management includes the development of business resilience plans to provide for situations where specific risks have the potential to severely impact our business. Global business resilience plans covering crisis management, business continuity and emergency responses are in place, supported by the training of relevant business managers and crisis simulation activities.

One of our strategic priorities, 'Promote a culture of responsibility and accountability', involves the continued nurturing of a culture of responsibility and accountability. Our Code of Conduct and our Global Policies and Standards set mandatory minimum standards of responsible behaviour for all employees. In addition, all employees receive annual training on the requirements of our Code of Conduct, as well as more specific targeted training on particular policies and standards. Employees are encouraged to raise questions on the practical application of these standards and to report suspected breaches and incidents of non-compliance through the reporting channels described in our Code of Conduct. During 2009, we developed and launched a combined Compliance and Corporate Responsibility (CR) 'Responsible Business' scorecard with defined objectives and accountabilities, to track performance consistently across all SET functions and enable quarterly reporting to the SET. the Audit Committee and Professor Dame Nancy Rothwell (the Non-Executive Director responsible for overseeing CR within the Group), as well as annual reporting to the Board and the SET.

### Key responsibilities Management of risk

Day-to-day management of risk is delegated from the Board to the CEO and through the SET to line managers. SET management areas are accountable for establishing an appropriate line management-led process and for providing the resources for supporting effective risk management. Line and project management are accountable for the management of risk within the context of their functional or crossfunctional remit or project. Line managers have primary responsibility for identifying and managing risk and for putting in place appropriate controls and procedures to monitor their effectiveness.

# Oversight and monitoring

The Board is responsible for overseeing and monitoring the effectiveness of the risk management processes implemented by management. Specialist risk and compliance functions (including Group Internal Audit (GIA)) support the Board by providing advice and monitoring and testing the adequacy of the processes.

Our compliance organisation comprises a wide range of specialist groups whose work includes liaising with line management and the SET to develop systems and processes for managing risk in specific regulated areas to ensure ongoing legal and regulatory compliance. These groups include: Good Laboratory; Clinical and Manufacturing Compliance; Safety, Health and Environment; Medical and Regulatory Affairs; Financial Control and Compliance; Information Security and Data Privacy; Sales and Marketing Compliance; and Security.

We have a dedicated Global CR team who are part of the Group Public Affairs function and whose work includes public policy and reputation management. The Global CR team leads the development of our CR strategy and the alignment of tactical delivery. The team works closely with senior leaders across AstraZeneca, and with our Global Compliance function, to ensure that the CR risks and opportunities are identified and managed appropriately, in line with business objectives, and to ensure compliance with all relevant policies and standards inclusive of the 16 Principles of our Code of Conduct. Identified risks are mapped to AstraZeneca's risk 'taxonomy', which provides a structured disaggregation of the potential strategic, operational, control/compliance and reputational risks facing AstraZeneca.

#### Management reporting and assurance

The Audit Committee is a Committee of the Board currently comprising five Non-Executive Directors and is accountable, amongst other things, for assessing the adequacy and effectiveness of the risk management systems and processes implemented by management. In addition to the reports it receives from the GIA function, the Audit Committee also regularly receives reports from: (i) the Global Compliance function (including quarterly reports addressing key compliance risks, performance against the 'Responsible Business' scorecard, compliance incidents and updates on key compliance initiatives); (ii) the Financial Control and Compliance Group; (iii) the external auditor; and (iv) management (including the performance management and monitoring processes and a Group-level risk summary from the annual business planning process and the QBRs), on a range of financial reporting, risk, governance, compliance and business areas. Amongst other things, the Audit Committee reviews and reports to the Board at each Board meeting on the overall framework of risk management and internal controls and is responsible for promptly bringing to the Board's attention any significant concerns about the conduct, results or outcome of internal audits. The Audit Committee also regularly receives reports relating to calls made by employees to the AZethics and MedImmune helplines. For further information on the Audit Committee see the Audit Committee section from page 94.

GIA is an independent assurance and advisory function that reports to and is accountable to the Audit Committee. GIA's budget, resources and programme of audits are approved by the Audit Committee on an annual basis and the findings from its audit work are reported to and are discussed at each meeting of the Audit Committee. A core part of the audit work carried out by GIA includes assessing the effectiveness of selected aspects of AstraZeneca's risk control framework, including the effectiveness of other assurance and compliance functions within the business. During 2009, GIA assessed the effectiveness of a number of core compliance and operational processes operating within the business as well as the effectiveness of risk mitigation plans in a number of high risk and/ or business critical areas.

### Principal risks and uncertainties

The pharmaceutical sector is inherently risky and a variety of risks and uncertainties may affect our business. Here we summarise, under the headings Product pipeline risks; Commercialisation and business execution risks; Supply chain and delivery risks; Legal, regulatory and compliance risks; and Economic and financial risks, the principal risks and uncertainties which we currently consider to be material to our business in that they may have a significant effect on our financial condition, results of operations and/ or reputation. These risks are not listed in any assumed order of priority. Other risks, unknown or not currently considered material, could have a similar effect. We believe that

the forward-looking statements about AstraZeneca in this Annual Report, identified by words such as 'anticipates', 'believes', 'expects' and 'intends', are based on reasonable assumptions. However, forward-looking statements involve inherent risks and uncertainties such as those summarised below because they relate to events and depend upon circumstances that will occur in the future, and may be influenced by factors beyond our control and/or may have actual outcomes materially different from our expectations.

# **Product pipeline risks** Failure to meet development targets

The development of any pharmaceutical product candidate is a complex, risky and time-intensive process involving significant financial, R&D and other resources, which may fail at any stage of the process due to a number of factors, including:

- > Failure to obtain the required regulatory or marketing approvals for the product candidate or the facilities in which it is manufactured.
- > Unfavourable data from key studies.
- > Adverse reactions to the product
- candidate or indications of other safety concerns.
- > Failure of R&D to develop new product candidates.
- Failure to demonstrate adequately cost-effective benefits to regulators.
- > The emergence of competing products.

A succession of negative drug project results and a failure to reduce development timelines effectively could adversely affect the reputation of our R&D capabilities. Furthermore, the failure of R&D to yield new products that achieve commercial success is likely to have a material adverse effect on our financial condition and results of operations.

Production and release schedules for biologics may be more significantly impacted by regulatory processes than other products due to more complex and stringent regulation on biologics development, marketing and manufacturing. In addition, various legislative and regulatory authorities are considering whether an abbreviated approval process is appropriate for biosimilars or follow-on biologics (similar versions of existing biologics). While it is uncertain when, or if, any such process may be adopted or how it would relate to intellectual property rights in connection with pipeline biologics, any such process could have a material adverse effect on the future commercial prospects for patented biologics.

# Difficulties of obtaining and maintaining regulatory approvals for new products

We are subject to strict controls on the manufacture, labelling, distribution and marketing of our pharmaceutical products. The requirements to obtain regulatory approval based on a product's safety, efficacy and quality before it can be marketed for a specified therapeutic indication or indications in a particular country, and to maintain and to comply with licences and other regulations relating to its manufacture, are particularly important. The submission of an application to regulatory authorities (which are different, with different requirements, in each region or country) may or may not lead to approval to market the product. Regulators can refuse to grant approval or may require additional data before approval is given, even though the medicine may already be launched in other parts of the world. The countries that constitute key markets for our pharmaceutical products include the US, the countries of the EU and Japan. The approval of a product is required by the relevant regulatory authority in each country, although a single pan-EU marketing authorisation approval can be obtained through a centralised procedure.

In recent years, companies sponsoring new drug applications and regulatory authorities have been under increased public pressure to apply more conservative benefit/risk criteria before a pharmaceutical product is approved. In addition, third party interpretation of publicly available data on our marketed products has the potential to influence the approval status or labelling of a currently approved and marketed product. Further, predicting when a product will be approved for marketing remains challenging. For example, a review of the FDA performance data indicates that for NDAs approved in 2008, the average review time (ie the time from submission to approval) increased from 2007, in part due to the FDA failing to meet the review time targets for NDAs specified under the Prescription Drug User Fee Act IV and the final 2009 data, once available, is expected to continue this trend. Delays in regulatory reviews could impact the timing of a new product launch. For example, the approval of motavizumab and the additional indications for Symbicort and Seroquel XR have been delayed by Complete Response Letters which requested further information in relation to the biologics licence application for motavizumab and the sNDAs for Symbicort and Seroquel XR.

#### Failure to obtain patent protection

Our policy is to protect our investment in R&D by applying for appropriate intellectual property protection in respect of our inventions and innovations; this is a key business priority. Our ability to obtain patents and other proprietary rights in relation to our products is, therefore, an important element of our ability to create long-term value for the business.

Many of the countries in which we operate are still developing their patent laws for pharmaceuticals and there is more uncertainty regarding the patent protection available now and in the foreseeable future in these countries than in countries with well developed intellectual property regimes. In addition, certain countries may seek to limit protection for existing patents - see the Patent litigation and early loss of intellectual property rights section on page 82. Limitations on the availability of patent protection in certain countries in which we operate could have a material adverse effect on the pricing and sales of our products and, consequently, could materially adversely affect our revenues from them. More information about protecting our intellectual property is contained in the Intellectual property section on page 31.

#### Delay to new product launches

Our continued success depends on the development and successful launch of innovative new drugs. The anticipated launch dates of major new products have a significant impact on a number of areas of our business, including investment in large clinical studies, the manufacture of pre-launch stocks of the products, investment in marketing materials ahead of a product launch, sales force training and the timing of anticipated future revenue streams from commercial sales of new products. These launch dates are primarily driven by the development programmes that we run and the demands of the regulatory authorities in the approvals process, as well as pricing negotiation in some countries. Delays to anticipated launch dates can result from a number of factors including adverse findings in pre-clinical or clinical studies, regulatory demands, competitor activity and technology transfer. Significant delays to anticipated launch dates of new products could have a material adverse effect on our financial condition and results of operations. For example, for the launch of products that are seasonal in nature. delays for regulatory approval or manufacturing difficulties can have the effect of delaying launch to the next season which, in turn, may significantly reduce the return on costs incurred in preparing for the launch for that season. In addition, a delay in the launch may give rise to increased costs if, for example, marketing and sales efforts need to be rescheduled or protracted for longer than expected.

# Strategic alliances formed as part of our externalisation strategy may be unsuccessful

We seek technology licensing arrangements and strategic collaborations to expand our product portfolio and geographical presence as part of our business strategy. Examples of such recent strategic arrangements and collaborations include:

- In conjunction with our agreement to acquire Novexel (subject to expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act), an agreement with Forest to co-develop and co-commercialise ceftazidime and ceftaroline, next generation anti-infectives
- > Worldwide licensing agreement with Nektar granting AstraZeneca rights to a late-stage product for the treatment of opioid-induced constipation together with rights to an early programme to deliver products for the treatment of pain without constipation side effects
- > Collaboration with Merck to investigate a novel combination anti-cancer regimen
- Collaboration with Targacept for the global development and commercialisation of Targacept's late-stage compound TC-5214
- > Agreement with Cancer Research Technology Limited and The Institute of Cancer Research (UK) to discover and develop potential new anti-cancer drugs.

Such licensing arrangements and strategic collaborations are key to enable us to grow and strengthen the business. If we fail to complete these types of collaborative projects in a timely manner, on a cost-effective basis, or at all, we may not realise the expected benefits of any such collaborative projects. The success of such current and future arrangements is largely dependent on the technology and other intellectual property we acquire and the resources, efforts and skills of our partners. There is a risk that these collaborative projects may be unsuccessful. Disputes and difficulties in such relationships may arise, often due to conflicting priorities or conflicts of interest of the parties, which may erode or eliminate the benefits of these alliances if, for example, the agreements are terminated; insufficient financial or other resources are made available to the alliances; intellectual property is negatively impacted; obligations are not performed as expected; controls and commercial limitations are imposed over the marketing and promotion of the collaboration products; or challenges in achieving commercial success of the product are encountered during the development process. Also, under many of our strategic alliances, we make milestone payments well in advance of the commercialisation of the

products, with no assurance that we will recoup these payments. If these types of transactions are unsuccessful, this may have a material adverse effect on our financial condition and results of operations.

Furthermore, we experience strong competition from other pharmaceutical companies in respect of licensing arrangements and strategic collaborations, which means that we may be unsuccessful in establishing some of our intended collaborative projects. If we are unsuccessful in establishing such collaborative projects in the future, this may have a material adverse effect on our financial condition and results of operations.

# Commercialisation and business execution risks Challenges to achieving commercial success of new products

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities, launch stocks and other items. The commercial success of our new medicines is of particular importance to us in order to replace sales lost as and when patent protection ceases. If a new product does not succeed as anticipated or its rate of sales growth is slower than anticipated, there is a risk that the costs incurred in launching it could have a material adverse effect on our financial condition and results of operations. We may ultimately be unable to achieve commercial success for any number of reasons, including:

- > Inability to manufacture sufficient quantities of the product candidate for development or commercialisation activities in a timely and cost-efficient manner
- > Excessive costs of, or difficulty in, manufacturing
- > Erosion of patent term and other intellectual property rights, and infringement of those rights and the intellectual property rights owned by third parties
- > Failure to show value or a differentiated profile for our products.

As a result, we cannot be certain that compounds currently under development will achieve success.

In addition, the methods of distributing and marketing biologics could have a material impact on the revenue we are able to generate from the sales of products such as *Synagis* and *FluMist*. The commercialisation of biologics is often more complex than for traditional pharmaceutical products. This is primarily due to differences in the mode of administration, the technical aspects of the product, and the rapidly changing distribution and reimbursement environments.

#### Performance of new products

Although we carry out numerous and extensive clinical studies on all our products before they are launched, for a new product it can be difficult, for a period following its launch, to establish from available data a complete assessment of its eventual efficacy and/or safety in broader clinical use on the market. Due to the relatively short time that a product has been tested and the relatively small number of patients who have taken the product in clinical studies, the available data may be immature. Simple extrapolation of the data may not be accurate and could lead to a misleading interpretation of the likely future commercial performance of a new product.

### Product counterfeiting

Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient (API) or no API at all. Counterfeit medicines are a danger to patients in all parts of the world. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of WHO estimates that up to 30% of medicines in emerging economies are counterfeit, a percentage which is exceeded in parts of Latin America, Asia and Africa. By contrast, in established economies with effective regulatory systems, counterfeit medicines represent less than 1% of the market by market value. Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting could materially adversely affect our reputation and financial performance. In addition, undue or misplaced concern about the issue might induce some patients to stop taking their medicines, with consequential risks to their health.

# Developing our business in emerging markets

The development of our business in emerging markets may be a critical factor in determining our future ability to sustain or increase the level of our global product revenues. Challenges that arise in relation to the development of the business in emerging markets include more volatile economic conditions, competition from companies that are already present in the market, the need to identify correctly and to leverage appropriate opportunities for sales and marketing, poor protection of intellectual property, inadequate protection against crime (including counterfeiting, corruption and fraud), inadvertent breaches of local law/regulation, not being able to recruit sufficient personnel with appropriate skills and experience, and interventions by national governments or regulators to restrict access to a market and/or to introduce

adverse price controls. The failure to exploit potential opportunities appropriately in emerging markets may have a material adverse effect on our financial condition and results of operations.

# Expiry of intellectual property rights

Pharmaceutical products, diagnostic and medical devices are normally only protected from competition from copying during the period of protection under patent rights or related intellectual property rights such as Regulatory Data Protection. Following expiry of such rights, the product is generally open to competition from generic copies. Products under patent protection or within the period of Regulatory Data Protection generally generate significantly higher revenues than those not protected by such rights. See the Intellectual property section on page 31 for a table of certain patent expiry dates for our key marketed products.

# Patent litigation and early loss of intellectual property rights

Any of the intellectual property rights protecting our products may be subjected to intellectual property litigation by third parties and/or be affected by validity challenges in patent offices. In either case, however, we expect that the greater number of challenges will be directed to our more valuable products. Despite our efforts to establish and defend robust patent protection for our products, we may not succeed in such challenges to our patents. If we are not successful in maintaining exclusive rights to market one or more of our major products, particularly in the US where we have our highest revenue and margins, our revenue and margins could be materially adversely affected.

In particular, generic drug manufacturers are seeking to market generic versions of many of our more important products prior to the expiry of our patents and Regulatory Exclusivity periods. For example, we are currently facing challenges from multiple generic manufacturers to certain of our patents for Nexium and Crestor, two of our best-selling products in the US, our largest market. If such challenges succeed and generic products are launched, or launched 'at risk' on the expectation that challenges to our intellectual property will be successful, this may have a material adverse effect on our financial condition and results of operations. In 2009, US sales for Nexium and Crestor were \$2,835 million and \$2,100 million, respectively. The more significant patent litigation relating to our products is described in Note 25 to the Financial Statements from page 166.

In addition to patent challenges by generic drug manufacturers seeking to market generic copies of our products, other third parties owning patents, including research-based pharmaceutical companies, may assert their intellectual property rights against our products or activities or processes related to our products. Consequently, there are risks that we may be found to infringe the patents of others, and managing such infringement disputes can be costly. We may be liable for damages or royalties or, alternatively, we may need to obtain costly licences or stop manufacturing, using or selling our products. These risks may be greater in respect of biologics and vaccines where intellectual property protection is sometimes not so clear. In the event of such risks arising we may be able to mitigate them through, for example, acquiring licences or making modifications to cease the infringement and permit commercialisation of our products but there is no certainty that any such action will be possible and any such action may entail significant costs. Details of significant claims that AstraZeneca is infringing third party intellectual property rights can be found in Note 25 to the Financial Statements from page 166.

In addition to the challenges to our patented products from manufacturers of generic or other patented pharmaceutical products, there is a risk that some countries, particularly some of those in the developing world, may seek to impose limitations on the availability of patent protection for pharmaceutical products, or on the extent to which such protection may be obtained and/or enforced, within their jurisdictions. As a result, generic manufacturers in these countries may be increasingly and more easily able to introduce competing products to the market earlier than they would have been able to had more robust patent protection been available.

Combined with patent protection and Regulatory Exclusivities, products protected by a valid trade mark usually generate higher revenues than those without a trade mark. We believe that we have robust trade mark protection for our products but cannot be certain that we would be able to defend any challenge successfully.

# Expiry or earlier loss of patents covering competing products

The expiry or earlier loss of patents covering others' innovator products may lead to the availability of generic products in the same product class as our currently patented products earlier than anticipated. Such events could have a material adverse effect on our

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financial condition and results of operations. For example, the loss/expiry of patent rights covering major products in the US, such as Lipitor<sup>™</sup> or Advair Diskus<sup>™</sup> before 2012 may adversely affect the growth of our still-patented products in the same product class (ie *Crestor* and *Symbicort*) in that market.

# Competition, price controls and price reductions

All our products compete directly with other products marketed either by major researchbased pharmaceutical companies or by generic pharmaceutical manufacturers. These competitors may invest greater resources in the marketing of their products than we do depending on the relative priority of these competitor products within their company's portfolio. Generic versions of products are often sold at lower prices than branded products because they do not have to recoup the significant cost of R&D investment. Also, generic pharmaceutical companies do not generally invest the same amounts in education services for healthcare professionals as research-based pharmaceutical companies, so the sales of their generic products do not need to cover these costs. Industry consolidation has resulted in a small number of very large companies, some of which have acquired generic businesses. This trend, if it continues, could materially adversely affect our competitive position, whilst consolidation among our customers may increase price pressures. All our patented products, including Nexium, Crestor, Seroquel and Symbicort, are subject to price pressure from competition from generic products in the same product class.

In most of our key markets there is continued economic, regulatory and political pressure to limit or reduce the cost of pharmaceutical products. A summary of the principal aspects of price regulation and how price pressures are affecting our business in our most important markets is set out in the Geographical Review from page 50.

In the US realised prices are being depressed through the use of a range of cost-control tools, such as restricted lists, or formularies, employing generic first strategies, and requiring physicians to obtain prior approval for the use of a branded medicine. These mechanisms put pressure on manufacturers to reduce prices and to limit access to branded products. Many of these mechanisms shift a greater proportion of the cost of medicines onto the individual via out-ofpocket payments at the pharmacy counter. The patient out-of-pocket spend is generally in the form of a co-payment or in some cases a co-insurance, which is designed, amongst other reasons, to encourage patients to use generic medicines. Many of these management tools are also employed by institutional customers in response to the current cost-containment environment and these increasingly restrictive reimbursement policies could have a material adverse effect on our financial condition and results of operations.

In the US, new legislation is possible that may allow the commercial importation of drugs into the US from selected countries. The adoption of such legislation could result in an increase in the volume of cross-border product movements which could have a material adverse effect on our financial condition and results of operations.

The US House of Representatives and Senate have passed their respective healthcare reform bills. However, Republican Scott Brown's upset Senate race win, in Massachusetts, has dramatically altered the course of health reform negotiations by ending the Democrats' filibuster-proof 60 vote majority in the US Senate. Democratic leaders insist they plan to press ahead with health reform, while continuing to debate the best way to proceed.

Certain aspects of comprehensive health reform would cause a significant change in the US pharmaceutical market, for example through mandating higher rebates and discounts on branded drugs for certain Medicare and Medicaid patients, increased financial obligations through other federal payer programmes and an industry-wide excise tax. These and other changes, such as whether further cost-containment measures would need to be incorporated in the final bill to finance the reform of the US healthcare system, could have a material adverse effect on our results of operations and financial condition.

In the EU, efforts by the European Commission to reduce inconsistencies and to improve standards and best practice in the disparate national regulatory systems have met with little immediate success. The industry is, therefore, exposed to greater application of reference pricing mechanisms and *ad hoc* national cost-containment measures on prices. This can lead to marked price differentials between countries and the consequent cross-border movement of products. The importation of pharmaceutical products from countries where prices are low due to government price controls or other market dynamics, to countries where prices for those products are higher, may increase.

We expect that pressures on pricing will continue and may increase. Due to these pressures, there can be no certainty that we will be able to charge prices for a product that, in a particular country or in the aggregate, enable us to earn an adequate return on our investment in that product.

# Any expected gains from productivity initiatives are uncertain

We are implementing various productivity initiatives and restructuring programmes, with the aim of enhancing the long-term efficiency of the business. However, the anticipated cost savings and other benefits are based on preliminary estimates and the actual savings may vary significantly. In particular, these cost reduction measures are based on current conditions and do not take into account any future changes to the pharmaceutical industry or our operations, including new business developments, wage and price increases and other factors. If inappropriately managed, the expected value of the initiative can be lost through low employee morale and hence productivity, increased absence levels and industrial action. Our failure to successfully implement these planned cost reduction measures, either through the successful conclusion of employee relations processes (including consultation and engagement, talent management and recruitment and retention), or the possibility that these efforts do not generate the level of cost savings we anticipate, could have a material adverse effect on our results of operations and financial condition. See the People section from page 33 for information about mitigating the risk of significant business change.

#### Acquisitions may be unsuccessful

The Group seeks to acquire complementary businesses as part of its business strategy. The integration of an acquired business could involve incurring significant debt and unknown or contingent liabilities, as well as having a negative effect on our reported results of operations from acquisition-related charges, amortisation of expenses related to intangibles and charges for impairment of long-term assets. These effects, individually or in combination, could cause a deterioration in our credit rating and/or increased borrowing costs and interest expense. We could also experience difficulties in integrating geographically separated organisations, systems and facilities, and personnel with different organisational cultures. Integration of an acquired business may also divert management resources that would otherwise be available for the continuing development of our existing business. The integration

process may result in business disruption, the loss of key employees, slower execution of various work processes, compliance failures due to a change in applicable regulatory requirements and other issues such as a failure to integrate information technology and other systems. In addition, if liabilities are uncovered in an acquired business, the Group may suffer losses and may not have remedies against the seller or third parties.

### Failure to manage a crisis

We handle chemical and biological materials, operate research and manufacturing plants and distribute products worldwide. Major disruption to our business and damage to our reputation may be triggered by an operational incident or by actions by our employees or third parties. In these circumstances, a plan for addressing operational and other issues should ensure a timely response and the ability to resume business as usual. Failure to institute proper communication to internal and external stakeholders and to mobilise a rapid operational response could have a material adverse effect on our financial condition and results of operations. Further information about our business resilience plans and processes are contained in the Managing risk section from page 79.

### Failure of information technology

We are dependent on effective IT systems. These systems support key business functions such as our R&D, manufacturing and sales capabilities, and are an important means of internal and external communication. Any significant disruption of these IT systems or failure to integrate new and existing IT systems could have a material adverse effect on our financial condition and results of operations.

#### Failure of outsourcing

We have outsourced a number of business critical operations to third party providers. Failure of the outsource provider to deliver services in a timely manner and to the required level of quality could have an adverse impact on our ability to meet business targets and maintain a good reputation within the industry and with stakeholders. It may also result in non-compliance with applicable laws and regulations. Failure to adequately manage the risk associated with outsourcing could have a material adverse effect on our financial condition and results of operations.

# Supply chain and delivery risks Manufacturing biologics

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms and facilities specifically designed and validated for this purpose, with sophisticated quality assurance and control procedures. Slight deviations in any part of the manufacturing process may result in lot failure, product recalls or spoilage, for example due to contamination.

# Reliance on third parties for goods and services

Like most, if not all, major research-based pharmaceutical companies we increasingly rely on third parties for the timely supply of goods, such as specified raw materials, equipment, formulated drugs and packaging, and services, all of which are key to our operations.

However, events beyond our control could result in the failure of supplies of goods and services, which could have a material adverse effect on our financial condition and results of operations. For example, suppliers of some of the key goods and services we rely upon may cease to trade. The consequence of this may be significant delays and/or difficulties in obtaining goods and services on commercially acceptable terms, or even at all.

In addition, we may have limited access to and/or supply of biological materials, such as cells, animal products or by-products. Furthermore, government regulations in multiple jurisdictions could result in restricted access to, use or transport of such materials. Loss of access to sufficient sources of such materials, or tighter restrictions on the use of such materials may interrupt or prevent our research activities as planned and/or increase our costs. We seek to mitigate these risks as described in the Managing sourcing risk section on page 33. We actively manage these third party relationships to ensure continuity of supplies on time and to our required specifications. Recently, we have established sourcing centres in China and India to identify high quality suppliers in those regions. Further information is contained in the Managing sourcing risk section on page 33.

# Legal, regulatory and compliance risks Adverse outcome of litigation and/or governmental investigations

We may be subject to any number of legal proceedings and/or governmental investigations. Note 25 to the Financial Statements includes information about material legal proceedings in which we are currently involved. Such investigations or legal proceedings, regardless of their outcome, could be costly, divert management attention, or damage our reputation and demand for our products.

Litigation, particularly in the US, is inherently unpredictable, and unexpectedly high awards of damages can result if AstraZeneca receives an adverse verdict. In many cases, particularly in the US, the practice of the plaintiff bar is to claim damages - compensatory, punitive and statutory - in extremely high amounts. Accordingly, it is difficult to quantify the potential exposure to claims in proceedings of the type referred to in Note 25 to the Financial Statements. Unfavourable resolution of current and similar future proceedings could have a material adverse effect on our financial condition and results of operations, particularly where such circumstances are not covered by insurance. We may become subject to fines, penalties and other monetary and/or non-monetary sanctions and/or may be required to make significant provisions in our accounts related to legal proceedings and/or governmental investigations, which would reduce earnings.

# Legal proceedings regarding business practices

The marketing, promotional, clinical and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers, prescribers, and patients, are subject to extensive regulation and litigation. Many companies, including AstraZeneca, have been subject to claims related to these practices asserted by federal and state governmental authorities and private payers and consumers. These have resulted in substantial expense and other significant consequences to AstraZeneca. For example, see Note 25 to the Financial Statements for a discussion of litigation and investigations regarding US sales and marketing practices, as well as pricing litigation. It is possible that additional such claims could be made in the future. As a general matter, these types of claims can result in criminal liability, fines, penalties, or other monetary or non-monetary remedies.

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#### Substantial product liability claims

Given the widespread impact that prescription drugs may have on the health of large patient populations, pharmaceutical, biopharmaceutical and medical device companies have, historically, been subject to large product liability damages claims, settlements and awards for injuries allegedly caused by the use of their products. Adverse publicity relating to the safety of a product or of other competing products may increase the risk of product liability claims. Substantial product liability claims that result in court decisions against us or in the settlement of proceedings could have a material adverse effect on our financial condition and results of operations, particularly where such circumstances are not covered by insurance. We are currently subject to extensive product liability litigation in relation to Seroquel, and further details about this are set out in Note 25 to the Financial Statements. Information about our approach to patient safety is set out in the Patient safety section from page 20.

# Failure to adhere to applicable laws, rules and regulations

We operate globally in complex legal and regulatory environments. Any failure to comply with applicable laws, rules and regulations in these jurisdictions may result in civil and/or criminal legal proceedings being filed against us, or in us becoming subject to regulatory sanctions, which could have a material adverse effect on the conduct of our business, our financial condition and results of operations. Regulatory authorities have wide-ranging administrative powers to deal with any failure to comply with continuing regulatory oversight (and this could affect us, whether such failure is our own or that of third parties with whom we have relationships). As these laws, rules and regulations change or as governmental interpretation of those laws, rules and regulations evolves, prior conduct may no longer be sufficient to ensure ongoing compliance.

For example, once a product has been approved for marketing by regulatory authorities, it is subject to continuing control and regulation, such as the manner of its manufacture, distribution, marketing and safety surveillance. In addition, any amendments that are made to the manufacturing, distribution, marketing and safety surveillance processes of our products may require additional regulatory approvals, which could result in significant additional costs and/or disruption to these processes. Such amendments may be imposed on us as a result of the continuing inspections to which we are subject or that may be made at our discretion. It is possible, for example, that regulatory issues concerning compliance with current Good Manufacturing Practice (cGMP) regulations for pharmaceutical products could arise and lead to product recalls and seizures, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the cGMP issues.

# Environmental/occupational health and safety liabilities

We have environmental and/or occupational health and safety related liabilities at some currently or formerly owned, leased and third party sites, the most significant of which are detailed in Note 25 to the Financial Statements. These liabilities are carefully managed by designated technical, legal and business personnel and there is no reason for us to believe that associated current and expected expenditure and/or risks are likely to have a material adverse effect on our financial condition and results of operations as a general matter, but, to the extent that they exceed applicable provisions, they could have a material adverse effect on our financial condition and results of operations for the relevant period. In addition, a change in circumstances (including a change in applicable laws or regulations) may result in such an effect.

A significant non-compliance issue or other environmental or occupational health or safety incident for which we were responsible could result in us being liable to pay compensation, fines or remediation costs. In some circumstances, such liability could have a material adverse effect on our financial condition and results of operations. In addition, our financial provisions for any obligations that we may have relating to environmental or occupational health and safety liabilities may be insufficient if the assumptions underlying the provisions, including our assumptions regarding the portion of waste at a site for which we are responsible, prove incorrect, or if we are held responsible for additional contamination or occupational health and safety related claims.

# **Economic and financial risks** Adverse impact of a sustained economic downturn

A variety of significant risks may arise from a sustained global economic downturn, including those referred to here. Additional pressure from governments and other healthcare payers on medicine prices and volumes of sales in response to recessionary pressures on budgets may cause a slowdown or a decline in growth in some markets. In addition, the Group's customers may cease to trade, which in turn may result in losses from writing-off debts. Further, we are highly dependent on being able to access a sustainable flow of liquid funds due to the high fixed costs of operating a global research-based pharmaceuticals business and the long and uncertain development cycles for our products. In a sustained and/or severe economic downturn, financial institutions that hold our cash and other short-term deposits may cease to trade and there can be no guarantee that we will be able to access our assets without a protracted, expensive and uncertain process, if at all, Although we have adopted conservative cash management and treasury policies to mitigate this risk (further information on which is contained in the Financial risk management policies section on page 44) we cannot be certain that these will be completely effective should a number of major financial institutions cease to trade. Additionally, if we need access to external sources of financing to sustain and/or grow our business, such as the debt or equity capital financial markets, this may not be available on commercially acceptable terms, if at all, in the event of a severe and/or sustained economic downturn. This may particularly be the case in the event of any default by the Group on its debt obligations, which may have materially adverse consequences on our ability to secure debt funding in the future or generally on our financial condition. Further information on debt-funding arrangements is contained in the Financial risk management policies section on page 44.

#### Impact of fluctuations in exchange rates

As a global business, currency fluctuations can significantly affect our results of operations, which are accounted for in US dollars. Approximately 49% of our global 2009 sales were in North America with a significant proportion of that figure being in respect of US sales, which is expected to remain our largest single market for the foreseeable future. Sales in other countries are predominantly in currencies other than the US dollar, including the euro, Japanese yen, Australian dollar and Canadian dollar. We also have a growing exposure to emerging market currencies, although the exchange rates of some of these currencies are linked to the US dollar. Major components of our cost base are located in the UK and Sweden, where an aggregate of approximately 30% of our employees are based. Movements in the exchange rates used to translate foreign currencies into US dollars may, therefore, have a material adverse effect on our financial condition and results of operations. Additionally, some of our subsidiaries import and export goods and services in currencies other than their own functional currency and so the results of such subsidiaries could be affected by currency fluctuations arising between the transaction dates and the settlement dates for these transactions. Further information is contained in Note 15 to the Financial Statements from page 144.

# Credit and return on substantial investments

As part of its normal operations, the Group will hold significant cash balances. The amount of cash held at any point reflects the level of cash flow generated by the business and the timing of the use of that cash. The majority of excess cash is centralised within the Group treasury function for investment and as such is subject to counterparty risk on the principal invested. See the Financial risk management policies section on page 44 for details of how the Group seeks to mitigate this risk.

#### Limited third party insurance coverage

Recent insurance loss experience in the pharmaceutical industry, including product liability exposures, has increased the cost of, and narrowed the coverage afforded by, pharmaceutical companies' product liability insurance. In order to contain insurance costs in recent years, we have continued to adjust our coverage profile, accepting a greater degree of uninsured exposure. The Group has not held product liability insurance since February 2006. In addition, where claims are made under insurance policies, insurers may reserve the right to deny coverage on various grounds. If such denial of coverage is ultimately upheld, this could result in material additional charges to our earnings. An example of a dispute with insurers relating to the availability of insurance coverage and in relation to which costs incurred by the Group may not ultimately be recovered through such coverage is included in Note 25 to the Financial Statements in the Seroquel – product liability section.

#### Taxation

The integrated nature of our worldwide operations can produce conflicting claims from revenue authorities as to the profits to be taxed in individual territories. The resolution of these disputes can result in a reallocation of profits between jurisdictions and an increase or decrease in related tax costs, and has the potential to affect our cash flows and EPS. Claims, regardless of their merits or their outcome, are costly, divert management attention and may adversely affect our reputation.

The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which enable us to ensure that our revenues and capital gains do not incur a double tax charge. If any of these double tax treaties should be withdrawn or amended, especially in a territory where a member of the Group is involved in a taxation dispute with a tax authority in relation to cross-border transactions, such withdrawal or amendment could have a material adverse effect on our financial condition and results of operations, as could a negative outcome of a tax dispute or a failure by the tax authorities to agree through competent authority proceedings. See the Financial risk management policies section on page 44 for further details of risk mitigation and Note 25 to the Financial Statements for details of current tax disputes.

### Pensions

A particular risk relates to the Group's pension obligations, the single largest of which is the UK Pension Fund. The obligations are backed by assets invested across the broad investment market. Sustained falls in these assets will put a strain on funding which may result in requirements for additional cash, restricting cash available for strategic business growth. Similarly, if the liabilities rise, there will be a strain on funding from the business. The likely increase in the IAS19 accounting deficit generated by any of these may cause the ratings agencies to review our credit rating, with the potential to affect negatively our ability to raise debt. See Note 23 to the Financial Statements from page 156 for further details on the Group's pension obligations.

Corporate Governance

# Business Organisation and Corporate Governance

# **Business organisation**

This section brief y describes how the Group is organised, including the overall structure and principal roles and responsibilities of the Board, its committees and the SET.

# Board composition, processes and responsibilities

The Board comprises two Executive Directors (the CEO and the CFO) and 10 Non-Executive Directors. The membership of the Board at 31 December 2009 and information about individual Directors is contained in the Board of Directors section from page 88.

All Directors are collectively responsible for the success of the Group. In addition, the Non-Executive Directors are responsible for exercising independent, objective judgement in respect of Board decisions and for scrutinising and challenging management. The Non-Executive Directors also have various responsibilities concerning the integrity of financial information, internal controls and risk management.

### **Board of Directors**

Non-Executive Chairman and Non-Executive Directors Chief Executive Officer and other Executive Directors

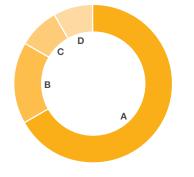
Chief Executive Officer

Senior Executive Team

#### Board Committee

(Audit Committee, Remuneration Committee, Nomination and Governance Committee and Science Committee)

# Balance of Non-Executive Directors and Executive Directors



#### A Independent Non-Executive Directors<sup>1</sup>

B Executive Directors

Gender split

of Directors

A Male

B Female

в

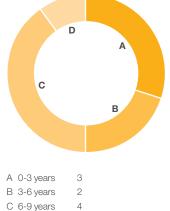
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C Non-Independent Non-Executive Director<sup>1</sup> D Non-Executive Chairman

<sup>1</sup> As determined by the Board in accordance with the Combined Code.





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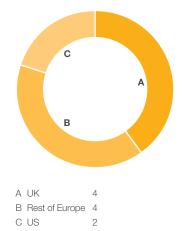
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# Geographical mix of Non-Executive Directors





# **Board of Directors**

at 31 December

#### 01 Louis Schweitzer (67) Non-Executive Chairman, Chairman of the Nomination and Governance Committee and Remuneration Committee Member

Appointed as a Director 11 March 2004 and as Chairman 1 January 2005. Non-Executive Chairman of Renault SA 2005-2009. Chairman and Chief Executive Officer of Renault SA 1992-2005. Non-Executive Director of BNP-Paribas, Veolia Environnement SA (senior Non-Executive Director) and L'Oréal SA. Non-Executive Chairman of Volvo AB and Journal Le Monde SA.

### 02 David Brennan (56)

Executive Director and Chief Executive Officer Appointed as a Director 14 March 2005 and as CEO 1 January 2006. Chairman of the Executive Board of the Pharmaceutical Research and Manufacturers of America (PhRMA). Vice-President of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Board Member of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Commissioner of the UK Commission for Employment and Skills (UKCES). Chairman of the Board of the Southeastern Pennsylvania Chapter of the American Heart Association 2004-2006.

Other officers of the Company at 31 December included members of the SET, as set out in the Senior Executive Team at 31 December section from page 90 and Adrian Kemp, Company Secretary (appointed on 1 January 2009).







#### 03 Simon Lowth (48)

**Executive Director and Chief Financial Officer** Appointed as a Director and as CFO 5 November 2007. Director of Finance and Strategy, Scottish Power plc (ScottishPower) 2005-2007 and Executive Director, Corporate Strategy and Development, ScottishPower 2003-2005. Director – Head of UK Industrial Practice, McKinsey & Company 2000-2003. Effective from 1 May 2010, Non-Executive Director of Standard Chartered PLC.

### 04 Michele Hooper (58) Senior independent Non-Executive Director,

Audit Committee Member and Nomination and Governance Committee Member Appointed as a Director 1 July 2003 and as

senior independent Non-Executive Director 26 April 2007. President and Chief Executive Officer, Directors' Council. President and Chief Executive Officer, Stadtlander Drug Company 1998-1999. Corporate Vice-President and President, International Businesses of Caremark International Inc. 1992-1998. Non-Executive Director of UnitedHealth Group Inc., PPG Industries, Inc. and Warner Music Group, Inc.

#### 05 Bo Angelin (60) Non-Executive Director and Science Committee Member

Appointed as a Director 24 July 2007. Professor of Clinical Metabolism at Karolinska Institutet and Head of the Department of Endocrinology, Metabolism and Diabetes at the Karolinska University Hospital in Stockholm, Sweden. Member of the Nobel Assembly and of the Swedish Royal Academy of Sciences. Member of the Medical Nobel Institute. Prior appointments include Chairman of the Nobel Committee for Physiology and Medicine.

#### 06 John Buchanan (66) Non-Executive Director, Chairman of the Audit Committee and Remuneration Committee Member

Appointed as a Director 25 April 2002. Executive Director and Group Chief Financial Officer of BP p.l.c. 1996-2002. Member of the UK Accounting Standards Board 1997-2001. Senior Independent Director of BHP Billiton Plc. Senior Independent Director and Deputy Chairman of Vodafone Group Plc. Chairman of Smith & Nephew plc. Chairman of International Chamber of Commerce (UK). Member of the Advisory Board of Ondra Bank.

#### 07 Jean-Philippe Courtois (49) Non-Executive Director and Audit Committee Member

Appointed as a Director 18 February 2008. President, Microsoft International and Senior Vice-President, Microsoft Corporation. CEO Microsoft EMEA 2003-2005. President Microsoft EMEA 2000-2003. Corporate Vice-President, Microsoft Worldwide Customer Marketing 1998-2000. Administrator for PlaNet Finance and representative at the Institut Montaigne.

#### 08 Jane Henney (62)

#### Non-Executive Director, Audit Committee Member, Nomination and Governance Committee Member and Science Committee Member

Appointed as a Director 24 September 2001. Currently Professor of Medicine, University of Cincinnati. Prior appointments include: Senior Vice-President and Provost for Health Affairs, University of Cincinnati Academic Health Center; Commissioner of Food and Drugs, FDA; Vice-President for Health Sciences, University of New Mexico; Deputy Commissioner for Operations, FDA; Vice-Chancellor for Health Programs and Policy, University of Kansas; Deputy Director, US National Cancer Institute. Non-Executive Director of AmerisourceBergen Corporation and CIGNA Corporation. Other board appointments include The Commonwealth Fund and China Medical Board.

#### 09 Rudy Markham (63) Non-Executive Director and Audit Committee Member

Appointed as a Director 12 September 2008. Chairman and Non-Executive Director of Moorfields Eye Hospital Foundation Trust. Non-Executive Director of United Parcel Services Inc., Financial Reporting Council, Standard Chartered PLC and Legal & General plc. Non-Executive member of the Board of the UK Foreign and Commonwealth Office. Fellow of the Chartered Institute of Management Accountants and Fellow of the Association of Corporate Treasurers.

#### 10 Dame Nancy Rothwell (54)

#### Non-Executive Director, Chairman of the Science Committee and Remuneration Committee Member

Appointed as a Director 27 April 2006. Also has responsibility for overseeing Corporate Responsibility. MRC Research Professor and Deputy President and Deputy Vice-Chancellor at the University of Manchester. Vice-President and Council member of the Royal Society; President of the Society of Biology. Prior appointments include: Trustee of Cancer Research UK and the Campaign for Medical Progress; Chair of the Research Defence Society; Chair of the Wellcome Trust Public Engagement Strategy Panel; President of the British Neuroscience Association; and Council member of the Medical Research Council and the Biotechnology and Biological Sciences Research Council.

#### 11 John Varley (53)

#### Non-Executive Director, Chairman of the Remuneration Committee and Nomination and Governance Committee Member

Appointed as a Director 26 July 2006. Executive Director of Barclays Bank plc and Barclays plc since 1998 and Group Chief Executive since 2004. Chairman of Business Action on Homelessness and President of the Employers' Forum on Disability and member of the International Advisory Panel of the Monetary Authority of Singapore. Honorary President of the UK Drug Policy Commission. Treasurer and Trustee of St. Dunstan's and Trustee of Thornton Smith & Plevins Young People's Trust.

#### 12 Marcus Wallenberg (53) Non-Executive Director

Appointed as a Director 6 April 1999. Formerly a Director of Astra AB (appointed 18 May 1989). Chairman of Skandinaviska Enskilda Banken AB, Electrolux AB and Saab AB. Vice-Chairman of Telefonaktiebolaget L M Ericsson (publ). Non-Executive Director of Stora Enso Oyj and the Knut and Alice Wallenberg Foundation. Board member of Temasek Holdings (Private) Limited. Honorary Chairman of International Chamber of Commerce.



# Senior Executive Team

at 31 December

#### 01 David Brennan Chief Executive Officer

David was appointed Chief Executive Officer of AstraZeneca in January 2006. From 2001 until then, David was President and Chief Executive Officer of the Company's North American subsidiary.

David began his career in 1975 at Merck, where he started as a sales representative in the US Division and later worked in sales and marketing management in the US and International divisions. He joined Astra Merck in 1992 and helped to build the joint venture into a multi-billion dollar business in the US.

He is an alumnus of Gettysburg College where he studied Business Administration.

For further information on David, see the Board of Directors at 31 December section from page 88.

#### 02 Simon Lowth Chief Financial Officer

Simon joined AstraZeneca as an Executive Director and Chief Financial Officer in November 2007. He was previously at ScottishPower where he was Finance Director. Simon left ScottishPower following completion of the sale to Iberdrola.

His move to ScottishPower followed 15 years' experience with the global management consultancy, McKinsey & Company where he advised leading multinational companies on a wide range of strategic, financial and operational issues.

Simon has an engineering degree from Cambridge University and an MBA from London Business School.

For further information on Simon, see the Board of Directors at 31 December section from page 88.

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#### 03 Bruno Angelici<sup>1</sup>

Executive Vice-President, International Sales and Marketing Organisation (until 31 December)

From 2001 until 31 December 2009, Bruno was responsible for Europe, Japan, Asia Pacific, Latin America, Middle East and Africa. Before this he served as President of AstraZeneca Japan. Bruno originally joined AstraZeneca in 1989 as President of ICI Pharma France. He began his career in the food industry and then joined Baxter Healthcare where he became Managing Director for Baxter in France.

He holds an MBA from the Kellogg School of Management, Chicago, is a member of the Supervisory Board of Wolters Kluwer and is President of the Supervisory Board of Reims Management School. He was received into the Légion d'honneur in December 2009.

Bruno will be leaving AstraZeneca in 2010.

# 04 Anders Ekblom

Executive Vice-President, Development Before he took over responsibility for Global Drug Development, Anders was responsible for Global Clinical Development, the largest single function in R&D, operating across medicine development and life-cycle management. He joined Astra in 1993 from the Karolinska Institute and Karolinska Hospital in Stockholm, where he was a senior lecturer and Director for the Perianesthetic Unit.

Anders is President of AstraZeneca Sverige AB, and Director of Albireo Ltd. He is an Associate Professor of Physiology at the Karolinska Institute, a medical doctor qualified in anaesthesiology and intensive care, and a doctor of dental surgery. He has long been active in both basic and clinical research resulting in over 60 original publications in peer-reviewed journals and book chapters.

#### 05 Christer Köhler Interim Executive Vice-President, Discovery Research

Christer was appointed to his current role in November. He joined Astra in 1979 and held a number of R&D positions before joining Hoffmann-La Roche in Basel, Switzerland in 1992 as Global Head CNS Discovery. He returned to Astra Arcus and became Global Vice-President and Head of CNS & Pain Research in 1999 and has since been a member of the global R&D leadership team.

Christer trained at the University of Bergen Medical School where he also obtained his PhD. He conducted postdoctoral studies in Lausanne, Switzerland and the Salk Institute, San Diego US. He became adjunct Professor of Neurobiology at the University of Bergen in 1984. He has published over 150 scientific papers in different areas of neuroscience and pharmacology.

#### 06 Jeff Pott General Counsel

Jeff was appointed General Counsel from

1 January 2009 and has overall responsibility for all aspects of AstraZeneca's Legal and Intellectual Property function.

He joined AstraZeneca in 1996 and has worked in various litigation roles, where he has had responsibility for intellectual property, anti-trust and product liability litigation. Prior to joining AstraZeneca, Jeff spent five years at US legal firm Drinker Biddle and Reath, where he specialised in pharmaceutical product liability litigation and anti-trust advice and litigation.

Jeff received his bachelor's degree in Political Science from Wheaton College and his Jurus Doctor Degree from Villanova University School of Law.

#### 07 David Smith

# **Executive Vice-President, Operations**

David joined AstraZeneca in 2006 as Executive Vice-President, Operations. He leads AstraZeneca's global manufacturing and supply organisation and is also responsible for the AstraZeneca Group Safety, Health and Environment, Regulatory Compliance, Purchasing and Engineering functions. As of 27 January 2010, David has assumed overall responsibility for Corporate Information Services.

David spent his early career in pharmaceuticals, initially with the Wellcome Foundation in the UK. He subsequently spent nine years in the consumer goods sector working for Estée Lauder in New York and Timberland as Senior Vice-President Global Supply Chain. In 2003, he returned to the pharmaceutical sector and joined Novartis and was based in Switzerland.

#### 08 Lynn Tetrault Executive Vice-President, Human Resources and Corporate Affairs

Lynn was appointed Executive Vice-President, Human Resources and Corporate Affairs in 2007 having already been appointed Vice-President Corporate Affairs. She had previously been Vice-President of Human Resources for Global Drug Development and was Vice-President of Human Resources for the US subsidiary of AstraZeneca following the merger between Astra and Zeneca.

Lynn started her career in private law practice where she specialised in general corporate and healthcare law. She joined Astra USA in 1993 as Associate General Counsel in the company's legal department.

Lynn received her bachelor's degree from Princeton University and her law degree from the University of Virginia Law School.

#### 09 Tony Zook<sup>1</sup>

#### Chief Executive Officer, North America, President, MedImmune and Executive Vice-President, Commercial Operations

Tony has responsibility for our worldwide sales and marketing activities, including Global Marketing. He took up this newly created post on 1 January 2010 in addition to his continuing responsibilities as Executive Vice-President, North America and President of MedImmune. He joined Astra USA in 1997 as Vice-President, Marketing and Sales, having begun his pharmaceutical career at Berlex Laboratories.

Tony earned a bachelor's degree in biology from Frostburg University, and an associate's degree in chemical engineering from Pennsylvania State University. He is a member of the board for First State Innovation, the Pennsylvania Division of the American Cancer Society and is a member of the Board of Trustees for the Healthcare Leadership Council.

<sup>1</sup>Changes affecting the positions of Bruno Angelici and Tony Zook in 2010 are described in the Reserved matters and delegation of authority section on page 92.

# Reserved matters and delegation of authority

The Board maintains and regularly reviews a full list of matters and decisions that are reserved to, and can only be approved by, the Board. These include the appointment, termination and remuneration of any Director; the annual budget; any item of fixed capital expenditure or any proposal for the acquisition or disposal of an investment or business which exceeds \$150 million; raising of capital or loans by the Company (subject to certain exceptions); any guarantee in respect of any borrowing of the Company; and allotting shares of the Company. The matters that have not been expressly reserved to the Board are either delegated by the Board to its committees or to the CEO.

The CEO is responsible to the Board for the management, development and performance of the Group's business in relation to those matters in respect of which he has been delegated authority from the Board. In exercising his authority, the CEO acts with the primary aim of enhancing long-term shareholder value and within the framework of the Group's policies and routine reporting requirements.

Although the CEO retains full responsibility for the authority delegated to him by the Board, the CEO has established and chairs the SET (pictured in the Board of Directors at 31 December section from page 88), which is the vehicle through which he exercises certain of that authority in respect of the Group's business. The SET normally meets once a month to consider and decide major business issues. Typically, it also reviews, in advance of submission to the Board, those matters that are to be submitted to the Board for review and decision.

In November, Jan Lundberg, Executive Vice-President, Discovery Research resigned to take up a position at another company. He left the Company on 31 December. On 13 November, Christer Köhler was appointed Interim Executive Vice-President, Discovery Research.

Bruno Angelici completed his role as Executive Vice-President, International Sales and Marketing Organisation on 31 December and will leave the Company in 2010 after nine years' service as a member of the SET and 20 years with the Company in total. With effect from 1 January 2010, Tony Zook was appointed to the newlycreated role of Executive Vice-President, Commercial Operations. In this role, he will have responsibility for worldwide sales and marketing activities.

# Board and Committee meeting attendance in 2009

	Number of meetings attended/(number of meetings Director was eligible to attend in 2009)					
		Audit	Remuneration	Nomination and Governance		
Name	Board	Committee	Committee	Committee		
Bo Angelin	8 (8)	-	-	-		
David Brennan	8 (8)	-	-	-		
John Buchanan	5 (8)	3 (4)	3 (6)	-		
Jean-Philippe Courtois	7 (8)	4 (4)	-	-		
Jane Henney	7 (8)	3 (4)	-	2 (2)		
Michele Hooper	8 (8)	4 (4)	-	2 (2)		
Simon Lowth	8 (8)	-	-	-		
Rudy Markham	7 (8)	4 (4)	-	-		
Håkan Mogren <sup>1</sup>	1 (2)	-	-	O (1)		
John Patterson <sup>2</sup>	1 (1)	-	-	-		
Nancy Rothwell	6 (8)	-	6 (6)	-		
Louis Schweitzer	8 (8)	-	6 (6)	2 (2)		
John Varley	8 (8)	-	6 (6)	2 (2)		
Marcus Wallenberg	6 (8)	-	-	_		

<sup>1</sup> Håkan Mogren retired from the Board on 30 April 2009.

<sup>2</sup> John Patterson retired from the Board on 31 March 2009.

The roles of the Board, the Board's committees, the Chairman, the CEO and the SET are documented, as are the Board's delegated authorities and reserved powers, the means of operation of the business and the roles of corporate functions.

# **R&D Executive Committee**

The R&D Executive Committee oversees and prioritises the portfolio of both small molecule and biological discovery and development projects across the Group (whether originating from our own R&D activities or from external sources). On an annual basis it takes a view across all Therapy Areas and makes decisions based on unmet medical need, commercial and scientific opportunity, competitive position and capability mix. It is also charged with overseeing a portfolio review process intended to ensure that internal and external opportunities are reviewed using the same criteria and that there is a clear externalisation strategy aligned with the disease area strategies.

During 2009 the R&D Executive Committee comprised the Interim Executive Vice-President, Discovery Research; the Executive Vice-President, Development; the Executive Vice-President, Research and Development, MedImmune; the Executive Vice-President, Clinical Research and Chief Medical Officer, MedImmune; the Chief Executive Officer, North America/President, MedImmune/ Executive Vice-President, Commercial Operations; the Senior Vice-President, Strategic Planning and Business Development; the Vice-President, R&D Finance; and the Vice-President, Development Projects. In 2010, the R&D Executive Committee will be replaced by the Portfolio Investment Board, which will be chaired by the CEO, and will include the CFO, the Executive Vice-President, Development, the Executive Vice-President, Commercial Operations and other members of senior management. The Portfolio Investment Board will be accountable for all R&D investments within the Group and will be charged with delivering a pipeline of products capable of generating attractive returns on invested capital and driving shareholder value.

#### **Operation of the Board**

The Board is responsible for the Group's corporate governance, sets the Group's strategy and policies, has overall responsibility for the oversight of risk and also monitors progress towards meeting its objectives and annual plans. The Board discharges these responsibilities through a programme of meetings that includes a formal, annual strategy review. The Board also assesses whether or not and to what extent its obligations to the Company's shareholders and others are understood and met. This includes regular reviews of the Group's financial performance and critical business issues.

In the view of the Board, at least half of the Board are, for the purposes of the Combined Code and the corporate governance listing standards of the NYSE (Listing Standards), independent Non-Executive Directors.

Prior to the publication of this Annual Report, the Board conducted the annual evaluation of its own performance and that of its committees. This was carried out internally, using a series of web-based questionnaires that covered a range of topics, including the nature and level of the Board's interaction with the Group's management; the quality, quantity and scope of information which f ows to the Board from management, and the way in which it f ows; the content of and presentations to Board meetings; the composition of the Board; the practical arrangements for the work of the Board; and the work and operation of the Board's committees. Overall, it was concluded that the Board and its committees were operating in an effective and constructive manner.

As part of the assessment process, each Non-Executive Director received feedback about his or her individual performance. The Non-Executive Directors reviewed the performance of the CEO and CFO in their absence. In addition, the Board, under the chairmanship of the senior independent Non-Executive Director, reviewed the performance of the Chairman in his absence. Each Director continues to perform effectively and demonstrate commitment to the role.

### **Board matters**

As part of the business of each meeting of the Board, the CEO typically submits a progress report on each key business area, giving details of progress against the goals the Board has approved and their activities. To ensure that the Board has good visibility of the key operating decisions of the business, members of the SET routinely attend Board meetings on a rotational basis and the Board regularly meets and consults other senior employees throughout the year. The Board also receives accounting and other management information about the Group's resources, presentations from internal and external speakers on legal, governance and regulatory developments and external perspectives. At the end of Board meetings, the Non-Executive Directors usually meet without the Executive Directors present, to review and discuss any matters that have arisen during the meeting and/or such other matters as may appear to the Non-Executive Directors to be relevant in properly discharging their duty to act independently.

The Company Secretary is responsible to the Chairman for ensuring that all Board and Board Committee meetings are properly conducted, that the Directors receive appropriate information prior to meetings to enable them to make an effective contribution, and that governance requirements are considered and implemented.

The Board held six scheduled and two *ad hoc* meetings in 2009. It also held a strategy review day, which was attended by all the SET members. With the exception of the

# **Board Committee membership**

board committee in	iember sinp				
			Nomination and		
	Audit	Remuneration	Governance	Science	
Name	Committee	Committee	Committee	Committee	Independent <sup>1</sup>
Bo Angelin	х	х	х	$\checkmark$	$\checkmark$
David Brennan	х	х	х	х	-
John Buchanan	Chair	$\checkmark$	х	х	$\checkmark$
Jean-Philippe Courtois	$\checkmark$	х	х	х	$\checkmark$
Jane Henney	$\checkmark$	х	$\checkmark$	$\checkmark$	$\checkmark$
Michele Hooper <sup>2</sup>	$\checkmark$	х	$\checkmark$	х	$\checkmark$
Simon Lowth	х	х	х	х	-
Rudy Markham	$\checkmark$	х	х	х	$\checkmark$
Håkan Mogren <sup>3</sup>	х	х	$\checkmark$	х	х
John Patterson <sup>4</sup>	х	х	х	$\checkmark$	-
Nancy Rothwell	х	$\checkmark$	х	Chair	$\checkmark$
Louis Schweitzer	х	$\checkmark$	Chair	х	_5
John Varley	х	Chair	$\checkmark$	х	$\checkmark$
Marcus Wallenberg	х	х	х	х	х

<sup>1</sup>As determined by the Board for Combined Code purposes.

<sup>2</sup> Michele Hooper is the senior independent Non-Executive Director.

<sup>3</sup>Håkan Mogren retired from the Board on 30 April 2009.

<sup>4</sup> John Patterson retired from the Board on 31 March 2009.

<sup>5</sup> Louis Schweitzer was considered independent by the Board upon his appointment as Chairman; in accordance with the Combined Code, the test of independence is not appropriate to the Chairman after his appointment.

September Board meeting and the strategy day, which were held in Södertälje, Sweden, all of the meetings were held in London, UK or by telephone. The Board is currently scheduled to meet six times and hold a strategy review day in 2010, and will meet at such other times as may be required to conduct business.

On those occasions when a Board or Board Committee member was unavoidably absent from a meeting, for example through illness or where a meeting clashed with his/her existing commitments, he/she still received and reviewed the papers for the meeting and provided verbal or written input ahead of the meeting, typically through the Chairman of the Board or the Chairman of the Board Committee, so that his/her views were made known and considered at the meeting.

In addition, given the nature of the business to be conducted, some Board meetings were convened at short notice, which made it difficult for some Directors to attend due to prior commitments.

As well as their work in relation to formal Board and Board Committee meetings, the Non-Executive Directors also continued to commit time throughout the year to meetings and telephone calls with various levels of executive management, visits to AstraZeneca's sites throughout the world and, for new Non-Executive Directors, induction sessions, meetings and site visits. In 2009, for example, various Non-Executive Directors made individual visits to AstraZeneca's sites in the UK, Sweden, the US, Canada, China, Japan and Vietnam. In January 2010, on his appointment as Non-Executive Chairman of Volvo AB, the Chairman consulted the Company and considered this new commitment against his ability to continue to commit sufficient time to the Company; it is not anticipated that his availability for the Company will be reduced.

#### Directors

In accordance with Article 65 of the Articles, all Directors retire at each AGM and may offer themselves for re-election by shareholders. Accordingly, all of the Directors will retire at the AGM in April 2010. The Notice of AGM will give details of those Directors presenting themselves for re-election. The Board reviews annually the status of succession to senior positions, including those at Board level, and ensures it has regular contact with, and access to, succession candidates.

### During 2009:

- > John Patterson, Executive Director, Development retired from the Board on 31 March 2009.
- Håkan Mogren, Non-Executive Deputy Chairman, retired from the Board on 30 April 2009.

For information relating to the appointment process for new Directors see the Nomination and Governance Committee section from page 95. Newly appointed Directors are provided with comprehensive documentation, setting out their obligations and duties as Directors. They also typically attend tailored induction programmes that take account of their individual skills and experience. To develop an understanding of major shareholders' views about the Company, the Non-Executive Directors (together with the rest of the Board) regularly receive reports and presentations from the Company's brokers and meet with senior managers throughout the year. Moreover, the Directors actively encourage shareholders to attend the AGM and ask questions.

The Company maintained directors' and officers' liability insurance cover throughout 2009. The Directors are also able to obtain independent legal advice at the expense of the Company, as necessary, in their capacity as Directors.

The Company has entered into a deed of indemnity in favour of each Board member since 2006. These deeds of indemnity are still in force and provide that the Company shall indemnify the Directors to the fullest extent permitted by law and the Articles, in respect of all losses arising out of, or in connection with, the execution of their powers, duties and responsibilities, as Directors of the Company or any of its subsidiaries. This is in line with current market practice and helps the Company attract and retain high-quality, skilled Directors.

# **Operation of Board Committees**

The Board has delegated certain responsibilities to the Audit, Remuneration, Nomination and Governance, and Science Committees. The Board provides adequate resources to enable each committee to undertake its duties. Further details of the role, membership and terms of reference for each committee are set out below. In addition to the standing committees of the Board, there may from time to time be constituted *ad hoc* committees for specific projects or tasks. In these cases, the scope and responsibilities of the committee is documented.

### **Audit Committee**

The current members of the Audit Committee are John Buchanan (Audit Committee Chairman), Jane Henney, Michele Hooper (senior independent Non-Executive Director), Jean-Philippe Courtois and Rudy Markham. They are all Non-Executive Directors. The Board considers each member to be independent under the Combined Code and under the general guidance and specific criteria of the Listing Standards concerning the composition of audit committees applicable to non-US companies. In April 2009, the Company submitted the required annual written affirmation to the NYSE confirming its full compliance with those standards. For the purposes of the Combined Code, the Board remains satisfied that at least one member of the Audit Committee has recent and relevant financial experience. At its meeting in December 2009, the Board determined that Michele Hooper and Rudy Markham are audit committee financial experts for the purposes of the Sarbanes-Oxley Act. The Deputy Company Secretary acts as secretary to this committee.

The core terms of reference of the Audit Committee continue to include reviewing and reporting to the Board on:

- Matters relating to the audit plans of the external auditor and GIA as well as oversight of the work of the Global Compliance function.
- > The Group's overall framework for internal control over financial reporting and for other internal controls and processes.
- > The Group's overall framework for risk management, particularly financial risks.
- > The accounting policies and practices of the Group.
- > The annual and quarterly financial reporting carried out by the Group.

The Audit Committee is responsible for notifying the Board of any significant concerns of the external auditor or the Vice-President, Group Internal Audit (GIA) arising from their audit work, any matters that may materially affect or impair the independence of the external auditor, any significant deficiencies or material weaknesses in the design or operation of the Group's internal control over financial reporting or other internal controls, and any serious issues of non-compliance.

The Audit Committee oversees the establishment, implementation and maintenance of the Code of Conduct and other related policies. It has established procedures for the receipt and handling of complaints concerning accounting or audit matters. It recommends to the Board the appointment of the external auditor, subject to the approval of the Company's shareholders at a general meeting. Shareholders in a general meeting authorise the Directors to fix the remuneration of the external auditor. The Audit Committee reviews and approves the appointment and any dismissal of the Vice-President, GIA.

The Audit Committee maintains policies and procedures for the pre-approval of all audit services and permitted non-audit services undertaken by the external auditor, the principal purpose of which is to ensure that the independence of the external auditor is not impaired. The policies and procedures cover three categories of work - audit services, audit-related services and tax services. The policies define the type of work that falls within each of these categories and the non-audit services that the external auditor is prohibited from performing under the rules of the SEC and other relevant UK and US professional and regulatory requirements. The pre-approval procedures permit certain audit, audit-related and tax services to be performed by the external auditor during the year, subject to fee limits agreed with the Audit Committee in advance. The CFO (supported by the Senior Vice-President, Group Finance) monitors the status of all services being provided by the external auditor. The procedures also deal with placing non-audit work out for tender, where appropriate. Authority to approve work in excess of the pre-agreed fee limits is delegated to the Chairman of the Audit Committee in the first instance. A standing agenda item at Audit Committee meetings covers the operation of the pre-approval procedures and regular reports are provided to the full Audit Committee.

The Audit Committee's terms of reference are available on our website, astrazeneca. com and on request from the Company Secretary.

The Audit Committee held four scheduled meetings in 2009. The individual attendance record of members of the Audit Committee is set out in the Board and Committee meeting attendance in 2009 table on page 92.

Following each Audit Committee meeting, the Chairman of the Audit Committee (or the senior independent Non-Executive Director in the absence of the Chairman of the Audit Committee) reported to the Board on the principal matters covered at the meeting and minutes of the meetings were circulated to all Board members.

During 2009, members of the Audit Committee met individual managers or groups of managers on a number of occasions, which helped the members gain a deeper insight into areas relevant to the Audit Committee's work and provided an opportunity to discuss specific areas of interest.

During the year, in line with its normal practice, the Audit Committee also held a number of private meetings, without management present, with the Vice-President, GIA, the Global Compliance Officer and the lead partners from the Company's external audit firm. The purpose of these meetings was to facilitate free and open discussions between the Audit Committee members and those individuals, separately from the main sessions of the Audit Committee, which were attended by the CFO and the Senior Vice-President, Group Finance.

During 2009 and January 2010, the business considered and discussed by the Audit Committee included the matters referred to below:

- > The Group's financial disclosures were reviewed and various accounting matters considered.
- > Reports were received from the external auditor concerning its audit of the Financial Statements of the Group and from management, GIA, Global Compliance and the external auditor on the effectiveness of the Group's system of internal controls and, in particular, its internal control over financial reporting. This included review and discussion of the results of the Group's 'continuous assurance' and annual 'letter of assurance' processes (described further below in the UK corporate governance requirements section from page 96). The Audit Committee also reviewed quarterly activity reports of audit work carried out by GIA and the status of follow-up actions with management as well as reports from the Global Compliance function.
- > The systems and processes that management has developed pertaining to risk identification, classification and mitigation.
- > Continuing work to comply with the applicable provisions of the Sarbanes-Oxley Act. In particular, the Audit Committee regularly reviewed the status of compliance with the programme of internal controls over financial reporting implemented pursuant to section 404 of the Sarbanes-Oxley Act; further information about this is set out in the Sarbanes-Oxley Act section 404 section on page 49.
- > Data about calls made by employees via the AZethics telephone lines and other routes regarding potential breaches of the Code of Conduct together with the results of enquiries into these matters.
- > The succession of the Vice-President, GIA.
- Accounting issues relevant to litigation and taxation matters.
- > Reports from the Group Treasury function and, in particular, the Group's liquidity and cash position and the appropriateness of its cash management policies in the context of the current economic situation.
- > Other reports concerning the GIA, Global Compliance and Finance functions, including the internal audit plan and progress and plans of the Global Compliance Officer.

- > The amount of audit and non-audit fees of the external auditor throughout 2009. The Audit Committee was satisfied throughout the year that the objectivity and independence of the external auditor were not in any way impaired by the nature of the non-audit work undertaken by the external auditor during the year, the level of non-audit fees charged for such work or any other facts or circumstances. Further information about the audit and non-audit fees for the year is disclosed in Note 27 to the Financial Statements on page 185.
- > A review and assessment of the Audit Committee's performance which concluded that such performance was satisfactory.

In line with best practice, the Group will periodically consider how the audit requirements of the Group are best served in the context of business need and the prevailing external environment and, against the background of this review, will from time to time undertake a formal tendering programme with audit firms of appropriate size and calibre. Following discussions at a meeting in January 2010, the Audit Committee unanimously recommended to the Board that a resolution for the re-appointment of KPMG as the Company's external auditor be proposed to shareholders at the AGM in April 2010. Based on its experience of working with external auditors, the Audit Committee believes that the quality of the interaction with and level of service received from KPMG were key factors supporting this recommendation. The Audit Committee was also satisfied that, notwithstanding the length of tenure of KPMG, KPMG met the independence criteria under the relevant statutory, regulatory and ethical standards applicable to auditors. Consistent with current market practice, KPMG's services to the Group are provided pursuant to terms of engagement which are reviewed by the Audit Committee. These terms of engagement do not include any contractual obligations under which the Directors would be prevented from appointing a different audit firm were they to consider this to be in the best interests of the Group. The Audit Committee, through management, continues to maintain contact and dialogue with other major audit firms who are familiar with the Group's business for succession purposes as required. This is reported to the Audit Committee in order to ensure a smooth transition from the current auditor, should this be necessary.

At the same meeting, the CEO and the CFO presented to the Audit Committee their conclusions following the evaluation of the effectiveness of the Group's disclosure controls and procedures required by Item 15(a) of Form 20-F at 31 December 2009. Based on their evaluation, the CEO and the CFO concluded that, as at that date, the Group maintains an effective system of disclosure controls and procedures.

There was no change in the Group's internal control over financial reporting that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, the Group's internal control over financial reporting.

The Audit Committee is currently scheduled to meet four times in 2010 and will meet at such other times as may be required.

### **Remuneration Committee**

The principal role of the Remuneration Committee continues to be to consider, on behalf of the Board, the remuneration (including pension rights and compensation payments) of Executive Directors, the Chairman and senior executives. More information is set out in the Directors' Remuneration Report from page 101.

#### Nomination and Governance Committee

The Nomination and Governance Committee's core role continues to be (after appropriate consultation with the Chairman and the CEO) to recommend to the Board any new appointments of Directors. Any decisions relating to the appointment of Directors are made by the entire Board based on the merits of the candidates and the relevance of their background and experience, measured against objective criteria, with care taken to ensure that appointees have enough time to devote to the job. The Nomination and Governance Committee also advises the Board periodically on significant developments in corporate governance and the Company's compliance with the Combined Code.

During 2009, the members of the Nomination and Governance Committee were Louis Schweitzer (Nomination and Governance Committee Chairman), Håkan Mogren (until his retirement from the Board on 30 April 2009), Jane Henney, Michele Hooper and John Varley. They are all Non-Executive Directors. The Board considers all current members of the Nomination and Governance Committee to be independent (Louis Schweitzer was considered by the Board to be independent upon his appointment as Chairman; in accordance with the Combined Code, the test of independence is not appropriate in relation to the Chairman after his appointment). The Company Secretary acts as secretary to this committee.

The Nomination and Governance Committee met twice in 2009. The individual attendance record of members of the Nomination and Governance Committee is set out in the Board and Committee meeting attendance in 2009 table on page 92. During 2009, the Nomination and Governance Committee reviewed the knowledge, experience and balance of the Board overall and considered its likely future requirements given the strategic and business objectives of the Group. In addition, the Nomination and Governance Committee received reports about the various corporate governance reviews and proposals that were a feature of 2009, and carefully monitored developments and their potential impact on the Group.

The Nomination and Governance Committee's terms of reference are available on our website, astrazeneca.com.

#### **Science Committee**

The Science Committee's core role continues to be to provide assurance to the Board regarding the quality, integrity and competitiveness of the Company's science-based R&D activities. It does not review individual projects. The Science Committee, together with external experts, where appropriate, does review important bioethical issues faced by the Group and assists in the formulation of, and agrees on behalf of the Board, appropriate policies in relation to such issues. In addition, the Science Committee is responsible for considering general future trends in medical science and technology, and any new areas of science or medicine in which the Group may be interested.

During 2009, the members of the Science Committee, all of whom have a knowledge of, or an interest in, life sciences, were Nancy Rothwell (Science Committee Chairman), Jane Henney, Bo Angelin, all Non-Executive Directors, and Jan Lundberg (until his resignation in November), John Patterson (until his retirement from the Board on 31 March 2009), Anders Ekblom and Christer Köhler (from his appointment as Interim Executive Vice-President, Discovery Research in November). The Vice-President, Business Performance and Continuous Improvement, R&D also attends all meetings and acts as secretary to this committee.

The Science Committee met twice in 2009. Its remit is available on the Company's website, astrazeneca.com.

# Principal corporate governance requirements UK corporate governance requirements

The Board has prepared this Annual Report with reference to the Combined Code and related guidance published in June 2008 by the Financial Reporting Council (FRC). It describes the way in which the Company is applying all the main and supporting principles of good governance in the Combined Code as described below. The Company has complied throughout the accounting period and is also continuing to comply with all of the provisions of the Combined Code. The Combined Code is publically available on the FRC website, frc.co.uk.

The Board has overall responsibility for the Group's system of internal controls and risk management policies and is also responsible for reviewing their effectiveness. During 2009, the Directors have continued to review the effectiveness of the Group's system of controls, risk management and the Group's high-level internal control arrangements. These reviews have included an assessment of internal controls, and in particular, internal, financial, operational and compliance controls and risk management and their effectiveness, supported by management assurance of the maintenance of control, reports from GIA, as well as the external auditor on matters identified in the course of its statutory audit work. The system is designed to manage rather than eliminate the risk of failure to achieve business objectives and can only provide reasonable (not necessarily absolute) assurance of effective operation and compliance with laws and regulations.

Underpinning these reviews is an annual 'letter of assurance' process by which responsible managers confirm the adequacy of their systems of internal financial and non-financial controls, their compliance with Group policies and relevant laws and regulations (including the industry's regulatory requirements), and that they have reported any control weaknesses through the Group's 'continuous assurance' process.

The internal control framework has been in operation for the whole of the year under review and continues to operate up to the date of the approval of this Annual Report. The Directors believe that the Group maintains an effective, embedded system of internal controls and complies with the Turnbull Report guidance and, in the view of the Directors, no significant failings have been identified in the system. Further information on the ways in which we manage our business risks is set out in the Managing risk section from page 79 and a list of the principal risks and uncertainties is set out in the Principal risks and uncertainties section from page 80.

During 2009, the Board considered the independence of each Non-Executive Director. With the exception of Marcus Wallenberg, the Board considers that all of the Non-Executive Directors are independent. Louis Schweitzer was considered by the Board to be independent upon his appointment as Chairman; in accordance with the Combined Code, the test of independence is not appropriate in relation to the Chairman after his appointment.

Marcus Wallenberg was appointed as a Director of Astra in May 1989 and subsequently became a Director of the Company in 1999. Until September 2005, he was a member of the board of directors and the Chief Executive Officer of Investor AB, which has a 3.55% interest in the issued share capital of the Company as at 28 January 2010. Wallenberg family foundations remain Investor AB's largest shareholders in terms of votes controlled. For these reasons, the Board does not believe that Marcus Wallenberg can be determined independent under the Combined Code. However, the Board believes that he has brought, and continues to bring, considerable business experience and makes a valuable contribution to the work of the Board

The Board has also considered, in particular, the position of Michele Hooper who joined the board of UnitedHealth Group as a Non-Executive Director in 2007. The Board's approval of this appointment was conditional upon Michele Hooper resigning from the board of UnitedHealth Group in the event of a confict or non-independence. It is the Board's view that Michele Hooper is independent and that she discharges her duties in a properly independent manner, constructively and appropriately challenging the Executive Directors and the Board.

Jane Henney is a Non-Executive Director of AmerisourceBergen Corporation and CIGNA Corporation, both of which are customers of the Group in the US. The Board has considered these relationships and concluded that they did not compromise her independence. The position of senior independent Non-Executive Director of the Company was established in 2002. Michele Hooper (who was appointed as a Non-Executive Director in 2003) became the Company's senior independent Non-Executive Director in April 2007.

At the AGM in 2008, a resolution was passed to amend the Articles to enable the Directors to authorise any situation in which a Director has an interest that conficts or has the potential to confict with the Company's interests and which would otherwise be a breach of the Director's duty, under section 175 of the Companies Act 2006. The Board has a formal system in place for Directors to declare such situations to be considered for authorisation by those Directors who have no interest in the matter being considered. In deciding whether to authorise a situation, the non-conficted Directors must act in the way they consider, in good faith, would be most likely to promote the success of the Company, and they may impose limits or conditions when giving the authorisation, or subsequently, if they think this is appropriate. Situations considered by the Board and authorisations given are recorded in the Board minutes and in a register of conficts maintained by the Company Secretary and reviewed annually by the Board. The Board considers that this system continues to operate effectively.

The disclosures that fulfil the requirements of a corporate governance statement under the Disclosure and Transparency Rules can be found in this Corporate Governance section of the Directors' Report and in other parts of this Annual Report as listed below, each of which is incorporated into this Corporate Governance section by reference:

- > Significant holders of the Company's shares (contained in the Shareholder Information section from page 199).
- > Articles (contained in the Corporate Information section on page 204).
- > Amendments to the Company's Articles (contained in the Corporate Information section on page 204).

#### US corporate governance requirements

The Company's ADSs are traded on the NYSE and, accordingly, the Company is subject to the reporting and other requirements of the SEC applicable to foreign private issuers. Section 404 of the Sarbanes-Oxley Act requires companies to include in their annual report on Form 20-F filed with the SEC, a report by management stating its responsibility for establishing internal control over financial reporting and to assess annually the effectiveness of such internal control. The Company has complied with those provisions of the Sarbanes-Oxley Act applicable to foreign private issuers. The Board continues to believe that the Group has a sound corporate governance framework, good processes for the accurate and timely reporting of its financial position and results of operations and an effective and robust system of internal controls. The Company has established a Disclosure Committee, further details of which can be found in the Disclosure Policy and Disclosure Committee section on page 98.

The Directors' assessment of the effectiveness of the internal control over financial reporting is set out in the Directors' Responsibilities for, and Report on, Internal Control over Financial Reporting section in the Financial Statements on page 122.

The Company must disclose any significant ways in which its corporate governance practices differ from those followed by US companies under the Listing Standards. In addition, the Company must comply fully with the provisions of the Listing Standards relating to the composition, responsibilities and operation of audit committees. These provisions incorporate the rules concerning audit committees implemented by the SEC under the Sarbanes-Oxley Act.

The Company has reviewed the corporate governance practices required to be followed by US companies under the Listing Standards and its corporate governance practices are generally consistent with those standards.

#### **Code of Conduct**

The Code of Conduct, which is available on our website, astrazeneca.com, applies to all Directors, officers, full-time, part-time, contractor and temporary staff at all levels in every country where we operate. It has been translated into over 40 languages and every employee has a copy in his/her local language. It is designed to provide clear direction as to how the Company's commitment to honesty and integrity is to be translated into consistent actions across all areas of the business. Compliance with the Code of Conduct and with the standards detailed by the Group in support of it is mandatory. The same applies to the laws and regulations of the countries in which we work and do business, as well as applicable national and international codes, and the Group seeks to operate to the highest of these standards.

The Code of Conduct also includes information on how to report possible violations of the Code of Conduct through the appropriate channels, including the AZethics telephone lines and the new global website, AZethics.com. Anyone who raises a possible breach in good faith will be supported by management and will not be subject to retaliation, which would itself be considered a serious violation of the Code of Conduct. We review all alleged compliance breaches and concerns, and we investigate and report on them to the Audit Committee, as appropriate.

During 2009, 289 reports of alleged compliance breaches or other ethical concerns were made via the telephone helplines, AZethics.com website or Global Compliance e-mail or postal addresses described in the Code of Conduct. The number of reports via the equivalent channels in 2008 was 206. We believe that the increase in the number of reports via these channels is due, in part, to our efforts to enhance these reporting channels and, in part, to an increased awareness of the Code of Conduct and the accompanying training and communications.

As with the Code of Conduct, our Global Policies apply to all members of the Group. Like the Code of Conduct, the Global Policies provide clear and comprehensive guidance, in plain language, to all managers and employees as to their accountabilities in key ethical, compliance and corporate responsibility risk areas.

A critical element of the effectiveness of the Code of Conduct and Global Policies is to deliver clear training and education to employees on an ongoing basis.

A Group Finance Code of Conduct complements the Code of Conduct. It applies to the CEO, the CFO, the Group's principal accounting officers (including key Finance staff in major overseas subsidiaries) and all Finance function employees, and it reinforces the importance of the integrity of the Group's Financial Statements, of the reliability of the accounting records on which they are based and of the robustness of the relevant controls and processes.

# **Compliance and Group Internal Audit**

The role of the Global Compliance function is to help embed a culture of ethics and integrity in the Group. Global Compliance works closely with GIA, with whom it provides joint assurance reporting to the Audit Committee. The key priorities for our Global Compliance function for 2009/2010 are closely aligned with the Group's strategic priorities. During 2010, the Global Compliance function will continue to focus on ensuring the delivery of an aligned approach to compliance that addresses key risk areas across the business. During 2009, the Global Compliance Committee met quarterly. The remit of the committee is to oversee and co-ordinate implementation of an effective global compliance programme and evaluate its effectiveness. It does this by assessing key compliance risks within and across the SET functions; working with GIA to ensure co-ordination of compliance auditing and monitoring; reviewing results; and addressing significant policy violations and identifying trends.

Global Compliance provides direct assurance to the Audit Committee on matters concerning compliance issues, with a particular focus on compliance with IFPMA, EFPIA and PhRMA codes. Complementing this, GIA carries out a range of audits that include compliance-related audits and reviews of the assurance activities of other Company assurance functions. The results from these activities are reported to the Audit Committee.

GIA is an independent appraisal function that derives its authority from the Board through the Audit Committee. Its primary role is to provide reasonable and objective assurance to the Directors about the adequacy and effectiveness of the Group's risk management and control framework and the internal controls over key business risks, including financial controls and compliance with laws, regulations and policies.

GIA seeks to discharge the responsibilities set down in its charter by reviewing:

- > The processes for ensuring that key business risks are effectively managed.
- > The financial and operational controls that help to ensure that the Group's assets are properly safeguarded from losses, including fraud.
- > The controls that help to ensure the reliability and integrity of management information systems.
- > The processes for ensuring compliance with policies and procedures, external legislation and regulation.
- > On an ad hoc basis, whether value for money is obtained (in terms of efficient use of the Group's resources).

GIA acts as a source of constructive advice and best practice, assisting senior management to improve governance, control, compliance and risk management.

# Disclosure Policy and Disclosure Committee

The Group's Disclosure Policy provides a framework for the handling and disclosure of inside information and other information of interest to shareholders and the investment community. It also defines the role of the Disclosure Committee. During 2009, the members of the Disclosure Committee were: the CFO; the Executive Vice-President, Development; the General Counsel; the Vice-President, Corporate Affairs; the Vice-President, Investor Relations; and the Senior Vice-President, Group Finance. The Deputy Company Secretary acts as secretary to this committee. The Disclosure Committee meets regularly to assist and inform the decisions of the CEO concerning inside information and its disclosure. Periodically, it reviews the Group's disclosure controls and procedures and its own operation as part of work carried out to enable management and the Board to assure themselves that appropriate processes are operating for the Company's planned disclosures, such as its quarterly results announcements and scheduled investor relations events. In addition, the Disclosure Committee members are members of the steering group that reviews the drafts of, and the process for preparing, this Annual Report.

# **Disclosure of information to auditors**

The Directors who held office at the date of approval of this Directors' Report confirm that, so far as they are each aware, there is no relevant audit information of which the Company's auditors are unaware; and each Director has taken all the steps that he/she ought to have taken as a Director to make himself/herself aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

# Other matters Subsidiaries and principal activities

The Company is the holding company for a group of subsidiaries whose principal activities are described in this Directors' Report. Principal subsidiaries and their locations are given in the Principal Subsidiaries section in the Financial Statements on page 186.

# Branches and countries in which the Group conducts business

In accordance with the Companies Act 2006, we disclose below the members of the Group that have representative or scientific branches/offices outside the UK:

- > AstraZeneca UK Limited: Albania, Algeria, Angola, Armenia, Azerbaijan, Bosnia and Herzegovina, Bulgaria, Chile, Costa Rica, Croatia, Cuba, Georgia, Ghana (scientific office), Ireland, Jordan, Kazakhstan, Kenya (scientific office), Macedonia, Romania, Russia, Serbia and Montenegro, Slovenia and Ukraine.
- > AstraZeneca AB: Egypt (scientific office), Latvia, Saudi Arabia (scientific office) and Slovakia.
- > AstraZeneca Export and Trading AB: Estonia, Lithuania, Romania and the United Arab Emirates.
- > AstraZeneca Singapore Pte Limited: Cambodia and Vietnam.

# Distributions to shareholders and dividends for 2009

The Company's stated distribution policy comprises both a regular cash dividend and a share re-purchase component, further details of which are set out in the Capitalisation and shareholder return section in the Financial Review on page 42 and Notes 20 and 21 to the Financial Statements from pages 153 and 154, respectively.

The Company's dividends for 2009 of \$2.30 (141.4 pence, SEK 16.84) per Ordinary Share amount to, in aggregate, a total dividend payment to shareholders of \$3,336 million.

Two of the Group's employee share trusts, AstraZeneca Share Trust Limited and AstraZeneca Quest Limited, waive their right to a dividend on the Ordinary Shares that they hold and instead receive a nominal dividend.

A shareholders' resolution was passed at the 2009 AGM authorising the Company to purchase its own shares. However, no share re-purchases took place in 2009. The Company will seek a renewal of its current permission from shareholders to purchase its own shares at the AGM on 29 April 2010.

During the Company's share re-purchase programmes that operated between 1999 and 2008, a total of 376.3 million Ordinary Shares were re-purchased, and subsequently cancelled, at an average price of 2661 pence per share for a consideration, including expenses, of \$18,099 million.

#### Going concern accounting basis

Information on the business environment in which the Group operates, including the factors underpinning the industry's future growth prospects, are included in the Business Environment section from page 12. Details of the product portfolio of the Group, our approach to product development and a summary of our development pipeline are included in the Research and Development section from page 22. Additional information on our Therapy Areas and a more detailed table of our development pipeline is included in the Therapy Area Review from page 55.

The financial position of the Group, its cash fows, liquidity position and borrowing facilities are described in the Financial Review. In addition, Notes 15 and 16 to the Financial Statements from pages 144 and 146, respectively, include the Group's objectives, policies and processes for managing its capital, its financial risk management objectives, details of its financial instruments and hedging activities and its exposures to credit, market and liquidity risk. Further details of the Group's cash balances and borrowings are included in Notes 13 and 14 to the Financial Statements from pages 143 and 144, respectively.

The Group has considerable financial resources available. At 31 December 2009, the Group had \$12.3 billion in financial resources (cash balances of \$9.9 billion and committed undrawn bank facilities of \$4.25 billion, with \$1.9 billion of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents and for which, in the short term at least, demand is relatively unaffected by changes in the global economy. In addition, the Group has a wide diversity of customers and suppliers across different geographic areas. As a consequence, the Directors believe that the Group is well placed to manage its business risks successfully despite the current uncertain economic outlook.

After making enquiries, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing this Annual Report and the Financial Statements.

#### Changes in share capital

Changes in the Company's Ordinary Share capital during 2009, including details of the allotment of new shares under the Company's share plans, are given in Note 20 to the Financial Statements from page 153.

## **Directors' shareholdings**

The Articles require each Director to be the beneficial owner of Ordinary Shares in the Company with an aggregate nominal value of \$125 (which currently represent at least 500 shares). Such holding must be obtained within two months of the date of the Director's appointment. At 31 December 2009, all of the Directors complied with this requirement and full details of each Director's interests in shares of the Company are set out in the Directors' interests in shares section on page 115. Information about the shareholding expectations of the Remuneration Committee (in respect of Executive Directors and SET members) and the Board (in respect of Non-Executive Directors) is also set out in the Directors' Remuneration Report on pages 108 and 110, respectively.

#### Shareholder communications

In its financial and business reporting to shareholders and other interested parties by means of quarterly, half-year and full-year reports, the Board aims to present a balanced and understandable assessment of the Group's financial position and prospects.

The Company makes available to shareholders information about the Company through a range of media, including a fully integrated html corporate website, astrazeneca.com, containing a wide range of information of interest to institutional and private investors. The Company considers its website to be an important means of communication with its shareholders. The Company has been authorised by shareholders to place shareholder communications (such as the Notice of AGM and this Annual Report) on its corporate website in lieu of sending paper copies to shareholders (unless specifically requested by shareholders). Whilst recognising and respecting the fact that some of our stakeholders may have different preferences regarding the manner in which they receive information about the Company, we will continue to promote the benefits of electronic communication given the advantages that this has over traditional paper-based communications both in terms of the configurability and accessibility of the information that is provided and the consequent cost savings and reduction in environmental impact associated with reduced printing and distribution costs.

The Company has frequent discussions with institutional shareholders on a range of issues affecting its performance. These include individual meetings with some of the Company's largest institutional shareholders to seek their views and any concerns can be reported to the Board. In addition, the Company responds to individual ad hoc requests for discussions from institutional shareholders and analysts. The Group's Investor Relations department acts as a main point of contact for investors throughout the year. The senior independent Non-Executive Director is also available to shareholders if they have concerns that contact through the normal channels of Chairman, CEO, CFO and/ or the Group Investor Relations department has failed to resolve, or in relation to which such contact is inappropriate. All shareholders, including private investors, have an opportunity at the AGM to put questions to members of the Board on matters relating to the Group's operation and performance. Formal notification of the AGM is sent to shareholders at least one month in advance. The Chairmen of the Board's committees ordinarily attend the AGM to answer questions raised by shareholders. In line with the Combined Code, details of proxy voting by shareholders, including votes withheld, are given at the AGM and are placed on our website following the AGM.

### **Political donations**

Neither the Company nor its subsidiaries made any EU political donations or incurred any EU political expenditure in 2009 and they do not intend to do so in the future in respect of which shareholder authority is required, or for which disclosure in this Annual Report is required, under the Companies Act 2006.

However, to enable the Company and its subsidiaries to continue to support interest groups or lobbying organisations concerned with the review of government policy or law reform without inadvertently breaching the Companies Act 2006, which defines political donations and other political expenditure in broad terms, a resolution will be put to shareholders at the 2010 AGM, similar to that passed at the AGM on 30 April 2009, to authorise the Company and its subsidiaries to make: (i) donations to political parties; (ii) donations to political organisations other than political parties; and (iii) incur political expenditure, up to an aggregate limit of \$250.000.

In 2009, the Group's US legal entities made contributions amounting in aggregate to \$733,687 (2008: \$815,838) to state political party committees and to campaign committees of various state candidates affiliated with the major parties in accordance with pre-established guidelines. No corporate donations were made at the federal level and all contributions were made only where allowed by US federal and state law. US citizens or individuals holding valid green cards exercised decision-making over the contributions and the funds were not provided or reimbursed by any non-US legal entity. Such contributions do not constitute political donations or political expenditure for the purposes of the Companies Act 2006 and were made without any involvement of persons or entities outside the US.

#### **Significant agreements**

There are no significant agreements to which the Company is a party that take effect, alter or terminate on a change of control of the Company following a takeover bid.

There are no persons, with whom the Company has contractual or other arrangements, who are deemed by the Directors to be essential to the business of the Company.

# Use of financial instruments

Notes 15 and 16 to the Financial Statements, from pages 144 and 146 respectively, include further information on the Group's use of financial instruments.

# **Creditor payment policy**

It is not Group policy formally to comply with the Confederation of British Industry's code of practice on the prompt payment of suppliers. It is, however, Group policy to agree to appropriate payment terms with all suppliers when agreeing to the terms of each transaction, to ensure that those suppliers are made aware of the terms of payment and, subject to their compliance, abide by the terms of payment. The total amount of money owed by the Company's subsidiaries to trade creditors at the balance

sheet date was equivalent to 56 days' average purchases (2008: 46 days). The methodology for this calculation has been amended in 2009 whereby rebates and chargeback accruals, previously included in this calculation, have been removed. The Company believes that as these amounts arise typically from our revenue arrangements, principally in the US, this methodology more accurately refects time taken on average to repay creditors. The comparative calculation for the prior year is also presented under the new methodology. A considerable part of the trade creditors balance relates to the Merck account in the US, which has particularly long contractual payment terms. By removing this balance and other items not directly related to trade purchases in the US, a more accurate average of 47 days is obtained (2008: 40 days).

The Company has no external trade creditors.

#### **Annual General Meeting**

The Company's AGM will be held on 29 April 2010. The meeting place will be in London. A Notice of AGM will be sent to all registered holders of Ordinary Shares and, where requested, to the beneficial holders of shares.

#### **External auditor**

A resolution will be proposed at the AGM on 29 April 2010 for the re-appointment of KPMG as auditor of the Company.

The external auditor has undertaken various non-audit work for the Company during 2009. More information about this work and the audit and non-audit fees paid by the Company are set out in Note 27 to the Financial Statements on page 185. The external auditor is not engaged by the Company to carry out any non-audit work on which it might, in the future, be required to express an audit opinion. As explained more fully in the Audit Committee section from page 94, the Audit Committee has established pre-approval policies and procedures for audit and non-audit work permitted to be carried out by the external auditor and has carefully monitored the objectivity and independence of the external auditor throughout 2009.

#### **Bureau Veritas**

Bureau Veritas UK Limited (Bureau Veritas) has provided external assurance on corporate responsibility related information within this Annual Report and of the detailed content of the 'Responsibility' section of our website. Bureau Veritas has found the information provided within this Annual Report to be accurate and reliable (based on the evidence provided and subject to the scope, objectives and limitations defined in the full assurance statement). The full assurance statement which contains detailed scope, methodology, overall opinion and recommendations can be found on AstraZeneca's website, astrazeneca.com; web page content assured by Bureau Veritas is marked at the bottom of each page.

Bureau Veritas is an independent professional services company that specialises in quality, health, safety, social and environmental management with a long history of providing independent assurance services, and an annual turnover in 2008 of €2.6 billion.

On behalf of the Board

# A C N Kemp

Company Secretary

28 January 2010

# My introduction to the 2009 Directors' Remuneration Report seeks to give context to the pages that follow.

As we indicated in last year's Directors' Remuneration Report, the Remuneration Committee has undertaken and completed a review of Executive Director and SET member remuneration during the course of the year. As part of this process, we have consulted a number of institutional investors, and are grateful for their contribution to the development of our proposals.

We have concluded that the fundamental principles that underpin the Company's approach to remuneration remain appropriate for the business and our current strategy. At the same time, we now have the opportunity, by developing our compensation structures, to build on the historical financial success of the Group, to invest for the future, and to focus on stewardship and shareholder value-creation over the long term. We are therefore proposing to reshape the Group's long-term incentive arrangements, not to increase the overall value of the package, but to recognise that AstraZeneca operates in a uniquely long-term industry. We aim to strengthen thereby the alignment between the time horizons over which our business investment decisions are taken and those to which our share incentive programmes relate.

You will see that we are proposing the introduction of a new share plan (to operate alongside the existing Performance Share Plan and simultaneous with the cessation of further grants of options under the Share Option Plan) with an eight-year time horizon. Shareholders have been receptive to a long-term plan of this nature, conditional on sustainable financial performance and delivery of shareholder returns. At the same time, our discussions with investors have recognised that the long-term nature of the plan means that the Remuneration Committee should retain some flexibility as to the operation of the plan to ensure that this combination of incentive structures supports the best interests of the business and shareholders over the medium and long term.

The 2009 Directors' Remuneration Report which follows describes the key principles that have informed the Remuneration Committee's thinking, and provides a summary of the proposals themselves. We will seek shareholder approval for the new share plan at the AGM on 29 April 2010. Detailed plan terms, along with the specific performance requirements that will apply to the initial awards, will be set out in the circular sent to shareholders in advance of the AGM.

These proposals will facilitate the delivery of AstraZeneca's business strategy. They explicitly reflect the discussions that we have had with shareholders. On behalf of the Remuneration Committee, I commend them to you.

#### John Varley

Non-Executive Director Chairman of the Remuneration Committee

# Directors' Remuneration Report

This Directors' Remuneration Report (Report) has been prepared in accordance with the Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 (Regulations) and meets the relevant requirements of the Financial Services Authority's Listing Rules. As required by the Regulations, a resolution to approve this Report will be proposed at the AGM on 29 April 2010.

The following sections of this Report, up to and including the Non-Executive Directors section on page 110, were not subject to audit by KPMG.

# Remuneration Committee membership and meetings

The members of the Remuneration Committee (Committee) are John Varley (Chairman of the Committee), John Buchanan, Louis Schweitzer and Nancy Rothwell. They are all Non-Executive Directors. The Board considers them all to be independent (Louis Schweitzer was considered by the Board to be independent upon his appointment as Chairman; in accordance with the Combined Code, the test of independence is not appropriate in relation to the Chairman after his appointment). The independence of the Non-Executive Directors is discussed in more detail in the Business Organisation and Corporate Governance section from page 87. The Company Secretary acts as the secretary to the Committee.

The Committee met six times in 2009. The individual attendance record of members of the Committee is set out in the Board and Committee meeting attendance in 2009 table on page 92.

At the invitation of the Committee, except where their own remuneration was being discussed, David Brennan (CEO); Lynn Tetrault (Executive Vice-President, Human Resources and Corporate Affairs); Simon Appleby (Vice-President, Performance and Reward); and Viv Gill (Vice-President, Global Compensation) attended Committee meetings in 2009 and provided advice and services that materially assisted the Committee. On one occasion in 2009, the Committee invited Simon Lowth (CFO) to attend a meeting to provide background information about performance measures that materially assisted the Committee in connection with its review of long-term incentive (LTI) arrangements for SET members. This was part of the overall review of the remuneration of SET members, including that of Executive Directors, which began in 2009 and is referred to in more detail below.

The Committee retains Carol Arrowsmith of Deloitte LLP (Deloitte) who provided independent advice on various matters it considered in 2009. During the year, Deloitte also provided taxation advice and other non-audit services to the Company.

# Committee terms of reference and key activities during the year Committee terms of reference

A copy of the Committee's terms of reference is available on the Company's website, astrazeneca.com, or by request from the Company Secretary.

The role of the Committee is to develop and deploy remuneration policies and practices for senior management, and for the Group more broadly, that support the implementation of our business strategy and which thereby help the organisation to create value for shareholders over time. The Committee has responsibility for determining on behalf of the Board the individual compensation paid to Executive Directors and SET members. It takes responsibility on behalf of the Board for reviewing the design and operation of total compensation structures and practices across AstraZeneca. In this regard, the Committee's approval is required in relation to, amongst other things, decisions regarding:

- > The eligibility, structure, award/grant levels, performance metrics and targets, costs and final vesting levels under LTI plans for Directors, other SET members and the Company Secretary.
- > Annual bonus payments for Executive Directors, other SET members and senior executives below SET level.
- > The pension entitlements of Executive Directors and other SET members.
- > The Chairman of the Board's remuneration (which is approved by the other members of the Committee and the senior independent Non-Executive Director).
- > Any single payment or award over \$1 million.
- > Shareholding guidelines for Executive Directors and other SET members.
- > The contractual terms and conditions of, and any potential or actual payments arising on termination to, Executive Directors, other SET members and the Company Secretary so as to ensure that they are fair to the individual and the Company, that failure is not rewarded and that the duty to mitigate loss is fully recognised.

The Committee will again conduct a review of its terms of reference during 2010, taking advice as appropriate from its external adviser.

### Key activities during the year

The Committee considered the following principal matters during 2009:

> The strategic review of the remuneration and incentive framework for Executive Directors and other SET members. This has represented a considerable proportion of the Committee's activities and focus during the course of the year. As part of its review, the Committee has undertaken a significant consultation with major shareholders and institutional investor organisations.

- > A review of the terms of senior executives' remuneration packages on appointment, promotion and termination.
- > The assessment of Company and individual performance against performance targets to determine the level of executive bonuses for 2008 and to set executive bonus performance targets for 2009.
- > The approval of awards made under the Group's main LTI plans: the AstraZeneca Performance Share Plan (PSP); the AstraZeneca Share Option Plan (SOP); and the AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan (RSU Plan) to SET members and other participants.
- A review of the Company's governance arrangements for global compensation matters.
- A benchmarking review of the Committee's activities and policies against institutional investor guidelines.
- A review of the pension entitlements of Executive Directors and other SET members.
- > A review of the impact on compensation policies and practices of the current economic environment, including ensuring the appropriate degree of risk adjustment to aggregate and individual compensation decisions.
- > The preparation, review and approval of this Report.

# **Review of SET remuneration**

The 2008 Directors' Remuneration Report explained that the Company would undertake a review of total remuneration for SET members (including Executive Directors) during 2009. This review is now drawing to a close and has led to the development of the forward-looking remuneration policy disclosed in this Report.

There were a number of factors that prompted this review:

> When the PSP was approved by shareholders at the AGM in early 2005 (following the last full-scale review of executive remuneration), the Committee undertook to review its operation within a period of five years, and to take into account the views of the Company's shareholders and the needs of the business at that time.

- Shareholder approval to operate the SOP expires during May 2010. This provided the Company with a natural opportunity to review the current approach to remuneration, pay policies and incentive structures and to consider how these may best be developed to support the business strategy going forward.
- > The Committee is aware that the subject of executive remuneration is much on the minds of shareholders and that, since its last review, a great deal has changed both in the general market and the corporate governance landscape and in the shape of, and strategic challenges faced by, the global pharmaceutical industry.

In conducting this review, the Committee has been mindful of shareholder views and expectations, and has sought to give major shareholders an opportunity to influence the direction of the proposals by dialogue during the course of the review.

# Key remuneration principles

The Committee concluded that the following objectives should continue to define its approach to the formation and execution of AstraZeneca's remuneration policy:

- > All aspects of executive remuneration should be developed in the context of shareholder views on 'best practice' and be designed to help AstraZeneca create sustainable growth in shareholder value by the successful implementation of strategy.
- > Reward structures and performance measures should support a strong performance culture enabling delivery of the business strategy, where all employees have a clear understanding of the Group's objectives, how their work will impact those objectives and how they will benefit from delivering high levels of performance.
- > Base pay and total compensation positioning against the market should be appropriate to attract and develop high-calibre talent and SET remuneration should continue to be referenced to competitive levels of remuneration in the relevant local markets.

Additionally, some specific objectives have been established as a consequence of the review. These support the introduction of a new incentive structure to allow us to rebalance our LTI framework and include the following:

- > A clear desire in the business, supported by the Committee, to move towards a longer-term framework which will strengthen alignment with the inherently long-term nature of pharmaceutical drug development.
- > Revised LTI structures, designed to provide a clear focus for the business to outperform our industry peers over time, to deliver operational efficiency and to engender a strong sense of stewardship that will deliver long-term sustainable shareholder value.

No other element of Executive Director or SET remuneration will change as a consequence of the review. In particular, there is no intention to increase the overall quantum of short-term bonus or long-term reward opportunity and the annual incentive structure remains unchanged.

The review has also concluded that the shareholding guidelines for Executive Directors and other SET members will be increased from current levels and, as such, the shareholding requirement for the CEO is being increased to 200% of base salary (from 100%) and the requirement for all other Executive Directors and SET members will be increased to 125% of base salary (from 100%).

#### Long-term share plans

The SOP will expire during 2010 and the review has concluded that no further grants will be made under the SOP.

From 2010 onwards, and subject to shareholder approval of the new share plan, it is proposed that the long-term share interests of Executive Directors and other SET members will be provided through two complementary share plans as detailed below.

The PSP will continue to operate. However, performance conditions will be rebalanced so that the current relative TSR performance condition will apply in respect of one half of any award made under the PSP (as opposed to 100%, as under the current terms of the PSP). The other half of the award will be subject to a new cash flow performance measure that will improve the focus on operational management of the business that is consistent with generating value for shareholders. We have chosen a cash flow measure because it will encompass all elements of operational and financial performance, represents a strong proxy through time for shareholder value-creation and is a key measure for the Group. In conjunction with this new measure, the TSR performance condition will continue to strengthen the focus on outperformance of competitors.

Shareholder approval will be sought at the AGM in April 2010 for the introduction of a new share plan called the AstraZeneca Investment Plan (AZIP) (to operate alongside the existing PSP) with an eight-year time horizon. Shareholders have been receptive to a long-term plan of this nature, conditional on sustainable shareholder returns and financial performance. Such a plan will provide annual awards to Executive Directors and other SET members which must be held for a total of eight years and are subject to a four-year performance requirement from the date of award.

The greater weighting within the LTI opportunity will be given to awards under the PSP. For 2010, awards under the PSP will be positioned so that interests under this plan can deliver 75% of the overall expected value from long-term remuneration. 25% of the overall long-term opportunity for 2010 will therefore be delivered through the AZIP. The Committee will keep under review the appropriateness of this weighting.

The combination of awards under these two plans will fundamentally improve the alignment between the time horizons over which our business investment decisions are taken and those to which our long-term remuneration vehicles relate.

# Performance conditions for the PSP

To date, awards to Executive Directors and other SET members under the PSP were subject to a TSR-only performance condition.

For awards to be made in 2010 under the PSP, it is intended that:

- > 50% of the award will be based on relative TSR against a selected peer group of global pharmaceutical companies, of which:
  - 25% of the maximum award will vest for performance at the median of the peer group; and
  - 75% of the maximum award will vest for upper quartile performance; the Committee will retain its existing discretion to determine the amount of vesting for performance significantly above upper quartile, up to 100% of the maximum award.
- > 50% of the award will vest subject to the achievement of a free cash flow target, which will operate as a cumulative cash flow target over a three-year performance period.

This free cash flow measure has been chosen because it encompasses a number of important elements of operational and financial performance and helps to align executives' rewards with shareholder value-creation. The level of vesting of this element will be based on a sliding scale against a target that is intended to represent a significant challenge for the business. It is intended that the Committee should have the discretion to adjust, but on an exceptional basis only, the free cash flow target during the performance period for material factors that might otherwise distort the performance measure in either direction. This is so that performance can be assessed against targets that have been set on a consistent basis. For example, adjustments may be required to reflect exchange rate movements, significant acquisitions or divestments and major legal and taxation settlements. Any major adjustments to the calculation will be disclosed to shareholders. There will be no retesting of performance. Further information about the applicable free cash flow target will be set out in the Notice of AGM and shareholders' circular.

# Performance requirement for awards under the AZIP

The AZIP will be aligned to AstraZeneca's targeted product development cycle, reflecting the long term investment horizons that are a feature of the industry. The performance requirements attached to awards under the AZIP will be a combination of dividend and dividend cover tests, assessed over a period of up to four financial years beginning at the start of the first financial year of the Company in which the award is granted. A subsequent sale restriction will apply over a period that extends to the full eight-year period, during which time forfeiture provisions will usually apply. Accordingly, participants will not generally be able to realise value until the full eight-year period has elapsed.

The Committee's intention in its choice of proposed performance tests has been to establish a performance requirement that motivates financial business performance that will generate returns for shareholders on a sustainable basis over an extended time period. Further details relating to the proposed performance requirement and targets for 2010 awards will be provided in the Notice of AGM and shareholders' circular.

# **Components of remuneration**

Component of remuneration	Role within the remuneration framework	Summary of Policy	Applies to	
Base salary (fixed)	Base fixed remuneration.	Based on conditions in the relevant geographic market and recognising the value of an individual's sustained personal performance and contribution to the business, taking account of the market rate for an individual's skills and experience. Benchmarked against external comparators.	All employees	
Pension arrangements (fixed)	Provision of retirement benefits.	Benchmarked against the relevant local employment market.	All employees	
Benefits (fixed)	Provision of standard non-cash employment benefits, such as healthcare, insurances and, for certain employees, facilitated car purchase arrangements.	Cost-effective and compatible with relevant welfare arrangements and local market norms.	All employees	
Short-term bonus (variable)	An annual cash incentive opportunity determined by reference to Group, functional and individual performance, measured over a single financial year of the Company and taking into account external expectations	Differs by market, but the Group performance measures ensure that all eligible employees receive an element of reward based on the Company's overall financial performance.	All eligible employees	
	of performance.	The functional goals are agreed by the Committee at the start of the year and are derived from the business scorecard, the key elements of which are set out in the Strategy, objectives and 2009 performance table from page 16, and are monitored as part of the quarterly business review (QBR) process.		
		Individual goals are based on annual objectives, which are linked to functional goals.		
Deferred bonus plan (variable)	Aligns SET members' interests with those of shareholders.	SET members must defer a proportion of their short-term bonus (currently one-third of pre-tax bonus for Executive Directors and one-sixth for other SET members) into Ordinary Shares or ADSs for a three-year period.	SET members	
LTI plans (variable) – for more nformation on these plans see the LTI plans section from	Long-term equity incentive awards to provide individual executives and employees with total compensation opportunities that	AstraZeneca Performance Share Plan.	SET members and other senior executives	
page 107	are competitive against local market practice, for the achievement of operational excellence, strong financial performance and	AstraZeneca Investment Plan (from 2010, subject to shareholder approval).	SET members	
	actions that are closely aligned with the interests of shareholders. Subject to shareholder approval, the primary LTI plans in which DTT results are found to the shareholder approval.	Share Option Plan (final awards made in 2009).	Senior management and SET members	
	in which SET members participate from 2010 will be the PSP and the AZIP.	Global Restricted Share Plan (from 2010, replacing existing restricted stock unit plans).	Eligible employees globally	
		Examples include the Share Incentive Plan and Savings-Related Share Option Plan (UK) <sup>1</sup> .	Eligible employees	
Shareholding guidelines         Aligning SET members' interests with those of shareholders.		The current expectation is for SET members to hold shares with a value equivalent to their base salary. From 2010, the CEO will be expected to hold shares equivalent to 200% of base salary and the CFO and other SET members will be expected to hold 125% of base salary in shares.	SET members	
Overall approach	When eccessing the overall value of a SET me	mber's remuneration the Committee considers	both separately and in aggregat	

<sup>1</sup> Further information on these plans is provided in Note 24 to the Financial Statements from page 161.

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# 2010 proposed components of SET remuneration

Fixe	d Elements	Variable Elements			
Basic	c salary	Linked to short-term performance		Linked to long-term performance	
Pens	ion	Bonus		AstraZeneca Investment Plan	
Bene	fits (such as healthcare)	Deferred Bonus Plan (share-based)		Performance Share Plan	

# 2009 components of remuneration

During 2009, the remuneration components for all Group employees (including those of SET members) comprised fixed and variable performance-related elements. Summaries of these elements are included in the table on page 104.

The way in which these elements of remuneration are combined and applied varies according to a range of factors, including specific business needs and practices in different markets, although, in general, the more senior the role within the business, the greater the proportion of total remuneration is made up of variable performance-related elements. The Committee seeks to ensure that the overall proportion of variable pay to which Executive Directors and other SET members may become entitled forms a significant part of their overall remuneration opportunity. The Committee's objective for senior management is to ensure that such variable pay is linked to a range of measures designed to promote both individual and team behaviour and performance in a way that supports the success of AstraZeneca and

creates value for its shareholders. Such measures are designed to stretch and challenge the relevant individuals whilst at the same time giving them an opportunity to participate as shareholders in the creation of long-term economic value.

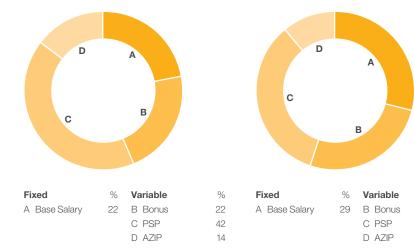
The Company has continued to take into account the wider business environment and employment conditions across the Group. In particular, no base pay increases were awarded in respect of the 2009 calendar year to Executive Directors or other SET members whose responsibilities were unchanged. In addition, award opportunities under the Group's LTI plan framework have been held at a consistent level since the adoption of the PSP in 2005.

For 2010, the Company will continue to benchmark against appropriate comparator companies and will assess whether or not and to what extent the overall opportunities for remuneration offered by the current structure of remuneration remain appropriate in the context of changes within the business and the external environment in which it operates.

**Chief Financial Officer** 

#### **Components of remuneration – expected value basis**

# **Chief Executive Officer**



### Executive Directors' base salaries in 2009 and 2010

	Annual salary in 2009	Annual salary in 2010	Increase
Executive Director	£	£	%
David Brennan	972,900	972,900	-
John Patterson <sup>1</sup>	540,000	n/a	n/a
Simon Lowth	550,000	620,000	13

<sup>1</sup> John Patterson retired from the Board on 31 March 2009.

# Remuneration and terms of employment for Executive Directors and other SET members Illustration of fixed and variable performance-related remuneration

Based on AstraZeneca's remuneration policy, the Components of remuneration expected value basis charts below illustrate the potential weighting given to fixed and variable performance-related elements of the remuneration package at Executive Director level. Variable performance-related elements of the package are shown on an 'expected value' basis, and in the event that performance conditions are not met, such elements would not deliver any value. The 'expected value' approach considers the range of possible outcomes and the probability attached to each, in order to provide a value that represents the average that would be delivered if the arrangements were operated over many years. The 'expected value' for bonus payment is taken to be the target payout level.

#### **Fixed remuneration**

Both Executive Directors' terms and conditions are UK-based and are benchmarked against external UK comparators, apart from David Brennan's pension and health insurance arrangements, which are described below.

#### Base salary

%

26

34

11

The base salary for Executive Directors and other SET members is determined by the Committee. Salary decisions reflect the experience and performance of the individuals to whom they apply, taking account of market competitiveness and the level of increases applicable to employees in the wider Group. The Committee has again decided that in the case of the CEO and those SET members (other than the CFO) whose responsibilities are unchanged, there will be no salary increases for 2010. For Executive Directors and other SET members, the policy has been to position salaries at the median of the relevant market. In accordance with this policy, and given that his base salary has remained at the same level since he was appointed as an Executive Director in 2007, Simon Lowth (CFO) has been awarded a base salary increase, effective from 2010, illustrated in the table opposite.

The base salaries of Executive Directors are set out opposite.

### Pension arrangements

The table in the Defined benefit arrangements section on page 113 gives details of the changes in the value of the Executive Directors' accrued pensions during 2009.

### CEO's pension arrangements

David Brennan is a member of the AstraZeneca US Defined Benefit Pension Plan (US DBP), by virtue of his membership of pension plans applicable to legacy Astra Merck employees. On his appointment to the Board, the rules of the US DBP were amended so as to remove bonus payments from the calculation of his pensionable pay. Benefits for members of the US DBP are delivered on a tax-qualified basis, with accrued benefits that exceed specific limits under the plan's formula and the US Tax Code being delivered through a supplementary, non-qualified plan.

The normal pension age under the US DBP is 65. However, on leaving or retiring from employment, David Brennan is eligible to take a pension or lump sum equivalent based on accrued service and final pensionable pay (ie without actuarial reduction) due to his satisfaction of a condition in the pension plan relating to the combined age and service exceeding 85 years, as previously disclosed.

David Brennan's participation in the US DBP is subject to a service cap at 35 years' service, which will be attained in January 2011, after which no further service accrual can be earned.

Members and, in the event of death, surviving spouses/dependants can elect, in relation to those benefits delivered on a tax-qualified basis under the US DBP, to take pensions in lump sum form based on actuarial valuation. Members or spouses/dependants may not make such an election in relation to any supplementary non-qualified benefits.

In addition, David Brennan (as a US citizen) is a contributing member of the US 401(k) savings plan<sup>1</sup>. He also contributes to an associated non-qualified plan, as described in the Defined contribution arrangements section on page 113.

In the event of a US participant becoming incapacitated then permanent health insurance cover will provide continuation of a proportion of salary, subject to the satisfaction of certain medical criteria. In the event of the death of a participant prior to retirement, a life assurance policy will provide surviving spouses/dependants with a lump sum equivalent to one times salary (such salary being capped at the maximum pensionable salary under the plan).

# UK Executive Directors' pension arrangements

UK Executive Directors have the option to participate in a UK pension plan according to their eligibility, or to take a cash allowance in lieu of pension. The cash allowance is consistent with the appropriate value of the alternative gross pension benefit.

John Patterson (formerly Executive Director, Development) elected to take the cash allowance in lieu of pension for the option year 1 July 2008 to 30 June 2009 (as detailed in the Defined contribution arrangements section on page 113).

In respect of pension accrued up to his retirement, he remained a member of the AstraZeneca main UK defined benefit pension plan (AstraZeneca Pension Fund). The normal pension age under this plan is 62. However, a member's accrued pension is available from age 60 without any actuarial reduction. John Patterson retired from the AstraZeneca Pension Fund on 6 April 2009 aged 61 and was eligible to take a pension based on accrued service and final pensionable pay. He opted to take a commutation lump sum on retirement, in lieu of part of his pension entitlement. This lump sum was calculated and granted in accordance with the rules of the AstraZeneca Pension Fund and amounted to £785,000. This reduced his pension entitlement after commutation to £303,000 per annum.

Pensions in payment are increased annually in line with inflation, as measured by the UK Retail Prices Index, up to a maximum of 5%.

Simon Lowth (CFO) is eligible to join the AstraZeneca main UK defined contribution pension plan (UK Defined Contribution Plan) at a company contribution rate of 24% of annual base salary or, alternatively, to take the company contribution as a cash allowance. For the option years 1 July 2008 to 30 June 2009 and 1 July 2009 to 30 June 2010, he elected to take the cash allowance (as detailed in the Defined contribution arrangements section on page 113).

In the event of a senior employee in the UK Defined Contribution Plan (or where an alternative cash allowance has been taken) becoming incapacitated, then permanent health insurance cover provides continuation of a proportion of salary subject to the satisfaction of certain medical criteria. In the event of death prior to retirement, dependants are entitled to a pension and/or lump sum secured from a multiple of 10 times salary.

#### Benefits

In conjunction with the majority of employers, certain benefits are made available to Executive Directors and other SET members via local benefits programmes offered by AstraZeneca. Benefits under these programmes typically include healthcare, insurances and facilitated car purchase arrangements.

### Variable performancerelated remuneration

Executive Directors and other SET members are eligible to participate in different elements of variable performance-related pay, which are described below. The decision as to whether or not in any given year they receive any or all of their elements of variable pay is determined by the Committee, which will typically have regard to the performance of the individual and the Group and will consider the elements of variable pay applicable to senior employees in other comparable organisations in making such a determination.

# Short-term bonus

#### Performance criteria

Executive Directors and other SET members are eligible for a short-term bonus. The basis for the payment of any short-term bonus is determined by reference to a range of factors linked to the underlying performance of AstraZeneca's business, the performance of the functional area for which the individual is responsible and the performance of the individual in his or her role.

Structure and assessment of performance As set out in the 2008 Directors' Remuneration Report, following a review by the Committee in 2008 of the performance criteria for the determination of annual bonuses for Executive Directors and other SET members, the performance criteria were adjusted in 2009 to align more closely with the current objectives and measures that are used by the business, and this approach will continue to apply for 2010. For 2010, the bonus ranges are the same as for 2009. The bonus deferral requirements, described in more detail below, are also unchanged for 2010. Executive Directors' and other SET members' bonuses for 2009 were based on performance criteria linked to the following targets:

<sup>1</sup> The 401(k) savings plan is a qualified plan to which eligible employees may make salary-deferral contributions on a post-tax and/or pre-tax basis. Employers may also make matching or non-elective contributions to the plan. There is a supplementary non-qualified plan in place for all eligible employees whose earnings exceed specific limits.

- > 60% by reference to EPS, cash flow targets and the objectives in each of the strategic priority areas identified by the Board for the business, the key elements of which are set out in the Strategy, objectives and 2009 performance table from page 16 and which are monitored as part of the QBR against targets set by the Committee at the beginning of the year and taking into account external expectations of performance; and
- > 40% by reference to individual measures and initiatives which link to the business objectives relevant to the individual's functional accountability (or, in the case of the CEO, the average of these individual outcomes).

These measures reinforce AstraZeneca's emphasis on individual and business accountability. The key measures referred to above are clearly set out in the Strategy, objectives and 2009 performance table from page 16, whereby Group and functional objectives and measures are managed in a robust and consistent way and assessed by the SET as part of the QBR. The outcome of this process is rigorously scrutinised by the Board.

#### Bonus ranges for 2010

For 2010, the bonus ranges for each Executive Director are shown below and are the same as for 2009.

#### Bonus outcomes for 2009

In assessing bonuses for 2009, the Committee took into account the strong EPS (excluding restructuring and synergy costs) and cash flow performance, which in both cases significantly exceeded budget, together with overall business and financial outcomes and relevant functional performance against clear measures and initiatives set at the beginning of the bonus year. The key elements of these strategic priorities and business objectives are set out in the Strategy, objectives and 2009 performance table from page 16, in relation to the following categories, which the Committee believes are consistent with delivering shareholder value:

- > Strengthen the pipeline
- > Grow the business
- > Reshape the business
- Promote a culture of responsibility and accountability.

When assessing the performance of the business in these categories, the Committee noted that during 2009 there had been three significant regulatory approvals across various jurisdictions, four regulatory submissions, the agreement of three major late-stage in-licensing deals and the announcement of four co-promotion collaborations. These achievements were underpinned by a continuing emphasis on reshaping the business and annualising the benefits from restructuring, the strong sales performance of the Group despite the ongoing challenging economic environment and a level of employee engagement which was above the industry average.

Having assessed the Company's performance against all the measures set out above, the Committee is satisfied that the bonus payments that have been earned against stretching performance targets are fully justified.

The bonus outcomes for the Executive Directors for 2009 are shown in the table below.

## Bonus share deferral requirements

Consistent with best practice, the Committee has put in place a requirement that certain proportions of any short-term bonus payment (as specified below) be deferred and invested into Ordinary Shares or ADSs. Broadly, these are acquired on the open market at the prevailing market price and held for a period of three years from the date of acquisition before being delivered to individual Executive Directors and other SET members. This arrangement is one of the ways in which, over time, Executive Directors and other SET members will be able to build up a significant shareholding in the Company. The proportion currently deferred into shares is one-third of the pre-tax bonus for Executive Directors and one-sixth for other SET members. On leaving, participants would normally have to wait for the shares to be released at the end of the three-year period. For Executive Directors and other SET members who cease employment for reasons other than that of good leaver (for example, those who are dismissed), the deferred bonus award will lapse, unless the Committee decides otherwise before the cessation of employment.

### LTI plans

During 2009, Executive Directors and other SET members were eligible to be granted share option awards under the SOP and performance share awards under the PSP. The grant of such options and award of such shares were determined by the Committee, as were the performance targets that apply to their vesting and/or exercise. The PSP and the SOP were intended to align the interests of Executive Directors and other SET members with those of shareholders. For share option awards granted under the SOP, it is the expectation of the Committee that Executive Directors and other SET members will retain the net number of shares from the exercise of options for a period of not less than six months from the date of exercise. As described above. no further share option awards will be granted under the SOP and this plan will expire at the end of its 10-year life in May 2010. The Company will not be seeking re-approval of the SOP by shareholders. Those share option awards granted to date under the SOP will remain exercisable until those options lapse. For further information on the SOP, see the AstraZeneca Share Option Plan section on page 109.

#### Bonus ranges for 2010

	Bonus range for 2010
Executive Director	%
David Brennan	0-180
Simon Lowth	0-150

### Bonus outcomes for 2009

	Short-term bonus (delivered as a combination	on of cash and shares,
	as shown in the Directors' emoluments in 2009 s	ection from page 111) <sup>1</sup>
Executive Director	£000	% of salary
David Brennan	1,751	180
John Patterson <sup>2</sup>	187	138
Simon Lowth	825	150

<sup>1</sup>Bonuses for Executive Directors are not pensionable.

<sup>2</sup> John Patterson's bonus for 2009 was considered by the Committee in January 2010 and his bonus was based on his eligible earnings for the period in 2009 prior to his retirement on 31 March 2009.

## Shareholding guidelines

For Executive Directors and other SET members, the Committee has established target shareholding guidelines, under which it is expected that they build up their own shareholding in the Company. For 2009, the Committee's expectation was a shareholding with a market value approximately equivalent to their base salary. As a result of the review of the remuneration of SET members carried out in 2009, the Committee concluded that the target should be increased from 2010, such that the CEO will be expected to hold shares in the Company with a market value approximately equivalent to 200% of his base salary. For other Executive Directors and SET members, the guideline is a shareholding with a market value approximately equivalent to 125% of their base salaries. It is expected that these shareholding targets will be reached over a period of five years through shares delivered from the various LTI plans as well as the deferred part of the short-term bonus (described above).

# AstraZeneca Performance Share Plan

The PSP was approved by shareholders at the AGM in 2005 and provides for the grant of performance share awards (Share Awards) over Ordinary Shares or ADSs (together, Shares).

# Basis of participation

The Committee is responsible for setting the policy for the way in which the PSP should operate, including agreeing performance targets, identifying which employees should be invited to participate in the PSP and the level of Share Awards. Participation is highly selective and tends only to include senior employees on the basis of their performance. Share Awards are not pensionable and may not generally be assigned or transferred.

Generally, Share Awards can be granted at any time (although in practice they are awarded annually), but not during a close or prohibited period of the Company. In 2009, the main grant of Share Awards was made on 27 March, with other Share Awards approved by the Committee in relation to, for example, new appointments, promotions or assignments being granted on 28 August. The value of Shares subject to a Share Award is determined by reference to the market price of Shares over the three-day period immediately preceding the date of grant.

Details of Share Awards granted to Executive Directors are shown in the Performance Share Plan table on page 116.

### Performance conditions

Save in exceptional circumstances, which are prescribed in the PSP rules, the vesting of Share Awards is contingent on the satisfaction of specified performance targets and continued employment with the Group. In addition to the satisfaction of these performance targets, Share Awards will generally not vest until the third anniversary of the date of grant, although Share Awards may vest in part on a time pro-rated basis where a participant ceases to be in relevant employment under certain circumstances during the vesting period, to the extent that the performance targets have been met.

## Performance period and vesting dates

In the case of all Share Awards granted to date, the performance target relates to the three-year period commencing on 1 January of the year of grant. Therefore, for the Share Awards made in 2009, the performance period runs from 1 January 2009 to 31 December 2011. The vesting date is the third anniversary of the date of grant.

### Performance targets

For all Share Awards granted so far to Executive Directors and other SET members, including Share Awards granted in 2009, the performance target is the Company's TSR over the relevant three-year period compared with the TSR of a selected peer group of pharmaceutical companies for the same period. For share awards granted up to and including 2007 these companies were: Abbott Laboratories, Inc., BMS, Eli Lilly & Company, GlaxoSmithKline plc, Johnson & Johnson, Merck, Novartis AG, Pfizer Inc., F. Hoffmann-La Roche Ltd, Sanofi-Aventis, Schering-Plough Corporation and Wyeth Inc. As a result of corporate actions in the pharmaceutical sector during 2009, Schering-Plough Corporation and Wyeth Inc. have been removed from the peer group. As a result of this, the Committee has decided the following in relation to outstanding unvested awards:

- Share Awards in 2007: the TSR performance for Schering-Plough Corporation and Wyeth Inc. was adjusted from a date a week before the announcement of the relevant corporate action to the end of the relevant performance period so as to track the TSR of the acquiring companies (Merck in the case of Schering-Plough and Pfizer Inc. in the case of Wyeth Inc.).
- > Share Awards in 2008 and 2009: Schering-Plough Corporation and Wyeth Inc. were removed from the peer group thus reducing the size of the peer group to 10 companies (excluding AstraZeneca).

For these awards, AstraZeneca's TSR will be compared with the TSR for the 10 companies remaining in the peer group in respect of the relevant performance period.

TSR measures share price growth and dividends re-invested in respect of a notional number of shares, from the beginning of the relevant performance period to the end of it, and ranks the companies in the selected comparator group by reference to their TSR achieved over that period. The rank which the Company's TSR achieves over the performance period will determine how many Shares will vest under the relevant Share Award. For the purposes of future communications to shareholders and PSP participants, payouts against performance in relation to TSR for all existing and future Share Awards will be expressed as a percentage of the maximum Share Award currently payable, shown within a range of 0 to 100%. This new presentation is shown in the table below.

TSR ranking of the Company	Vesting percentage (%)
Below median	0
Median	25
Upper quartile	75
Between median and upper quartile	Pro rata
Significantly above upper quartile	Up to 100

To alleviate any short-term volatility, the return index is averaged in the TSR calculations for each company over the three months prior to the start and end of the relevant performance period.

In addition to the TSR performance target being met for each Share Award as set out above, the Committee also has to satisfy itself that achievement of the TSR performance target is a genuine reflection of the Company's underlying financial performance and has the discretion to prevent Share Awards from vesting or only to allow them to partially vest where this appears to the Committee to be warranted.

At the discretion of the Committee, more than 75% of the maximum Share Award may vest, up to the limit of the maximum award, if the Company's TSR performance is substantially better than that of the upper quartile of the comparator group. For Share Awards to vest at this level, the Company would need to have sustained a level of performance significantly in excess of upper quartile over a period of years and the Committee would need to be satisfied that this was warranted. The number of any additional Shares that may vest in this way may not exceed 25% of the total number of Shares made the subject of a Share Award on the date of grant. For those Share Awards to be made in 2010. as described above, 50% of the Share Awards will continue to be based on relative TSR against a selected peer group of pharmaceutical companies. The remaining 50% will vest subject to performance against an adjusted free cash flow target. In respect of these awards, the relevant peer group for the TSR measure will be: Abbott Laboratories, Inc., BMS, Eli Lilly & Company, GlaxoSmithKline plc, Johnson & Johnson, Merck, Novartis AG, Pfizer Inc., F. Hoffmann-La Roche Ltd and Sanofi-Aventis. Further information about the applicable free cash flow target will be set out in the Notice of AGM and shareholders' circular.

#### Individual limit

In respect of any financial year of the Company, the maximum market value of Shares that may be put under a Share Award in respect of an employee is 500% of that employee's base salary.

The actual individual limits that apply under the PSP, subject to this maximum, are set by the Committee from time to time.

### Performance under the PSP in 2009

The TSR graphs on page 114 show, for each Share Award, how the Company's TSR performance has compared with the TSR for the companies in the comparator group from the first day of the relevant performance period to 31 December 2009 and how the Company ranks against those other peer companies on this basis. We will continue to report on the performance of each Share Award against the relevant performance target during the relevant vesting period.

### Change of control provisions

On a change of control of the Company as a result of a general offer to acquire all of the Ordinary Shares in the Company, Share Awards will vest pro-rata to the time elapsed between the date of grant of the Share Award and the date of the change of control to the extent that the relevant performance targets have been met up to the date of the change of control (or the most practicable earlier date). The Committee will, however, have discretion to take into account any other factors it believes to be relevant in determining the extent to which Share Awards will vest in these circumstances.

### AstraZeneca Share Option Plan

The SOP was approved by shareholders at the AGM in 2000 and provided for the grant of share option awards (Option Awards) over Shares. The SOP was approved for a period of 10 years and will expire in May 2010. The Company will not be seeking re-approval of the SOP by shareholders.

### Basis of participation

The Committee was responsible for setting the policy for the way in which the SOP should operate, including agreeing performance targets and identifying which employees should be invited to participate and the level of Option Awards. Participation was highly selective and tended only to include senior employees on the basis of their performance (except in the US where for reasons of custom and practice, participation in the SOP was more widespread). Option Awards were not pensionable and may not generally be assigned or transferred.

In 2009, the main grant of Option Awards was made on 27 March, with other Option Awards approved by the Committee in relation to, for example, new appointments, promotions or assignments being granted on 28 August. The exercise price was fixed by reference to the market price of Shares over the three-day period immediately preceding the date of grant.

Details of Option Awards granted to Executive Directors are shown in the Share options table on page 118.

#### Performance conditions

The SOP rules require that the Committee, before agreeing to grant an Option Award to Executive Directors and others, considers whether or not the underlying performance of the Company justifies a grant. In addition, it must also be satisfied that each individual nominated is performing to the necessary standard.

In agreeing grants of Option Awards in 2009, the Committee took into account strong underlying financial performance and progress towards achieving longer-term goals.

The Committee also sought and received assurances that each individual proposed for the grant of an Option Award has been performing in a manner that justified a grant to them. There was some variation in the level of grants being proposed between individuals, to reflect differing levels of performance and their seniority within the business.

As well as taking into account these performance considerations at the point of granting Option Awards, the Committee imposed performance conditions in respect of the exercise of such Option Awards by SET members (including the Executive Directors) which, in the view of the Committee, were considered appropriately stretching. In order for Option Awards to vest, the EPS of the Group must increase at least in line with the UK Retail Prices Index plus 5% per annum on average, over a three year period, the base figure being the EPS for the financial year preceding the date of grant, with no retesting. In addition, since the review of executive remuneration in 2004, the Committee has included a condition that, if an event occurs which causes material reputational damage to the Company, such that it is not appropriate for the Option Awards to vest and become exercisable, the Committee can make a determination to reflect this.

# Change of control provisions

On a change of control of the Company as a result of a general offer to acquire all of the Ordinary Shares in the Company, any unvested Option Awards vest immediately following the change of control. All outstanding vested Option Awards can be exercised during the period of six months from the date of the change of control. The Company will use its reasonable endeavours to ensure that any Shares acquired from an exercise following a change of control are subject to the same terms as shares of the same class that were acquired under the general offer. Unexercised Option Awards will lapse at the end of the six-month period following a change of control or, if the Option Award is exchanged for an option relating to shares in a different company, the date of exchange, whichever is earlier.

### Dilution

The dilutive effect of the grants of Option Awards on the Company's issued share capital was also considered by the Committee, in accordance with its commitment, reflecting the guidance of the Association of British Insurers, that the percentage of the issued share capital that could be allocated under all of the Company's employee share plans over a period of 10 years should be under 10%. This commitment is applied by the Committee in practice as a limit, on average, of under 1% per annum. The Committee concluded that a grant of Option Awards to those SOP participants and individual Executive Directors proposed for a grant was appropriate given the level of performance achieved. None of the other LTI plans currently operated by the Company have a dilutive effect because they do not involve the issue and allotment of new Ordinary Shares but rather rely on the market purchase of Ordinary Shares or ADSs that have already been issued.

# Restricted Stock Unit Plans

The RSU Plan was introduced in 2007 and provides for the grant of restricted stock unit awards to selected employees (predominantly in the US). The MedImmune, Inc. Restricted Stock Unit Award Plan (MedImmune RSU Plan) was introduced in 2008 to make restricted stock unit awards to employees of Medlmmune. The RSU Plan and Medlmmune RSU Plan are used in conjunction with the SOP to provide a mix of restricted stock units and share options. Restricted stock unit awards typically vest on the third anniversary of the date of grant and are contingent on continued employment with AstraZeneca. In 2009, restricted stock unit awards were made under the RSU Plan and the Medlmmune Plan on 27 March. Neither the RSU Plan nor the Medlmmune RSU Plan are used to make restricted stock unit awards to Executive Directors or other SET members, nor may they operate in respect of newly issued Shares or Ordinary Shares transferred from treasury.

### **Global Restricted Stock Plan**

It is the intention of the Committee that during 2010 two currently operated restricted stock plans (the RSU Plan and the MedImmune RSU Plan) applicable to below SET-level employees will be discontinued. They will be replaced by a single new Global Restricted Stock Plan (GRSP) (again operated only for below SET-level employees and on broadly similar terms to the existing plans) for the purposes of simplifying the administration and operation of restricted stock awards. Awards granted under the GRSP will not involve the issue and allotment of new Ordinary Shares but rather rely on the market purchase of Ordinary Shares or ADSs that have already been issued. There is no intention to increase the overall quantum of awards applicable to target employees through the introduction of the GRSP.

### **Restricted Share Plan**

The AstraZeneca Restricted Share Plan (RSP) was introduced in 2008 and provides for the grant of restricted share awards (RS Awards) to key employees, excluding Executive Directors. RS Awards are made on an *ad hoc* basis with variable vesting dates and may not operate in respect of newly issued Shares or Ordinary Shares transferred from treasury. The RSP has been used twice in 2009 to make RS Awards to 12 employees. The Committee has responsibility for agreeing any RS Awards under the RSP and for setting the policy for the way in which the RSP should operate.

# Zeneca 1994 Executive Share Option Scheme

The Zeneca 1994 Executive Share Option Scheme (Zeneca Plan) was replaced by the SOP. The last grant of options under the Zeneca Plan was in March 2000. Certain Executive Directors and other SET members have options outstanding under the Zeneca Plan, all of which are exercisable, the performance conditions having been satisfied. A description of the Zeneca Plan can be found in Note 24 to the Financial Statements from page 161.

# Other plans

In addition to the plans described above, the Company operates a Share Incentive Plan and a Savings-Related Share Option Plan in the UK, both of which are HM Revenue & Customs approved plans. Certain Executive Directors and other SET members are eligible to participate in these plans, more detailed descriptions of which can be found in Note 24 to the Financial Statements.

### Service contracts

Details of the service contracts for each of the Executive Directors, including their notice periods, are set out below. Either the Company or the Executive Director may terminate the service contract on 12 months' notice. It is the Board's intention that, in the event of early termination of an Executive Director's employment, any compensation payable under his/her service contract should not exceed the salary and benefits that would have been received had the contractual notice period been worked and this may be further reduced in line with the Executive Director's duty to mitigate losses. None of the Executive Directors has any provision in their service contracts giving them a right to liquidated damages or an automatic entitlement to bonus for the duration of their notice period. Compensation for any bonus entitlement will be assessed initially as 'on target' but subject to adjustment by the Committee to take account of the particular circumstances of the termination.

# Policy on external appointments and retention of fees

Subject to the specific approval of the Board in each case, Executive Directors and other SET members may accept external appointments as non-executive directors of other companies and retain any related fees paid to them, provided always that such external appointments are not considered by the Board to prevent or reduce the ability of the executive to perform his or her role within the Group to the required standard. Such appointments are seen as a way in which executives can gain a broader business experience and, in turn, benefit the Company.

John Patterson retired as an Executive Director on 31 March 2009. During 2009, he continued to serve as a non-executive director of Cobham plc. In respect of such position, he retained the fees paid to him for his services which, during the period from 1 January to 31 March, amounted to £16,875.

### **Non-Executive Directors**

None of the Non-Executive Directors has a service contract but all have letters of appointment. The effective dates of appointment for each of the Non-Executive Directors are set out in the table opposite. In accordance with the Company's Articles, following their appointment, Directors must retire at each AGM and may present themselves for election or re-election. None of the Non-Executive Directors has any provision in their letter of appointment giving them a right to compensation payable upon early termination of their appointment. They are not eligible for performance-related bonuses or the grant of share options. No pension contributions are made on their behalf. None of the Non-Executive Directors has participated or will participate in any decision made by the Board in relation to the determination of their own fees. The Chairman's annual fee is £325,000, and the annual fees applicable to other Non-Executive Directors are set out opposite. In addition to the mandatory shareholding requirement imposed on all Directors under the Articles described in the Directors' shareholding section on page 99, in December 2008 the Board agreed that each Non-Executive Director should also be encouraged to build up, over time, a shareholding in the Company with a value approximately equivalent to the basic annual fee for a Non-Executive Director (£60,000) or, in the case of the Chairman, approximately equivalent to his annual fee (£325,000).

### Audit

The Directors' emoluments in 2009 disclosed in the Directors' emoluments in 2009 section from page 111 and the details of the Directors' interests in Ordinary Shares disclosed in the Directors' interests in shares section on page 115, have been audited by KPMG.

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### Details of Executive Directors' service contracts at 31 December 2009

	Date of	Unexpired term at	Notice
Executive Director <sup>1</sup>	service contract	31 December 2009	period
David Brennan	1 January 2006	12 months	12 months
Simon Lowth	5 November 2007	12 months	12 months

<sup>1</sup>Neither of the Executive Directors has any provision in their service contracts giving them a right to liquidated damages or an automatic entitlement to a bonus for the duration of their notice period.

# **Non-Executive Directors' terms and conditions**

	Effective date of
Non-Executive Director <sup>1, 2</sup>	appointment
Bo Angelin	24 July 2007
John Buchanan	25 April 2002
Jean-Philippe Courtois	18 February 2008
Jane Henney	24 September 2001
Michele Hooper	1 July 2003
Rudy Markham	12 September 2008
Dame Nancy Rothwell	27 April 2006
Louis Schweitzer	11 March 2004
John Varley	26 July 2006
Marcus Wallenberg	6 April 1999

<sup>1</sup>None of the letters of appointment applicable to Non-Executive Directors confers upon them any right to compensation payable on early termination of their appointment.

<sup>2</sup> Pursuant to the Articles, the continued appointment of each Non-Executive Director is subject to their election or re-election at each AGM.

# **Non-Executive Directors' fees**

Σ.
60,000
(an additional) 25,000
15,000
(an additional) 20,000
10,000
(an additional) 7,000
_

### **Directors' emoluments in 2009**

The aggregate remuneration, excluding pension contributions and the value of shares under option and shares subject to Share Awards, paid to or accrued for all Directors for services in all capacities during the year ended 31 December 2009 was £6.2 million (\$9.6 million). The remuneration of individual Directors is set out below in pounds sterling and US dollars. All salaries, fees, bonuses and other benefits for Directors are established in pounds sterling.

# **Directors' remuneration – pounds sterling**

	Salary	Bonus	Bonus	Taxable	Other payments	Total	Total	Total
	and fees	Cash	Shares <sup>1</sup>	benefits	and allowances	2009	2008	2007
Name	£000	£000	£000	£000	£000	£000	£000	2000
Louis Schweitzer	325	-	-	-	-	325	303	260
David Brennan	973 <sup>3</sup>	1,167	584	26	436 <sup>2</sup>	3,186	2,506	2,150
Simon Lowth	550	550	275	8	434	1,426 <sup>8</sup>	1,304	172
Bo Angelin	70	-	-	-	-	70	63	21
John Buchanan	110	-	-	-	-	110	96	69
Jean-Philippe Courtois	75	_	_	-	-	75	58	-
Jane Henney	85	_	_	_	_	85	76	57
Michele Hooper	100	_	_	_	-	100	90	64
Rudy Markham	75	_	_	-	-	75	23	-
Nancy Rothwell	92	_	-	-	_	92	80	54
John Varley	95	_	-	-	-	95	83	56
Marcus Wallenberg	60	_	_	-	-	60	53	40
Former Directors								
John Patterson <sup>6</sup>	135	187	-	3	1215	446 <sup>8</sup>	1,081	982
Håkan Mogren <sup>7</sup>	33	_	_	-	_	33	100	100
Others	_	_	_	_	-	-	_	463
Total	2,778	1,904	859	37	600	6,178	5,916	4,488

# **Directors' remuneration - US dollars**

	Salary and fees	Bonus Cash	Bonus Shares <sup>1</sup>	Taxable benefits	Other payments and allowances	Total 2009	Total 2008	Total 2007
Name	\$000	\$000	\$000	\$000	\$000	\$000	\$000	\$000
Louis Schweitzer	504	_	-	_	-	504	567	520
David Brennan	1,508 <sup>3</sup>	1,808	905	40	676 <sup>2</sup>	4,937	4,692	4,300
Simon Lowth	852	852	426	12	674	2,209 <sup>8</sup>	2,442	345
Bo Angelin	108	-	-	-	-	108	118	42
John Buchanan	170	_	-	_	-	170	180	138
Jean-Philippe Courtois	116	_	-	-	-	116	109	-
Jane Henney	132	-	-	-	-	132	142	114
Michele Hooper	155	_	-	_	-	155	169	128
Rudy Markham	116	_	-	-	-	116	43	-
Nancy Rothwell	143	-	-	-	-	143	150	108
John Varley	147	-	-	-	-	147	155	113
Marcus Wallenberg	93	_	-	-	-	93	99	80
Former Directors								
John Patterson <sup>6</sup>	209	290	-	5	188 <sup>5</sup>	692 <sup>8</sup>	2,024	1,965
Håkan Mogren <sup>7</sup>	51	_	-	-	-	51	187	200
Others	-	-	-	-	-	-	-	929
Total	4,304	2,950	1,331	57	931	9,573	11,077	8,982

<sup>1</sup> These figures represent that portion of the 2009 bonuses required to be deferred into Shares to be held for a three-year period, as explained in the Bonus share deferral requirements section on page 107.

<sup>2</sup> Relates to relocation allowances, a car allowance and cash payments in respect of dividends accrued on vesting of LTI share plan awards.

<sup>3</sup> This figure includes a sum of \$83,000/£54,000 in respect of member contributions to the AstraZeneca Executive Deferred Compensation Plan which were paid into the plan by means of a salary sacrifice (see the Defined contribution arrangements section on page 113 for further details).

 <sup>4</sup> Relates to remaining cash following selection of benefits within AstraZeneca's UK flexible benefits programme.
 <sup>5</sup> Relates to cash payments in respect of dividends accrued on vesting of LTI share plan awards and remaining cash following selection of benefits within AstraZeneca's UK flexible benefits programme. UK flexible benefits programme.

<sup>6</sup> Part-year only as ceased to be a Director on 31 March 2009.

<sup>7</sup> Part-year only as ceased to be a Director on 30 April 2009.

<sup>8</sup> Does not include a cash allowance received in lieu of pension (see the Defined contribution arrangements section on page 113 for further details).

For John Patterson, member contributions to the AstraZeneca Pension Fund of only a minimal amount for 2009 were paid through salary sacrifice, and as such no employee contributions are shown above or included within emoluments.

In the tables on this page and on the previous page, salaries have been converted between pounds sterling and US dollars at the average exchange rate for the year in question. These rates were:

	GBP/USD
2009	0.645
2008	0.534
2007	0.500

Executive Directors were also granted Share Awards and Option Awards. Details of share options granted to, and exercised by, Directors and the aggregate of gains realised on the exercise of options, and of awards under the LTI plans, in the year are given in the Share options section on page 118 and in the Gains by Directors on exercise of share options section on page 119.

No Director has a family relationship with any other Director.

#### Pensions

### **Defined benefit arrangements**

Pensions are payable to Directors in pounds sterling, with the exception of David Brennan's, whose pension is payable in US dollars. For ease of understanding, the table below has been presented in both pounds sterling and US dollars using the exchange rates for 2009 set out above. Except where otherwise stated, figures for John Patterson (a former Executive Director) reflect the period to 31 March 2009 when he retired as a Director.

	David Brennan £000	John Patterson £000	David Brennan \$000	John Patterson \$000
Defined benefit arrangements				
1. Accrued pension at 1 January 2009	822	365	1,275	566
2. Increase in accrued pension during year as a result of inflation	_	-	_	_
3. Adjustment to accrued pension as a result of salary increase relative to inflation	77	-	119	-
4. Increase in accrued pension as a result of additional service	16	-	25	-
5. Accrued pension at 31 December 2009	915	365	1,419	566
6. Employee contributions during 2009	-	-	-	-
7. Transfer value of accrued pension at 31 December 2008	11,249	8,288	17,441	12,850
8. Transfer value of accrued pension at 31 December 20091	12,850	9,124	19,922	14,146
9. Change in transfer value during the period less employee contributions	1,600	836	2,481	1,296
10. Age at 31 December 2009	56 <sup>4</sup> /12	61%12	561/12	612/12
11. Pensionable service (years) at 31 December 2009	34	3310/12	34	3311/12

<sup>1</sup> The transfer value of John Patterson's accrued pension is calculated as at 6 April 2009, the date on which he retired from the AstraZeneca Pension Fund.

John Patterson opted to take a commutation lump sum on 6 April 2009 in lieu of part of his pension entitlement. This lump sum was calculated and granted in accordance with the rules of the plan and amounted to £785,000 (\$1,218,000). This reduced his pension entitlement after commutation to £303,000 per annum (\$470,000). For John Patterson, transfer values are calculated on the market related basis used by the AstraZeneca Pension Fund, in accordance with current UK legislation.

For David Brennan, transfer values are calculated to be consistent with the value of the lump sum distribution equivalent to his deferred accrued pension annuity. The minimum permissible value of such a lump sum distribution was modified in 2008.

For John Patterson, member contributions to the AstraZeneca Pension Fund of only a minimal amount for 2009 were paid through salary sacrifice, and as such no employee contributions are shown above or included within emoluments.

### **Defined contribution arrangements**

In addition to the defined benefit arrangements set out in the Defined benefit arrangements section above, David Brennan participates in a 401(k) plan. He also participates in AstraZeneca's Executive Deferred Compensation Plan (EDCP) which is operated as a supplemental non-qualified plan in respect of US employees should annual contributions exceed the limit applicable to contributions under the qualified 401(k) plan. Total employer matching contributions of \$98,000 (£64,000) were made to his 401(k) plan and EDCP during 2009 (2008: \$14,000 (£7,000)). David Brennan also made member contributions of \$83,000 (£54,000) by way of salary sacrifice to the EDCP (2008: \$nil). Additionally, in January 2009, David Brennan, along with other eligible participants in the EDCP, received an automatic one-off excess match employer contribution in respect of his eligible earnings for 2008 under the EDCP. This amounted to \$110,000 (£70,000) relating to the 2008 plan year, \$77,000 (£41,000) of which was disclosed in the 2008 Directors' Remuneration Report.

In addition to the defined benefit arrangements as described in the Defined benefit arrangements section above, John Patterson chose to receive a cash allowance in lieu of pension, which during 2009 amounted to £42,000 (\$65,000) (2008: £84,000 (\$157,000)).

As described in the UK Executive Directors' pension arrangements section on page 106, Simon Lowth chose to receive a cash allowance in lieu of pension, which during 2009 amounted to £132,000 (\$205,000) (2008: £132,000 (\$247,000)).

### **Transactions with Directors**

There were no material recorded transactions between the Company and the Directors during 2009 or 2008.

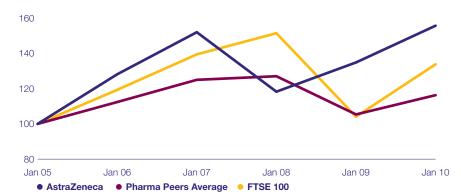
## **Total shareholder return**

The Regulations require the inclusion of a graph showing total shareholder return (TSR) over a five-year period in respect of a holding of the Company's shares, plotted against TSR in respect of a hypothetical holding of shares of a similar kind and number by reference to which a broad equity market index is calculated. The Company is a member of the FTSE 100 Index and consequently, for the purposes of this graph, which is set out opposite, we have selected the FTSE 100 Index as the appropriate index. This graph is re-based to 100 at the start of the rolling five-year period. We have also included a 'Pharma Peers Average' (excluding Schering-Plough Corporation and Wyeth Inc.), which reflects the TSR of the same comparator group used for the PSP graphs opposite.

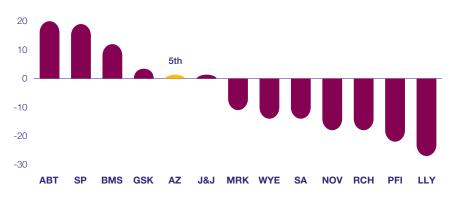
The PSP requires that the TSR in respect of a holding of the Company's shares over the relevant performance period be compared with the TSR of a peer group of pharmaceutical companies (as described in the Performance targets section on page 108). The graphs opposite show how the Company's TSR performance has compared with the TSR for the relevant companies in the comparator group from the first day in the relevant three-year performance period in respect of each Share Award to 31 December 2009 and how the Company ranks against those other companies on this basis.

To alleviate any short-term volatility, the return index is averaged in the TSR calculations for each company over the three months prior to the start of the relevant performance period (as stipulated in the PSP) and, for the purposes of the graphs opposite, over the last three months of 2009.

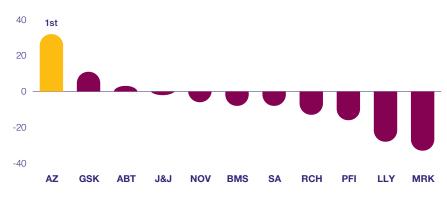
# TSR over a five-year period



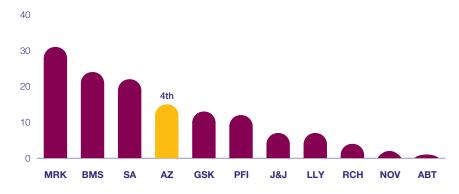
TSR – AstraZeneca compared with peer group 1 Jan 2007 to 31 Dec 2009 (for the 2007 award) %











# Directors' interests in shares

# **Beneficial interests**

The table below shows any change in the interests of the Directors (including the interests of their Connected Persons, as such term is defined in the Financial Services and Markets Act 2000) in Ordinary Shares from 1 January 2009 to 31 December 2009 or on the date of resignation of such Director (if earlier). All such interests were beneficial except as otherwise stated. However, interests in Ordinary Shares or ADSs that are the subject of Share Awards under the PSP and/or the AstraZeneca Deferred Bonus Plan discussed elsewhere, are not included in the table below but are shown in the Performance Share Plan and Deferred Bonus Plan tables on pages 116 and 117, respectively. None of the Directors has a beneficial interest in the shares of any of the Company's subsidiaries. Between 31 December 2009 and 28 January 2010, there was no change in the interests in Ordinary Shares shown in the table below.

Name	Beneficial interest in Ordinary Shares at 1 January 2009 or (if later) appointment date	Change to beneficial interest	Beneficial interest in Ordinary Shares at 31 December 2009 or (if earlier) resignation date
Louis Schweitzer	4,000	1,356	5,356
Håkan Mogren <sup>1</sup>	62,164	_	62,164
David Brennan	112,848	15,527 <sup>2</sup>	128,375 <sup>3</sup>
Simon Lowth	850	_	850
John Patterson⁴	8,640	20,877	29,517
Bo Angelin	500	287	787
John Buchanan	2,500	_	2,500
Jean-Philippe Courtois	500	2,135	2,635
Jane Henney	500	287	787
Michele Hooper	500	1,200	1,700
Rudy Markham	1,137	283	1,420
Nancy Rothwell	500	287	787
John Varley	500	_	500
Marcus Wallenberg	67,264	-	67,264

<sup>1</sup> Part-year only as ceased to be a Director on 30 April 2009.

<sup>2</sup> This figure represents the difference between the net number of ADSs acquired by David Brennan from the vestings of his 2006 Share Awards under the PSP and the AstraZeneca Deferred Bonus Plan and the net reduction in his notional beneficial interest in ADSs held within the unitised stock plans (see separate tables and footnotes below).

<sup>3</sup> The total number of Ordinary Shares and ADSs in which David Brennan has an interest (including potential interests in unreleased shares held in Company plans as detailed in the tables below) has increased in 2009 by 67,968 to 576,790 as at 31 December 2009.

<sup>4</sup> Part-year only as ceased to be a Director on 31 March 2009.

### **Unitised stock plans**

David Brennan, in common with other participating executives in the US, has interests which were awarded to him prior to him becoming CEO in the following plans: the AstraZeneca Executive Deferral Plan, the AstraZeneca Executive Deferred Compensation Plan and the AstraZeneca Savings and Security Plan. These are unitised stock plans into which the value of certain previous share incentive awards has been deferred (and are not incentive awards in their own right). Participants hold units in each plan, which represents a long-term equity interest in the Company. A unit comprises part cash and part ADSs. The overall unit value can be determined daily by taking the market value of the underlying ADSs and adding the cash position. The ADSs held within these units carry both voting and dividend rights. David Brennan is deemed to have a notional beneficial interest in these ADSs, calculated by reference to the fund value and the closing price of ADSs. Therefore, the number of ADSs in which a notional beneficial interest arises can vary daily as a consequence of stock price movements.

Unitised stock plan	ADSs held at 1 January 2009	Net ADSs acquired/(disposed) during 2009	ADSs held at 31 December 2009
AstraZeneca Executive Deferral Plan	40,940	(5,034)1	35,906
AstraZeneca Executive Deferred Compensation Plan	32,003	(32,003)1	-
AstraZeneca Savings and Security Plan	7,700	403	8,103

<sup>1</sup> These figures relate to scheduled distributions in February 2009.

No Director or senior executive beneficially owns, or has options over, 1% or more of the issued share capital of the Company, nor do they have different voting rights to other shareholders.

# **Performance Share Plan**

The interests of Directors at 31 December 2009 in Shares that are the subject of Share Awards under the PSP are not included in the table on the previous page but are shown below:

		Award price	Price on vesting date			
	Number of shares	pence	pence	Grant date <sup>1</sup>	Vesting date <sup>1</sup>	Performance period <sup>1</sup>
David Brennan						
2006 Share Award	73,109	2975	2287	24.03.06	24.03.09	01.01.06 - 31.12.08
2006 Share Award – Part 2	19,092	2848	2604	19.05.06	19.05.09	01.01.06 - 31.12.08
2007 Share Award	107,051	2744		30.03.07	30.03.10	01.01.07 - 31.12.09
2008 Share Award	161,546	1882		28.03.08	28.03.11	01.01.08 - 31.12.10
Total at 1 January 2009	360,798					
Partial vesting of 2006 Share Award <sup>2</sup>	(65,067) <sup>3</sup>		2287			
Partial lapse of 2006 Share Award	(8,042)					
Partial vesting of 2006 Share Award – Part 2 <sup>2</sup>	(16,992)4		2604		· · ·	
Partial lapse of 2006 Share Award – Part 2	(2,100)					
2009 Share Award	133,347	2280		27.03.09	27.03.12	01.01.09 - 31.12.11
Total at 31 December 2009	401,944					
John Patterson						
2006 Share Award	32,319	2975	2287	24.03.06	24.03.09	01.01.06 - 31.12.08
2007 Share Award	36,785	2744		30.03.07	30.03.10	01.01.07 - 31.12.09
2008 Share Award	57,385	1882		28.03.08	28.03.11	01.01.08 - 31.12.10
Total at 1 January 2009	126,489					
Partial vesting of 2006 Share Award <sup>2</sup>	(28,764)5		2287			
Partial lapse of 2006 Share Award	(3,555)					
Pro-rata forfeiture of 2007 Share Award	(12,183)6				·	
Pro-rata forfeiture of 2008 Share Award	(38,047)6					
Total at 31 March 2009	43,940 <sup>7</sup>					
Simon Lowth						
2007 Share Award	15,554	2210		16.11.07	16.11.10	01.01.07 - 31.12.09
2008 Share Award	58,448	1882		28.03.08	28.03.11	01.01.08 - 31.12.10
Total at 1 January 2009	74,002				·	
2009 Share Award	54,276	2280		27.03.09	27.03.12	01.01.09 - 31.12.11
Total at 31 December 2009	128,278					

<sup>1</sup> UK date convention applies. <sup>2</sup> Share Awards granted in 2006 vested in 2009 at 89% based on the outcome of the performance conditions and targets (which are set out in the AstraZeneca Performance Share Plan section from page 108).

<sup>4</sup> Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 38,389 Ordinary Shares.
 <sup>4</sup> Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 10,025 Ordinary Shares.
 <sup>5</sup> Following certain mandatory tax deductions, John Patterson became beneficially interested in a net number of 16,970 Ordinary Shares.

<sup>6</sup> In accordance with the PSP rules.

<sup>7</sup>The remaining 24,602 Shares of the 2007 Share Award and 19,338 Shares of the 2008 Share Award will vest on the relevant scheduled vesting date subject to the achievement of the performance conditions measured over the whole of the relevant performance period (as set out in the AstraZeneca Performance Share Plan-Performance conditions section on page 108).

## **Deferred bonus plan**

As described in the Bonus share deferral requirements section on page 107, there is a requirement for Executive Directors and SET members to defer a certain proportion of any short-term bonus payments into Ordinary Shares or ADSs. The proportion of bonus currently deferred into Ordinary Shares or ADSs is one-third of the pre-tax bonus for Executive Directors and one-sixth for all other SET members. The interests of Directors and former Directors at 31 December 2009, or on the date of resignation (if earlier), in Ordinary Shares or ADSs that are the subject of awards under these arrangements are not included in the table on the previous page but are shown below:

		Award price	Price on vesting date		
	Number of shares	pence	pence	Grant date <sup>1</sup>	Vesting date <sup>1</sup>
David Brennan					
2006 Award	6,352	2639	2415	24.02.06	24.02.09
2007 Award	12,014	2911		23.02.07	23.02.10
2008 Award	16,810	1999		25.02.08	25.02.11
Total at 1 January 2009	35,176				
Vesting of 2006 Award	$(6,352)^2$		2415		
2009 Award	17,992	2400		25.02.09	25.02.12
Total at 31 December 2009	46,816				
John Patterson					
2006 Award	6,623	2639	2415	24.02.06	24.02.09
2007 Award	5,600	2911		23.02.07	23.02.10
2008 Award	7,810	1999		25.02.08	25.02.11
Total at 1 January 2009	20,033				
Vesting of 2006 Award	(6,623)3		2415		
2009 Award	7,256	2400		25.02.09	25.02.12
Total at 31 March 2009	20,6664				
Simon Lowth					
2008 Award	1,340	1999		25.02.08	25.02.11
Total at 1 January 2009	1,340				
2009 Award	9,775	2400		25.02.09	25.02.12
Total at 31 December 2009	11,115				

<sup>1</sup> UK date convention applies.

<sup>2</sup> Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 3,747 Ordinary Shares.
 <sup>3</sup> Following certain mandatory tax deductions, John Patterson became beneficially interested in a net number of 3,907 Ordinary Shares.

<sup>4</sup> In accordance with the plan rules on leavers, John Patterson's 2007, 2008 and 2009 awards will vest on the relevant scheduled vesting date.

### Share options

The interests of Directors, and of former Directors who served during 2009, in options to subscribe for Ordinary Shares, granted under the SOP, the AstraZeneca Savings-Related Share Option Plan and the Zeneca Plan, are included in the following table. No options were exercised during 2009. All grants in 2009 were made under the SOP, unless otherwise indicated.

		Number of Ordinary Shares under option <sup>1</sup>	Exercise price per Ordinary Share <sup>2</sup>	First day exercisable <sup>3, 4</sup>	Last day exercisable <sup>3, 4</sup>
Håkan Mogren	At 1 January 2009	244,896	2848p	13.12.02	24.03.13
	- market price above option price	139,530	2499p	13.12.02	24.03.13
	- market price at or below option price	105,366	3309p	23.08.03	27.03.12
	At 30 April 2009 <sup>5</sup>	244,896	2848p	13.12.02	24.03.13
	– market price above option price	65,551	2231p	25.03.06	24.03.13
	– market price at or below option price	179,345	3073p	13.12.02	27.03.12
David Brennan	At 1 January 2009 – options over Ordinary Shares	432,959	2410p	24.03.09	27.03.18
	– market price above option price (Ordinary Shares)	322,318	2226p	30.03.10	27.03.18
	– market price at or below option price (Ordinary Shares)	110,641	2949p	24.03.09	18.05.16
	Granted 27 March 2009 (Ordinary Shares)	160,016	2280p	27.03.12	26.03.19
	At 31 December 2009 – options over Ordinary Shares	592,975	2375p	24.03.09	26.03.19
	– market price above option price (Ordinary Shares)	505,244	2271p	19.05.09	26.03.19
	– market price at or below option price (Ordinary Shares)	87,731	2975p	24.03.09	23.03.16
	At 1 January 2009 – options over ADSs	355,246	\$45.22	16.03.03	23.03.15
	– market price above option price (ADSs)	110,987	\$40.35	24.03.08	23.03.15
	<ul> <li>market price at or below option price (ADSs)</li> </ul>	244,259	\$47.44	16.03.03	25.03.14
	At 31 December 2009 – options over ADSs	355,246	\$45.22	16.03.03	23.03.15
	<ul> <li>market price above option price (ADSs)</li> </ul>	210,255	\$42.91	26.03.07	23.03.15
	<ul> <li>market price at or below option price (ADSs)</li> </ul>	144,991	\$48.58	29.03.04	27.03.12
Simon Lowth	At 1 January 2009	88,803	1951p	16.11.10	27.03.18
	<ul> <li>market price above option price</li> </ul>	88,803	1951p	16.11.10	27.03.18
	- market price at or below option price	-	n/a	n/a	n/a
	Granted 27 March 2009	65,131	2280p	27.03.12	26.03.19
	At 31 December 2009	153,934	2090p	16.11.10	26.03.19
	- market price above option price	153,934	2090p	16.11.10	26.03.19
	<ul> <li>market price at or below option price</li> </ul>	-	n/a	n/a	n/a
John Patterson	At 1 January 2009	305,396	2544p	25.03.02	27.03.18
	<ul> <li>market price above option price</li> </ul>	213,606	2279p	25.03.02	27.03.18
	- market price at or below option price	91,790	3163p	23.08.03	23.03.16
	Lapsed	(2,916)	2674p	25.03.02	24.03.09
	At 31 March 2009 <sup>6</sup>	302,480	2543p	16.03.03	27.03.18
	<ul> <li>market price above option price</li> </ul>	122,213	1991p	24.03.08	27.03.18
	- market price at or below option price	180,267	2917p	16.03.03	29.03.17

<sup>1</sup> Vesting is subject to satisfying the relevant performance conditions set out in each of the relevant share option plans. Further information on the performance conditions applicable to SOP is set out in the AstraZeneca Share Option Plan - Performance conditions section on page 109. As a Save-As-You-Earn scheme, the AstraZeneca Savings-Related Share Option Plan is not subject to any performance conditions. Awards granted under the Zeneca Plan are no longer subject to any performance conditions. <sup>2</sup>Exercise prices are weighted averages.

<sup>a</sup> First and last exercise dates of groups of options, within which period there are shorter exercise periods.
 <sup>4</sup>UK date convention applies.

<sup>5</sup>Håkan Mogren ceased to be a Director on 30 April 2009.
 <sup>6</sup>John Patterson ceased to be a Director on 31 March 2009.

# Gains by Directors on exercise of share options

The aggregate amount of gains made by Directors on the exercise of share options during the year and the two previous years is set out below. No options were exercised during 2009.

Year	Gains made by Directors on the exercise of share options \$	Gains made by the highest paid Director \$
2009	-	_
2008	1,764.96	_
2007	783,858.08	-

During 2009, the market price of Ordinary Shares or ADSs was as follows:

Stock Exchange	Ordinary Share/ADS market price as at 31 December 2009	Range of the Ordinary Share/ADS market price during 2009
London	2910.5p	2147p to 2947p
Stockholm	307.00 SEK	261.50 SEK to 356.00 SEK
New York	\$46.94	\$30.24 to \$47.54

On behalf of the Board

A C N Kemp

Company Secretary

28 January 2010

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# Preparation of the Financial Statements and Directors' Responsibilities

The Directors are responsible for preparing the Annual Report and Form 20-F Information and the Group and Parent Company Financial Statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Group and Parent Company Financial Statements for each financial year. Under that law they are required to prepare the Group Financial Statements in accordance with IFRSs as adopted by the EU and applicable law and have elected to prepare the Parent Company Financial Statements in accordance with UK Accounting Standards and applicable law (UK Generally Accepted Accounting Practice).

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and Parent Company and of their profit or loss for that period. In preparing each of the Group and Parent Company Financial Statements, the Directors are required to:

- > Select suitable accounting policies and then apply them consistently.
- > Make judgements and estimates that are reasonable and prudent.
- > For the Group Financial Statements, state whether they have been prepared in accordance with IFRSs as adopted by the EU.

- > For the Parent Company Financial Statements, state whether applicable UK Accounting Standards have been followed, subject to any material departures disclosed and explained in the Parent Company Financial Statements.
- > Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and the Parent Company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Parent Company's transactions and disclose with reasonable accuracy at any time the financial position of the Parent Company and enable them to ensure that its financial statements comply with the Companies Act 2006. They have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities.

Under applicable law and regulations, the Directors are also responsible for preparing a Directors' Report, Directors' Remuneration Report and Corporate Governance Statement that complies with that law and those regulations. The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the UK governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

# Directors' responsibility statement pursuant to DTR 4

The Directors confirm that to the best of our knowledge:

- > The Financial Statements, prepared in accordance with the applicable set of accounting standards, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole.
- > The Directors' Report includes a fair review of the development and performance of the business and the position of the issuer and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

On behalf of the Board of Directors on 28 January 2010:

David R Brennan Director

# Directors' Responsibilities for, and Report on, Internal Control over Financial Reporting

The Directors are responsible for establishing and maintaining adequate internal control over financial reporting. AstraZeneca's internal control over financial reporting is designed to provide reasonable assurance over the reliability of financial reporting and the preparation of consolidated financial statements in accordance with generally accepted accounting principles. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

The Directors assessed the effectiveness of AstraZeneca's internal control over financial reporting as at 31 December 2009 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, the Directors believe that, as at 31 December 2009, the internal control over financial reporting is effective based on those criteria.

KPMG Audit Plc, an independent registered public accounting firm, has audited the effectiveness of internal control over financial reporting as at 31 December 2009 and, as explained on page 123, has issued an unqualified report thereon.

# Auditor's Reports on the Financial Statements and on Internal Control over Financial Reporting (Sarbanes-Oxley Act Section 404)

The report set out below is provided in compliance with International Standards on Auditing (UK and Ireland). KPMG Audit Plc has also issued reports in accordance with auditing standards of the Public Company Accounting Oversight Board in the US, which will be included in the Annual Report on Form 20-F to be filed with the US Securities and Exchange Commission. Those reports are unqualified and include opinions on the Group Financial Statements and on the effectiveness of internal control over financial reporting as at 31 December 2009 (Sarbanes-Oxley Act Section 404). The Directors' statement on internal control over financial reporting is set out on page 122. KPMG Audit Plc has also reported separately on the Company Financial Statements of AstraZeneca PLC and on the information in the Directors' Remuneration Report that is described as having been audited. This audit report is set out on page 187.

# Independent Auditor's Report to the Members of AstraZeneca PLC

We have audited the Group Financial Statements of AstraZeneca PLC for the year ended 31 December 2009 set out on pages 124 to 186. The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the EU.

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's 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 and the Company's members, as a body, for our audit work, for this report, or for the opinions we have formed.

# Respective responsibilities of directors and auditors

As explained more fully in the Directors' Responsibilities Statement set out on page 122, the Directors are responsible for the preparation of the Group Financial Statements and for being satisfied that they give a true and fair view. Our responsibility is to audit the Group Financial Statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's (APB's) Ethical Standards for Auditors.

# Scope of the audit of the financial statements

A description of the scope of an audit of financial statements is provided on the APB's website, frc.org.uk/apb/scope/UKP.

# **Opinion on financial statements**

In our opinion, the Group Financial Statements:

- > Give a true and fair view of the state of the Group's affairs as at 31 December 2009 and of its profit for the year then ended.
- Have been properly prepared in accordance with IFRSs as adopted by the EU.
- > Have been prepared in accordance with the requirements of the Companies Act 2006 and Article 4 of the IAS Regulation.

# Separate opinion in relation to IFRSs as issued by the IASB

As explained in the Accounting Policies section to the Group Financial Statements set out on pages 128 to 132, the Group, in addition to complying with its legal obligation to apply IFRSs as adopted by the European Union, has also applied IFRSs as issued by the International Accounting Standards Board (IASB).

In our opinion, the Group Financial Statements comply with IFRSs as issued by the IASB.

# Opinion on other matter prescribed by the Companies Act 2006

In our opinion the information given in the Directors' Report for the financial year for which the Group Financial Statements are prepared is consistent with the Group Financial Statements.

# Matters on which we are required to report by exception

We have nothing to report in respect of the following:

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- Certain disclosures of Directors' Remuneration specified by law are not made.
- > We have not received all the information and explanations we require for our audit.

Under the Listing Rules we are required to review:

- > The Directors' Statement, set out on pages 128 and 129, in relation to going concern.
- > The part of the corporate governance statement relating to the Company's compliance with the nine provisions of the June 2008 Combined Code specified for our review.

# Other matters

We have reported separately on the Parent Company Financial Statements of AstraZeneca PLC for the year ended 31 December 2009 and on the information in the Directors' Remuneration Report that is described as having been audited.

## **Jimmy Daboo**

Senior Statutory Auditor

For and on behalf of KPMG Audit Plc Statutory Auditor Chartered Accountants 8 Salisbury Square, London, EC4Y 8BB

28 January 2010

# Consolidated Statement of Comprehensive Income for the year ended 31 December

Nets         Sm         S			2009	2008	2007
Cost of sales         (5,775)         (6,598)         (6,419)           Gross profit         27,029         25,003         23,140           Distrbution costs         (298)         (291)         (248)           Research and development         (4,409)         (5,179)         (5,162)           Selling, general and administrative costs         2         (11,332)         (10,913)         (10,080)           Operating income and expense         2         553         554         728           Operating profit         2         11,543         9,144         8,094           Finance expense         3         (14,99)         (1,177)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit before tax         7,544         6,130         5,627           Other Comprehensive Income:	Revenue		*	+	+
Gross profit         27,029         25,003         23,140           Distribution costs         (298)         (291)         (248)           Bessarch and development         (4,409)         (5,179)         (5,162)           Selling, general and administrative costs         2         (11,332)         (10,0913)         (10,0943)           Other operating income and expense         2         553         524         728           Operating profit         2         11,543         9,144         8,094           Finance income         3         462         854         959           Finance expense         3         (1,198)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,2551)         (2,356)           Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:         7         7544         6,130         5,627           Oreign exchange arising on consolidation         388         (1,336)         492         (40)           Gair/(Dos) on cash fow hedge in connection with debt issue         1         1         (20)         (21)           Int an		I	,	- ,	-,
Distribution costs         (298)         (291)         (248)           Research and development         (4,409)         (5,179)         (5,162)           Selling, general and administrative costs         2         (11,332)         (10,913)         (10,364)           Other operating income and expense         2         553         524         728           Operating profit         2         11,543         9,144         8,094           Finance expense         3         (462         854         959           Finance expense         3         (1198)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:				( , ,	
Research and development         (4,409)         (5,179)         (5,172)           Selling, general and administrative costs         2         (11,322)         (10,013)         (10,364)           Other operating income and expense         2         553         524         728           Operating profit         2         11,543         9,144         8,094           Finance income         3         462         854         9659           Finance expense         3         (1,198)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,883           Taxation         4         (3,263)         (2,551)         (2,356)           Profit before tax         7,544         6,130         5,527           Other Comprehensive Income:		· · · · · · · · · · · · · · · · · · ·	,		
Selling: general and administrative costs         2         (11,332)         (10,913)         (10,943)           Other operating income and expense         2         553         524         728           Operating profit         2         11,543         9,144         8,094           Finance income         3         462         854         959           Finance expense         3         (1,198)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:			. ,	( )	( - )
Other operating income and expense         2         553         524         728           Operating profit         2         11,543         9,144         8,094           Finance income         3         462         854         959           Finance expense         3         (1,188)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit before tax         7,544         6,130         6,627           Other comprehensive Income:		2		( , , ,	( , , ,
Operating profit         2         11,543         9,144         8,094           Finance income         3         462         854         959           Finance expense         3         (1,198)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit period         7,544         6,130         5,627           Other Comprehensive Income:				( , )	
Finance expense         3         (1,198)         (1,317)         (1,070)           Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:		2	11,543	9,144	8,094
Profit before tax         10,807         8,681         7,983           Taxation         4         (3,263)         (2,551)         (2,356)           Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:         Foreign exchange arising on consolidation         388         (1,336)         492           Foreign exchange differences on borrowings forming net investment hedges         (68)         291         (40)           Gain/(loss) on cash fow hedge in connection with debt issue         1         1         (21)           Net available for sale gains/(losses) taken to equity         2         2         (9)           Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         0         0         33         29         32           Owners of the Parent         7,521         6,101         5,595         Non-controlling interests         23         48	Finance income	3	462	854	959
Taxation         4         (3,263)         (2,551)         (2,366)           Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:	Finance expense	3	(1,198)	(1,317)	(1,070)
Profit for the period         7,544         6,130         5,627           Other Comprehensive Income:         Foreign exchange arising on consolidation         388         (1,336)         492           Foreign exchange differences on borrowings forming net investment hedges         (68)         291         (40)           Gain/(loss) on cash f ow hedge in connection with debt issue         1         1         (21)           Net available for sale gains/(losses) taken to equity         2         2         (9)           Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         0         0         5,955           Non-controlling interests         23         29         32           Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5,19         \$4,20         \$3,74           Diluted earnings per \$0.25 Ordinary Shares in issue (millions)         5         1,448 </td <td>Profit before tax</td> <td></td> <td>10,807</td> <td>8,681</td> <td>7,983</td>	Profit before tax		10,807	8,681	7,983
Other Comprehensive Income:           Foreign exchange arising on consolidation         388         (1,336)         492           Foreign exchange differences on borrowings forming net investment hedges         (68)         291         (40)           Gain/(loss) on cash f ow hedge in connection with debt issue         1         1         (21)           Net available for sale gains/(losses) taken to equity         2         2         (9)           Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:	Taxation	4	(3,263)	(2,551)	(2,356)
Foreign exchange arising on consolidation         388         (1,336)         492           Foreign exchange differences on borrowings forming net investment hedges         (68)         291         (40)           Gain/(loss) on cash f ow hedge in connection with debt issue         1         1         (21)           Net available for sale gains/(losses) taken to equity         2         2         (9)           Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:	Profit for the period		7,544	6,130	5,627
Index detailing of the gene schange differences on borrowings forming net investment hedges         (40)           Gain/(loss) on cash f ow hedge in connection with debt issue         1         1         (21)           Net available for sale gains/(losses) taken to equity         2         2         (9)           Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         0         0         32         29         32           Owners of the Parent         7,521         6,101         5,595         Non-controlling interests         23         29         32           Owners of the Parent         7,467         4,176         5,934         Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5,19         \$4.20         \$3,73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495 <td>Other Comprehensive Income:</td> <td></td> <td></td> <td></td> <td></td>	Other Comprehensive Income:				
Gain/(loss) on cash fow hedge in connection with debt issue         1	Foreign exchange arising on consolidation		388	(1,336)	492
Net available for sale gains/(losses) taken to equity         2         2         (9)           Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         0         0         5,595           Owners of the Parent         7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         0         7,467         4,176         5,934           Non-controlling interests         23         48         35         35         35,19         \$4,20         \$3,74           Diluted earnings per \$0.25 Ordinary Share         5         \$5,19         \$4,20         \$3,73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,493	Foreign exchange differences on borrowings forming net investment hedges		(68)	291	(40)
Actuarial loss for the period         (569)         (1,232)         (113)           Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:          7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:               Owners of the Parent         7,467         4,176         5,934            Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,453         1,498	Gain/(loss) on cash fow hedge in connection with debt issue		1	1	(21)
Income tax relating to components of Other Comprehensive Income         4         192         368         33           Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         7,467         4,176         5,934           Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5,19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5,19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,453         1,498	Net available for sale gains/(losses) taken to equity		2	2	(9)
Other Comprehensive Income for the period, net of tax         (54)         (1,906)         342           Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         7,521         6,101         5,595           Owners of the Parent         7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         7,467         4,176         5,934           Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5,19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,453         1,495	Actuarial loss for the period		(569)	(1,232)	(113)
Total Comprehensive Income for the period         7,490         4,224         5,969           Profit attributable to:         7,521         6,101         5,595           Owners of the Parent         7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         7,467         4,176         5,934           Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,453         1,498	Income tax relating to components of Other Comprehensive Income	4	192	368	33
Profit attributable to:         7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         0wners of the Parent         7,467         4,176         5,934           Owners of the Parent         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,453         1,498	Other Comprehensive Income for the period, net of tax		(54)	(1,906)	342
Owners of the Parent         7,521         6,101         5,595           Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         7,467         4,176         5,934           Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,493	Total Comprehensive Income for the period		7,490	4,224	5,969
Non-controlling interests         23         29         32           Total Comprehensive Income attributable to:         7,467         4,176         5,934           Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,493	Profit attributable to:				
Total Comprehensive Income attributable to:Owners of the Parent7,4674,1765,934Non-controlling interests234835Basic earnings per \$0.25 Ordinary Share5\$5.19\$4.20\$3.74Diluted earnings per \$0.25 Ordinary Share5\$5.19\$4.20\$3.73Weighted average number of Ordinary Shares in issue (millions)51,4481,4531,495Diluted weighted average number of Ordinary Shares in issue (millions)51,4501,4531,495	Owners of the Parent		7,521	6,101	5,595
Owners of the Parent         7,467         4,176         5,934           Non-controlling interests         23         48         35           Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,493	Non-controlling interests		23	29	32
Non-controlling interests234835Basic earnings per \$0.25 Ordinary Share5\$5.19\$4.20\$3.74Diluted earnings per \$0.25 Ordinary Shares in issue (millions)5\$5.19\$4.20\$3.73Weighted average number of Ordinary Shares in issue (millions)51,4481,4531,495Diluted weighted average number of Ordinary Shares in issue (millions)51,4501,4531,495	Total Comprehensive Income attributable to:				
Basic earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.74           Diluted earnings per \$0.25 Ordinary Share         5         \$5.19         \$4.20         \$3.73           Weighted average number of Ordinary Shares in issue (millions)         5         1,448         1,453         1,495           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,450         1,453         1,498	Owners of the Parent		7,467	4,176	5,934
Diluted earnings per \$0.25 Ordinary Share5\$5.19\$4.20\$3.73Weighted average number of Ordinary Shares in issue (millions)51,4481,4531,495Diluted weighted average number of Ordinary Shares in issue (millions)51,4501,4531,498	Non-controlling interests		23	48	35
Weighted average number of Ordinary Shares in issue (millions)51,4481,4531,495Diluted weighted average number of Ordinary Shares in issue (millions)51,4501,4531,498	Basic earnings per \$0.25 Ordinary Share	5	\$5.19	\$4.20	\$3.74
Diluted weighted average number of Ordinary Shares in issue (millions)51,4501,4531,498	Diluted earnings per \$0.25 Ordinary Share	5	\$5.19	\$4.20	\$3.73
	Weighted average number of Ordinary Shares in issue (millions)	5	1,448	1,453	1,495
Dividends declared and paid in the period         21 <b>3,026</b> 2,767         2,658	Diluted weighted average number of Ordinary Shares in issue (millions)	5	1,450	1,453	1,498
	Dividends declared and paid in the period	21	3,026	2,767	2,658

All activities were in respect of continuing operations.

\$m means millions of US dollars.

# Consolidated Statement of Financial Position at 31 December

		2009	2008	2007
	Notes	\$m	\$m	\$m
Assets				
Non-current assets				
Property, plant and equipment	7	7,307	7,043	8,298
Goodwill	8	9,889	9,874	9,884
Intangible assets	9	12,226	12,323	11,467
Derivative financial instruments	16	262	449	117
Other investments	10	184	156	182
Deferred tax assets	4	1,292	1,236	1,044
		31,160	31,081	30,992
Current assets				
Inventories	11	1,750	1,636	2,119
Trade and other receivables	12	7,709	7,261	6,668
Other investments	10	1,484	105	91
Derivative financial instruments	16	24	_	-
Income tax receivable		2,875	2,581	2,251
Cash and cash equivalents	13	9,918	4,286	5,867
		23,760	15,869	16,996
Total assets		54,920	46,950	47,988
Liabilities				
Current liabilities				
Interest-bearing loans and borrowings	14	(1,926)	(993)	(4,280)
Trade and other payables	17	(8,687)	(7,178)	(6,968)
Derivative financial instruments	16	(90)	(95)	(31)
Provisions	18	(1,209)	(600)	(387)
Income tax payable		(5,728)	(4,549)	(3,552)
		(17,640)	(13,415)	(15,218)
Non-current liabilities				,
Interest-bearing loans and borrowings	14	(9,137)	(10,855)	(10,876)
Derivative financial instruments	16		(71)	
Deferred tax liabilities	4	(3,247)	(3,126)	(4,119)
Retirement benefit obligations	23	(3,354)	(2,732)	(1,998)
Provisions	18	(477)	(542)	(633)
Other payables	17	(244)	(149)	(229)
		(16,459)	(17,475)	(17,855)
Total liabilities		(34,099)	(30,890)	(33,073)
Net assets		20,821	16,060	14,915
Equity			,	,
Capital and reserves attributable to equity holders of the Company				
Share capital	20	363	362	364
Share premium account	19	2,180	2.046	1,888
Capital redemption reserve	19	94	94	91
Merger reserve	19	433	433	433
Other reserves	19	1,392	1,405	1,378
Retained earnings	19	16,198	11,572	10,624
	10	20,660	15,912	14,778
Non-controlling interests	19	161	148	137
Total equity	19	20,821	16,060	14,915
	13	20,021	10,000	17,010

The Financial Statements on pages 124 to 186 were approved by the Board of Directors on 28 January 2010 and were signed on its behalf by:

David R Brennan Simon Lowth

Director

Director

# Consolidated Statement of Changes in Equity for the year ended 31 December

	Share capital	Share premium account	Capital redemption reserve	Merger	Other	Retained earnings	Total	Non- controlling interests	Total equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 January 2007	383	1,671	71	433	1,398	11,348	15,304	112	15,416
Profit for the period	-	-	-	-	_	5,595	5,595	32	5,627
Other comprehensive income	-	-	-	-	-	339	339	3	342
Transfer to other reserves <sup>1</sup>	-	-	-	-	(20)	20	_	-	-
Transactions with owners									
Dividends	-	-	-	-	-	(2,658)	(2,658)	-	(2,658)
Issue of Ordinary Shares	1	217	-	-	_	_	218	-	218
Re-purchase of Ordinary Shares	(20)	-	20	-	_	(4,170)	(4,170)	-	(4,170)
Share-based payments	-	-	-	-	_	150	150	-	150
Transfer from non-controlling interests to payables	-	-	-	-	_	_	-	(10)	(10)
Net movement	(19)	217	20	-	(20)	(724)	(526)	25	(501)
At 31 December 2007	364	1,888	91	433	1,378	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 reserves <sup>1</sup>	-	-	-	-	27	(27)	_	-	_
Transactions with owners									
Dividends	-	-	-	-	-	(2,767)	(2,767)	-	(2,767)
Issue of Ordinary Shares	1	158	-	-	-	-	159	-	159
Re-purchase of Ordinary Shares	(3)	-	3	-	-	(610)	(610)	-	(610)
Share-based payments	-	-	-	-	-	176	176	-	176
Transfer from non-controlling interests to payables	-	-	-	-	_	_	-	(11)	(11)
Dividend paid by subsidiary to non-controlling interest	-	-	-	-	-	-	-	(26)	(26)
Net movement	(2)	158	3	-	27	948	1,134	11	1,145
At 31 December 2008	362	2,046	94	433	1,405	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 reserves <sup>1</sup>	-	-	-	-	(13)	13	_	-	_
Transactions with owners									
Dividends	-	-	-	-	_	(3,026)	(3,026)	-	(3,026)
Issue of Ordinary Shares	1	134	-	-	-	-	135	-	135
Share-based payments	-	-	-	-	-	172	172	-	172
Transfer from non-controlling interests to payables	-	-	-	-	-	-	-	(9)	(9)
Dividend paid by subsidiary to non-controlling interest	-	-	-	-	-	-	-	(1)	(1)
Net movement	1	134	-	-	(13)	4,626	4,748	13	4,761
At 31 December 2009	363	2,180	94	433	1,392	16,198	20,660	161	20,821

<sup>1</sup> Amounts charged or credited to other reserves relate to exchange adjustments arising on goodwill.

# Consolidated Statement of Cash Flows for the year ended 31 December

Notes	2009 \$m	2008 \$m	2007 \$m
Cash flows from operating activities	ψΠ	ψΠ	ψΠ
Profit before tax	10,807	8.681	7.983
Finance income and expense 3	,	463	111
Depreciation, amortisation and impairment	2,087	2.620	1,856
Increase in trade and other receivables	(256)	(1,032)	(717)
Decrease in inventories	6	185	442
Increase/(decrease) in trade and other payables and provisions	1,579	637	(168)
Other non-cash movements	(200)	87	901
Cash generated from operations	14,759	11,641	10,408
Interest paid	(639)	(690)	(335)
Tax paid	(2,381)	(2,209)	(2,563)
Net cash inflow from operating activities	11,739	8,742	7,510
Cash flows from investing activities			
Acquisitions of business operations 22	-	-	(14,891)
Movement in short term investments and fixed deposits	(1,371)	1	894
Purchase of property, plant and equipment	(962)	(1,095)	(1,130)
Disposal of property, plant and equipment	138	38	54
Purchase of intangible assets	(624)	(2,944)	(549)
Disposal of intangible assets	269	-	-
Purchase of non-current asset investments	(31)	(40)	(35)
Disposal of non-current asset investments	3	32	421
Interest received	113	149	358
Payments made by subsidiaries to non-controlling interests	(11)	(37)	(9)
Net cash outflow from investing activities	(2,476)	(3,896)	(14,887)
Net cash inflow/(outflow) before financing activities	9,263	4,846	(7,377)
Cash flows from financing activities			
Proceeds from issue of share capital	135	159	218
Re-purchase of shares	_	(610)	(4,170)
Issue of loans	-	787	9,692
Repayment of loans	(650)	-	(1,165)
Dividends paid	(2,977)	(2,739)	(2,641)
Movement in short term borrowings	(137)	(3,959)	4,117
Net cash (outflow)/inflow from financing activities	(3,629)	(6,362)	6,051
Net increase/(decrease) in cash and cash equivalents in the period	5,634	(1,516)	(1,326)
Cash and cash equivalents at beginning of the period	4,123	5,727	6,989
Exchange rate effects	71	(88)	64
Cash and cash equivalents at the end of the period 13	9,828	4,123	5,727

# Accounting Policies

# Basis of accounting and preparation of financial information

The Consolidated Financial Statements have been prepared under the historical cost convention, modified to include revaluation to fair value of certain financial instruments as described below, in accordance with the Companies Act 2006 and International Financial Reporting Standards (IFRSs) as adopted by the European Union ('adopted IFRS') in response to the IAS regulation (EC 1606/2002). The Consolidated Financial Statements also comply fully with IFRSs as issued by the International Accounting Standards Board.

The Company has applied IAS 1 'Presentation of Financial Statements (revised 2007)' which has introduced a number of terminology changes (including titles for the financial statements) and has resulted in a number of changes in presentation and disclosure. The revised standard has had no impact on the Group's profit for the period, net assets or cash f ows.

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 Senior Executive Team (SET) is AstraZeneca's chief operating decision-making body (as defined by IFRS 8). The operation of the SET is principally driven by the management of the commercial operations, research and development, and manufacturing and supply. The SET also includes Finance, HR and General Counsel representation. All significant operating decisions are taken by the SET. While members of the SET have responsibility for implementation of decisions in their respective areas, operating decisionmaking 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 and 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 Group plc, 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 amendments to IFRS 7 'Improving Disclosures about Financial Instruments' have been adopted and have resulted in additional disclosure. IFRS 2 'Amendment regarding Vesting Conditions and Cancellations', IAS 23 'Borrowing Costs (revised 2007)', Amendments to IAS 36 'Impairment of Assets', Amendments to IAS 19 'Employee Benefits', Amendments to IAS 38 'Intangible Assets' and Amendments to IAS 32 'Financial Instruments: Presentation' and IAS 1 'Presentation of Financial Statements' have all been adopted, none of which have had a significant effect on the Group's profit for the period, net assets or cash fows.

IFRIC 13 'Customer loyalty programmes', IFRIC 15 'Agreements for the Construction of Real Estate' and IFRIC 16 'Hedges of a Net Investment in a Foreign Operation' have all been adopted but have had no impact on the overall reported results.

The Company has elected to prepare the Company Financial Statements in accordance with UK Accounting Standards. These are presented on pages 188 to 192 and the accounting policies in respect of Company information are set out on page 189.

The Consolidated Financial Statements are presented in US dollars, which is the Company's functional currency.

In preparing their individual financial statements, the accounting policies of some overseas subsidiaries do not conform with adopted IFRSs. Therefore, where appropriate, adjustments are made in order to present the Group Financial Statements on a consistent basis.

# Basis for preparation of financial statements on a going concern basis

Information on the business environment AstraZeneca operates in, including the factors underpinning the industry's future growth prospects, are included in the Directors' Report. Details of the product portfolio of the Group, our approach to product development and our development pipeline are covered in detail with additional information by Therapy Area in the Directors' Report.

The financial position of the Group, its cash fows, liquidity position and borrowing facilities are described in the Financial Review. In addition, Notes 15 and 16 to the Financial Statements include the Group's objectives, policies and processes for managing its capital, its financial risk management objectives, details of its financial instruments and hedging activities and its exposures to credit, market and liquidity risk. Further details of the Group's cash balances and borrowings are included in Notes 13 and 14 of the Financial Statements.

The Group has considerable financial resources available. As at 31 December 2009, the Group has \$12.3 billion in financial resources (cash balances of \$9.9 billion and committed bank facilities of \$4.25 billion, with \$1.9 billion of debt due within one year). 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. In addition, the Group has a wide diversity of customers and suppliers across different geographic areas. As a consequence, the Directors believe that the Group is well placed to manage its business risks successfully despite the current uncertain economic outlook.

After making enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the Annual Report and Financial Statements.

### **Estimates and judgements**

The preparation of the Financial Statements in conformity with generally accepted accounting principles requires management to make estimates and judgements that affect the reported amounts of assets and liabilities at the date of the Financial Statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Judgements include classification of transactions between profit and the consolidated statement of financial position, whilst estimates focus on areas such as carrying values and estimated lives.

AstraZeneca's management considers the following to be the most important accounting policies in the context of the Group's operations.

The accounting policy descriptions set out the areas where judgement needs exercising, the most significant of which are revenue recognition, research and development, business combinations and goodwill, litigation and environmental liabilities, employee benefits, taxation and share-based payments. Further information on critical judgements made in applying accounting policies, including details of significant methods and assumptions used, is included in Notes 6, 8, 9, 16, 22, 23, 24 and 25. The financial risk management policies are detailed in Note 15.

## Revenue

Revenues comprise sales and income under co-promotion and co-development agreements.

Income under co-promotion and codevelopment agreements is recognised when it is earned as defined in the contract and can be reliably estimated. In general this is upon the sale of the co-promoted/ developed product or upon the delivery of a promotional or developmental service.

Revenues exclude inter-company revenues and value-added taxes and represent net invoice value less estimated rebates, returns and settlement discounts. Revenues are recognised when the significant risks and rewards of ownership have been transferred to a third party. In general this is upon delivery of the products to wholesalers. In markets where returns are significant (currently only in the US), estimates of returns are accounted for at the point revenue is recognised. In markets where returns are not significant they are recorded when returned.

When a product faces generic competition particular attention is given to the possible levels of returns and, in cases where the circumstances are such that the level of returns (and, hence, revenue) cannot be measured reliably, revenues are only recognised when the right of return expires which is generally on ultimate prescription of the product to patients.

For the US market we estimate the quantity and value of goods which may ultimately be returned at the point of sale. Our returns accruals are based on actual experience over the preceding 12 months for established products together with market-related information such as estimated stock levels at wholesalers and competitor activity which we receive via third-party information services. For newly launched products, we use rates based on our experience with similar products or a pre-determined percentage.

### **Research and development**

Research expenditure is recognised in profit in the year in which it is incurred.

Internal development expenditure is capitalised only if it meets the recognition criteria of IAS 38 'Intangible Assets'. Where regulatory and other uncertainties are such that the criteria are not met the expenditure is recognised in profit and this is almost invariably the case prior to approval of the drug by the relevant regulatory authority. Where, however, recognition criteria are met, intangible assets are capitalised and amortised on a straightline basis over their useful economic lives from product launch. As at 31 December 2009, no amounts have met recognition criteria.

Payments to in-license products and compounds from external third parties. generally taking the form of up-front payments and milestones, are capitalised. Since these products and compounds will only generate sales and cash infows following launch, if it is in AstraZeneca's control to do so, our policy is to minimise the period between final approval and launch. These assets are amortised, generally on a straight-line basis, over their useful economic lives from product launch. Under this policy, it is not possible to determine precise economic lives for individual classes of intangible assets. However, lives range from three years to 20 years. These assets are not used in the research and development activities of other products.

Intangible assets relating to products in development (both internally generated and externally acquired) are subject to impairment testing annually. All intangible assets are tested for impairment when there are indications that the carrying value may not be recoverable. Any impairment losses are recognised immediately in profit. Intangible assets relating to products which fail during development (or for which development ceases for other reasons) are tested for impairment at the point of termination and are written down to their fair value (which is usually zero).

# **Business combinations and goodwill**

On the acquisition of a business, fair values are attributed to the identifiable assets and liabilities and contingent liabilities unless the fair value cannot be measured reliably in which case the value is subsumed into goodwill. Where fair values of acquired contingent liabilities cannot be measured reliably, the assumed contingent liability is not recognised but is disclosed in the same manner as other contingent liabilities. Goodwill is the difference between consideration paid and the fair value of net assets acquired. Goodwill arising on acquisitions is capitalised and subject to an impairment review, both annually and when there is an indication that the carrying value may not be recoverable. Between 1 January 1998 and 31 December 2002, goodwill was amortised over its estimated useful life; such amortisation ceased on 31 December 2002.

The Group's policy up to and including 1997 was to eliminate goodwill arising upon acquisitions against reserves. Under IFRS 1 'First-time Adoption of International Financial Reporting Standards' and IFRS 3 'Business Combinations', such goodwill will remain eliminated against reserves.

# **Employee benefits**

The Group accounts for pensions and other employee benefits (principally healthcare) under IAS 19 'Employee Benefits'. In respect of defined benefit plans, obligations are measured at discounted present value whilst plan assets are measured at fair value. The operating and financing costs of such plans are recognised separately in profit; current service costs are spread systematically over the lives of employees and financing costs are recognised in full in the periods in which they arise. Actuarial gains and losses are recognised immediately in other comprehensive income.

Where the calculation results in a benefit to the Group, the recognised asset is limited to the present value of any available future refunds from the plan or reductions in future contributions to the plan. Payments to defined contribution plans are recognised in profit as they fall due.

# **Taxation**

The current tax payable is based on taxable profit for the year. Taxable profit differs from Reported profit because it excludes items that are never taxable or tax deductible. The Group's current tax assets and liabilities are calculated using tax rates that have been enacted or substantively enacted by the reporting date.

Deferred tax is provided using the balance sheet liability method, providing for temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the asset can be utilised. This requires judgements to be made in respect of the availability of future taxable income. No deferred tax asset or liability is recognised in respect of temporary differences associated with investments in subsidiaries, branches and joint ventures where the Group is able to control the timing of reversal of the temporary differences and it is probable that the temporary differences will not reverse in the foreseeable future.

The Group's deferred tax assets and liabilities are calculated using tax rates that are expected to apply in the period when the liability is settled or the asset realised based on tax rates that have been enacted or substantively enacted by the reporting date.

Accruals for tax contingencies require management to make judgements and estimates of ultimate exposures in relation to tax audit issues. Tax benefits are not recognised unless the tax positions will probably be sustained. Once considered to be probable, management reviews each material tax benefit to assess whether a provision should be taken against full recognition of that benefit on the basis of potential settlement through negotiation and/or litigation. All provisions are included in current liabilities. Any recorded exposure to interest on tax liabilities is provided for in the tax charge. See Note 25 for further details.

# **Share-based payments**

All plans are assessed and have been classified as equity settled. The grant date fair value of employee share option awards is generally calculated using the Black-Scholes model. In accordance with IFRS 2 'Sharebased Payment', the resulting cost is recognised in profit over the vesting period of the options, being the period in which the services are received. The value of the charge is adjusted to refect expected and actual levels of awards vesting, except where the failure to vest is as a result of not meeting a market condition. Cancellations of equity instruments are treated as an acceleration of the vesting period and any outstanding charge is recognised in profit immediately.

# Property, plant and equipment

The Group's policy is to write off the difference between the cost of each item of property, plant and equipment and its residual value systematically over its estimated useful life. Assets under construction are not depreciated.

Reviews are made annually of the estimated remaining lives and residual values of individual productive assets, taking account of commercial and technological obsolescence as well as normal wear and tear. Under this policy it becomes impractical to calculate average asset lives exactly. However, the total lives range from approximately 10 to 50 years for buildings, and three to 13 years for plant and equipment. All items of property, plant and equipment are tested for impairment when there are indications that the carrying value may not be recoverable. Any impairment losses are recognised immediately in profit.

## **Borrowing costs**

The Group has no borrowing costs with respect to the acquisition or construction of qualifying assets. All other borrowing costs are recognised in profit as incurred and in accordance with the effective interest rate method.

## Leases

Rentals under operating leases are charged to profit on a straight-line basis.

## **Subsidiaries**

A subsidiary is an entity controlled, directly or indirectly, by AstraZeneca PLC. Control is regarded as the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities.

The financial results of subsidiaries are consolidated from the date control is obtained until the date that control ceases.

## Inventories

Inventories are stated at the lower of cost and net realisable value. The first in, first out or an average method of valuation is used. For finished goods and work in progress, cost includes directly attributable costs and certain overhead expenses (including depreciation). Selling expenses and certain other overhead expenses (principally central administration costs) are excluded. Net realisable value is determined as estimated selling price less all estimated costs of completion and costs to be incurred in selling and distribution.

Write-downs of inventory occur in the general course of business and are recognised in cost of sales.

# Trade and other receivables

Trade and other receivables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest rate method, less any impairment losses.

# Trade and other payables

Trade and other payables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest rate method.

# **Financial instruments**

The Group's financial instruments include interests in leases and rights and obligations under employee benefit plans which are dealt with in specific accounting policies.

The Group's other financial instruments include:

- > Cash and cash equivalents
- > Fixed deposits
- > Other investments
- > Loans and borrowings
- > Derivatives.

### **Cash and cash equivalents**

Cash and cash equivalents comprise cash in hand, current balances with banks and similar institutions and highly liquid investments with maturities of three months or less when acquired. They are readily convertible into known amounts of cash and are held at amortised cost.

# **Fixed deposits**

Fixed deposits, comprising principally funds held with banks and other financial institutions, are initially measured at fair value (including direct transaction costs) and are subsequently remeasured to amortised cost using the effective interest rate method at each reporting date. Changes in carrying value are recognised in profit.

## **Other investments**

Where investments have been classified as held for trading, they are measured initially at fair value and subsequently at fair value. Changes in fair value are recognised in profit.

In all other circumstances, the investments are initially measured at fair value (including direct transaction costs) and are subsequently remeasured to fair value at each reporting date. Changes in carrying value due to changes in exchange rates or impairments are recognised in profit. All other changes in fair value are recognised in other comprehensive income.

Impairments are recorded in profit when there is a decline in the value of an investment that is deemed to be other than temporary. On disposal of the investment, the cumulative amount recognised in other comprehensive income is recognised in profit as part of the gain or loss on disposal.

# Bank and other borrowings

The Group uses derivatives, principally interest rate swaps, to hedge the interest rate exposure inherent in a portion of its fixed interest rate debt. In such cases the Group will either designate the debt as fair value through profit or loss when certain criteria are met or as the hedged item under a fair value hedge.

If the debt instrument is designated as fair value through profit, the debt is initially measured at fair value (with direct transaction costs being included in profit as an expense) and is remeasured to fair value at each reporting date with changes in carrying value being recognised in profit (along with changes in the fair value of the related derivative). Such a designation has been made where this significantly reduces an accounting mismatch which would result from recognising gains and losses on different bases.

If the debt is designated as the hedged item under a fair value hedge, the debt is initially measured at fair value (with direct transaction costs being amortised over the life of the bonds), and is remeasured for fair value changes in respect of the hedged risk at each reporting date with changes in carrying value being recognised in profit (along with changes in the fair value of the related derivative).

If certain criteria are met, non-US dollar denominated loans are designated as net investment hedges of foreign operations. Exchange differences arising on retranslation of net investments and of foreign currency loans which are designated in an effective net investment hedge relationship, are recognised in other comprehensive income. All other exchange differences giving rise to changes in the carrying value of foreign currency loans and overdrafts are recognised in profit.

Other interest-bearing loans are initially measured at fair value (including direct transaction costs) and are subsequently remeasured to amortised cost using the effective interest rate method at each reporting date. Changes in carrying value are recognised in profit.

# **Derivatives**

Derivatives are initially measured at fair value (with direct transaction costs being included in profit as an expense) and are subsequently remeasured to fair value at each reporting date. Changes in carrying value are recognised in profit.

### **Foreign currencies**

Foreign currency transactions, being transactions denominated in a currency other than an individual Group entity's functional currency, are translated into the relevant functional currencies of individual Group entities at average rates for the relevant monthly accounting periods, which approximate to actual rates.

Monetary assets, arising from foreign currency transactions, are retranslated at exchange rates prevailing at the reporting date. Exchange gains and losses on loans and on short-term foreign currency borrowings and deposits are included within finance expense. Exchange differences on all other foreign currency transactions are taken to operating profit in the individual Group entity's accounting records.

Non-monetary items arising from foreign currency transactions are not retranslated in the individual Group entity's accounting records.

In the Consolidated Financial Statements, income and expense items for Group entities with a functional currency other than US dollars, are translated into US dollars at average exchange rates, which approximate to actual rates, for the relevant accounting periods. Assets and liabilities are translated at the US exchange rates prevailing at the reporting date. Exchange differences arising on consolidation are taken in other comprehensive income.

Exchange differences arising on retranslation of net investments in subsidiaries and of foreign currency loans which are designated in an effective hedge relationship are taken in other comprehensive income in the Consolidated Financial Statements. Gains and losses accumulated in the translation reserve will be recycled to profit when the foreign operation is sold.

# Litigation and environmental liabilities

Through the normal course of business, AstraZeneca is involved in legal disputes, the settlement of which may involve cost to the Group. Provision is made where an adverse outcome is probable and associated costs, including related legal costs, can be estimated reliably. In other cases, appropriate disclosures are included.

Where it is considered that the Group is more likely than not to prevail, legal costs involved in defending the claim are charged to profit as they are incurred. Where it is considered that the Group has a valid contract which provides the right to reimbursement (from insurance or otherwise) of legal costs and/or all or part of any loss incurred or for which a provision has been established, the best estimate of the amount expected to be received is recognised as an asset.

AstraZeneca is exposed to environmental liabilities relating to its past operations, principally in respect of soil and groundwater remediation costs. Provisions for these costs are made when there is a present obligation and where it is probable that expenditure on remedial work will be required and a reliable estimate can be made of the cost. Provisions are discounted where the effect is material.

# Impairment

The carrying value of non-financial assets, other than inventories and deferred tax assets, are reviewed at least annually to determine whether there is any indication of impairment. For goodwill, intangible assets under development and for any other assets where such indication exists, the asset's recoverable amount is estimated based on the greater of its value in use and its fair value less cost to sell. In assessing value in use, the estimated future cash fows, adjusted for the risks specific to each asset, are discounted to their present value using a discount rate that refects current market assessments of the time value of money and the general risks affecting the pharmaceutical industry. For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inf ows from continuing use that are largely independent of the cash fows of other assets. Impairment losses are recognised in profit.

## International accounting transition

On transition to using adopted IFRS in the year ended 31 December 2005, the Company took advantage of several optional exemptions available in IFRS 1 'First-time Adoption of International Financial Reporting Standards'. The major impacts which are of continuing importance are detailed below:

> Business combinations – IFRS 3 'Business Combinations' has been applied from 1 January 2003, the date of transition, rather than being applied fully retrospectively. As a result, the combination of Astra and Zeneca is still accounted for as a merger, rather than through purchase accounting. If purchase accounting had been adopted, Zeneca would have been deemed to have acquired Astra.  Cumulative exchange differences – the Group chose to set the cumulative exchange difference reserve at 1 January 2003 to zero.

# Accounting standards and interpretations issued but not yet adopted

A revised IFRS 3 'Business Combinations' was issued in January 2008. The following changes will be relevant to the Group's operations:

- > Contingent consideration will be measured at fair value, with subsequent changes to the fair value being recognised in profit.
- > Transaction costs, other than share and debt issue costs, will be expensed as incurred.
- > Any pre-existing interest in the acquiree will be measured at fair value with the gain or loss recognised in profit.
- > Any non-controlling (minority) interest will be measured at either fair value, or at its proportionate interest in the identifiable assets and liabilities of the acquiree, on a transaction-by-transaction basis.

The revised Standard is effective for AstraZeneca business combinations on or after 1 January 2010 and will be applied prospectively from that date.

An amendment to IAS 27 'Consolidated and Separate Financial Statements (2008)' was issued in January 2008. The amendment requires changes in ownership interests in a subsidiary, while maintaining control, to be recognised as an equity transaction. If control of a subsidiary is lost, any retained interest is measured at fair value with the gain or loss recognised in profit. The amendment is effective for accounting periods beginning on or after 1 July 2009 and will not have a significant impact upon the net results, net assets or disclosures of AstraZeneca.

A revised IFRS 1 'First-time Adoption of International Financial Reporting Standards' was issued in November 2008 and will have no impact on AstraZeneca.

IFRS 9 'Financial Instruments' was issued in November 2009. It is applicable to financial assets and requires classification and measurement in either the amortised cost or the fair value category. It is effective for accounting periods beginning on or after 1 January 2013. The adoption of IFRS 9 is not expected to have a significant impact upon the net results or net assets of AstraZeneca. An amendment to IFRS 5 'Non-current Assets Held for Sale and Discontinued Operations' was issued in May 2008 and provides clarification that assets and liabilities of a subsidiary should be classified as held for sale if the Parent is committed to a plan involving loss of control of the subsidiary, regardless of whether the entity will retain a non-controlling interest after the sale. The amendment is effective for accounting periods beginning on or after 1 July 2009 and will not have a significant impact upon the net results, net assets or disclosures of AstraZeneca.

The amendment to IAS 39 'Financial Instruments: Recognition and Measurement – Eligible Hedged Items' deals with two situations where diversity in practice exists on the designation of inf ation as a hedged risk and the treatment of 'one-sided' risks on hedged items. The amendment is effective for accounting periods beginning on or after 1 July 2009. The amendment is not expected to have a significant impact upon the net results, net assets or disclosures of AstraZeneca.

Revised IFRS 3 'Business Combinations' was endorsed by the EU during 2009. The amendments to IAS 27 'Consolidated and Separate Financial Statements (2008)', IAS 39 'Financial Instruments: Recognition and Measurement – Eligible Hedged Items' and IFRS 5 'Non-current Assets Held for Sale and Discontinued Operations' were endorsed by the EU in 2009. IFRS 9 'Financial Instruments' has not yet been endorsed by the EU.

The following IFRIC interpretations have been issued but are not yet adopted by AstraZeneca:

- > Amendments to IFRIC 14 'Prepayments of a Minimum Funding Requirement'.
- > IFRIC 17 'Distributions of Non-cash Assets to Owners'.
- > IFRIC 19 'Extinguishing Financial Liabilities with Equity Instruments'.

The interpretations are effective for accounting periods commencing on or after 1 January 2011, 1 July 2009 and 1 July 2010 respectively. IFRIC 17 is not expected to have a significant impact upon adoption.

There is no impact expected from any other standards that are available for early adoption but that have not been adopted.

# Notes to the Financial Statements

# **1 Product revenue information**

1 Product revenue information			
	2009 \$m	2008 \$m	2007 \$m
Gastrointestinal:	ŞIII	φΠ	φΠ
Nexium	4,959	5,200	5,216
Losec/Prilosec	946	1,055	1,143
Others	106	89	84
Total Gastrointestinal	6,011	6,344	6,443
Cardiovascular:	0,011	0,044	0,440
Crestor	4,502	3,597	2,796
Seloken/Toprol-XL	1,443	807	1,438
Atacand	1,436	1,471	1,430
Zestril	184	236	295
Plendil	241	268	293
Onglyza <sup>™</sup>	11	- 208	211
Ohgiyza	559	584	599
Total Cardiovascular	8,376	6,963	6,686
Respiratory:	0.004	0.004	4 575
Symbicort	2,294	2,004	1,575
Pulmicort	1,310	1,495	1,454
Rhinocort	264	322	354
Oxis	63	71	86
Others	201	236	242
Total Respiratory	4,132	4,128	3,711
Oncology:			
Arimidex	1,921	1,857	1,730
Casodex	844	1,258	1,335
Zoladex	1,086	1,138	1,104
Iressa	297	265	238
Faslodex	262	249	214
Nolvadex	88	85	83
Abraxane™	-	64	62
Ethyol	15	28	43
Others	5	10	10
Total Oncology	4,518	4,954	4,819
Neuroscience:			
Seroquel	4,866	4,452	4,027
Local anaesthetics	599	605	557
Zomig	434	448	434
Diprivan	290	278	263
Others	48	54	59
Total Neuroscience	6,237	5,837	5,340
Infection and Other:			
Merrem	872	897	773
Synagis	1,082	1,230	618
FluMist	145	104	53
H1N1 Influenza Vaccine	389	-	-
Other Products	143	220	270
Total Infection and Other	2,631	2,451	1,714
Aptium Oncology	393	395	402
Astra Tech	506	529	444
Total	32,804	31,601	29,559

# **2 Operating profit**

Operating profit includes the following items:

# Selling, general and administrative costs

AstraZeneca is defending its interests in various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices and in respect of which the Company has made provisions in aggregate of \$636m during 2009. \$524m of this has been made in respect of the US Attorney's Office investigation into sales and marketing practices involving *Seroquel* and \$112m relates to average wholesale price litigation. The current status of these matters is described in Note 25. These provisions constitute our best estimate at the time of losses expected for these matters.

# Other operating income and expense

	2009 \$m	2008 \$m	2007 \$m
Royalties			i
Income	255	288	236
Amortisation	(79)	(84)	_
Impairment	(150)	(91)	-
Net gain on disposal of property, plant and equipment	8	6	9
Gains on disposal of product rights	170	-	-
Net gain/(loss) on disposal of other intangible assets	1	(17)	(1)
Gains on divestments of non-core products	216	118	192
Impairment of intangible assets relating to future licensing and contractual income	(115)	-	-
Other income	265	304	310
Other expense	(18)	-	(18)
Other operating income and expense	553	524	728

Royalty amortisation relates to income streams acquired with MedImmune. The amortisation in 2007 (\$53m) was posted to SG&A and not adjusted.

# **Restructuring and synergy costs**

During 2009 the Group continued the restructuring and synergy programmes approved by the SET and announced in 2007 and 2008. In addition, the Group announced further programmes during the year. The tables below show the costs that have been charged in respect of these programmes by cost category and type. Severance provisions are detailed in Note 18.

m \$m 8 405 8 166 3 310 9 881	415 73
8 166 3 310	73 478
<b>3</b> 310	478
<b>9</b> 881	966
	000
9 2008	2007
<b>m</b> \$m	\$m
<b>2</b> 499	678
8 219	203
9 163	85
9 881	966
	2 499 8 219 9 163

## 3 Finance income and expense

	2009 \$m	2008 \$m	2007 \$m
Finance income			
Returns on fixed deposits and equity securities	20	15	52
Returns on short-term deposits	22	127	298
Expected return on post-employment defined benefit plan assets	388	584	573
Fair value gains on debt, interest rate swaps and investments	1	128	36
Net exchange gains	31	-	_
Total	462	854	959

# 3 Finance income and expense continued

	2009 \$m	2008 \$m	2007 \$m
Finance expense			
Interest on debt and commercial paper	(542)	(664)	(513)
Interest on overdrafts and other financing costs	(18)	(50)	(9)
Interest on post-employment defined benefit plan liabilities	(493)	(589)	(539)
Fair value charges on debt, interest rate swaps and investments	(145)	(2)	(6)
Net exchange losses	_	(12)	(3)
Total	(1,198)	(1,317)	(1,070)
Net finance expense	(736)	(463)	(111)

The amount of exchange gains and losses recognised in profit, other than those arising on financial instruments measured at fair value through profit or loss in accordance with IAS 39 (see Note 16), is a gain of \$31m (2008: loss of \$12m; 2007: loss of \$3m).

# 4 Taxation

Taxation recognised in the profit for the period in the consolidated statement of comprehensive income is as follows:

	2009 Sm	2008 \$m	2007 \$m
Current tax expense	÷	φ	
Current year	2,854	2,946	1,890
Adjustment for prior years	251	130	261
	3,105	3,076	2,151
Deferred tax expense			
Origination and reversal of temporary differences	98	(486)	379
Adjustment to prior years	60	(39)	(174)
	158	(525)	205
Taxation recognised in the profit for the period	3,263	2,551	2,356

Taxation relating to components of other comprehensive income is as follows:

	2009	2008	2007
	\$m	\$m	\$m
Current and deferred tax			
Foreign exchange arising on consolidation	16	20	32
Actuarial loss for the period	158	340	35
Share-based payments	17	9	(8)
Deferred tax impact of reduction in UK tax rate	-	-	(28)
Other	1	(1)	2
Taxation relating to components of other comprehensive income	192	368	33

Taxation has been provided at current rates on the profits earned for the periods covered by the Group Financial Statements. The 2009, 2008 and 2007 prior period current tax adjustments relate mainly to tax accrual to tax return adjustments, an increase in provisions in respect of a number of transfer pricing audits and double tax relief. The 2009, 2008 and 2007 prior year deferred tax adjustments relate to tax accrual to tax return adjustments and the recognition of previously unrecognised deferred tax assets. To the extent that dividends remitted from overseas subsidiaries, joint ventures and associates are expected to result in additional taxes, appropriate amounts have been provided for. No deferred tax has been provided for unremitted earnings of Group companies overseas as these are considered permanently employed in the businesses of these companies. Unremitted earnings may be liable to overseas taxes and/or UK taxation (after allowing for double taxation relief) if distributed as dividends. The aggregate amount of temporary differences associated with investments in subsidiaries and branches for which deferred tax liabilities have not been recognised totalled approximately \$14,846m at 31 December 2009 (2008: \$8,449m; 2007: \$12,639m).

## Factors affecting future tax charges

As a Group involved in worldwide operations, AstraZeneca is subject to several factors that may affect future tax charges, principally the levels and mix of profitability in different jurisdictions, transfer pricing regulations and tax rates imposed. A number of material items currently under audit and negotiation are set out in detail in Note 25.

# 4 Taxation continued

# Tax reconciliation to UK statutory rate

The table shown below reconciles the UK statutory tax charge to the Group's total tax charge.

	2009	2008	2007
	\$m	\$m	\$m
Profit before tax	10,807	8,681	7,983
Notional taxation charge at UK corporation tax rate of 28% (28.5% for 2008, 30% for 2007)	3,026	2,474	2,395
Differences in effective overseas tax rates	(212)	(8)	(105)
Deferred tax credit relating to reduction in Swedish, UK and other tax rates!	-	(70)	(57)
Unrecognised deferred tax asset	2	(7)	(1)
Items not deductible for tax purposes	156	119	70
Items not chargeable for tax purposes	(20)	(48)	(33)
Adjustments in respect of prior periods	311	91	87
Total tax charge for the year	3,263	2,551	2,356

<sup>1</sup> The 2008 item relates to the reduction in the Swedish statutory corporation tax rate from 28% to 26.3% effective from 1 January 2009. The majority of the 2007 item relates to the reduction in the UK statutory corporation tax rate from 30% to 28%.

### **Deferred tax**

Deferred tax assets and liabilities and the movements during the year, before offset of balances within countries, are as follows:

	Property, plant and equipment \$m	Intangible assets \$m	Pension and post- retirement benefits \$m	Inter- company inventory transfers \$m	Untaxed reserves <sup>1</sup> \$m	Accrued expenses \$m	Share schemes \$m		Losses and tax credits carried forward \$m	Other \$m	Total \$m
Deferred tax assets at 1 January 2007	37	2	604	853	-	323	113	-	57	28	2,017
Deferred tax liabilities at 1 January 2007	(502)	(819)	-	-	(881)	-	-	(99)	-	(55)	(2,356)
Net deferred tax balance at 1 January 2007 <sup>2</sup>	(465)	(817)	604	853	(881)	323	113	(99)	57	(27)	(339)
Taxation expense	(130)	201	(99)	(71)	(225)	190	(45)	12	(96)	58	(205)
Other comprehensive income	-	-	8	-	-	-	(8)	-	-	-	-
Acquisition of subsidiary undertaking <sup>3</sup>	3	(2,973)	-	58	-	74	-	-	369	(29)	(2,498)
Exchange	(35)	(5)	15	46	(65)	11	2	(1)	-	(1)	(33)
Net deferred tax balance at 31 December 2007	(627)	(3,594)	528	886	(1,171)	598	62	(88)	330	1	(3,075)
Deferred tax assets at 31 December 2007	66	59	531	907	-	611	62	-	330	71	2,637
Deferred tax liabilities at 31 December 2007	(693)	(3,653)	(3)	(21)	(1,171)	(13)	-	(88)	-	(70)	(5,712)
Net deferred tax balance at 31 December 2007 <sup>2</sup>	(627)	(3,594)	528	886	(1,171)	598	62	(88)	330	1	(3,075)
Taxation expense	122	375	24	55	(119)	37	43	-	12	(24)	525
Other comprehensive income	-	-	340	-	-	-	9	-	-	(1)	348
Exchange	168	130	(113)	(35)	199	(37)	(14)	24	(7)	(3)	312
Net deferred tax balance at 31 December 2008	(337)	(3,089)	779	906	(1,091)	598	100	(64)	335	(27)	(1,890)
Deferred tax assets at 31 December 2008	136	42	786	935	_	598	100	-	335	45	2,977
Deferred tax liabilities at 31 December 2008	(473)	(3,131)	(7)	(29)	(1,091)	-	-	(64)	-	(72)	(4,867)
Net deferred tax balance at 31 December 2008	(337)	(3,089)	779	906	(1,091)	598	100	(64)	335	(27)	(1,890)
Taxation expense	175	232	(61)	17	(303)	(146)	5	-	(100)	23	(158)
Other comprehensive income	-	-	140	-	-	-	17	-	-	-	157
Exchange	(46)	(36)	54	29	(80)	18	7	(7)	(4)	1	(64)
Net deferred tax balance at 31 December 2009	(208)	(2,893)	912	952	(1,474)	470	129	(71)	231	(3)	(1,955)
Deferred tax assets at 31 December 2009	266	47	918	968	_	553	129	-	231	34	3,146
Deferred tax liabilities at 31 December 2009	(474)	(2,940)	(6)	(16)	(1,474)	(83)	-	(71)	-	(37)	(5,101)
Net deferred tax balance at 31 December 2009	(208)	(2,893)	912	952	(1,474)	470	129	(71)	231	(3)	(1,955)

Analysed in the Statement of Financial Position, after offset of balances within countries, as:	2009 \$m	2008 \$m	2007 \$m
Deferred tax assets	1,292	1,236	1,044
Deferred tax liabilities	(3,247)	(3,126)	(4,119)
Net deferred tax balance	(1,955)	(1,890)	(3,075)

<sup>1</sup> Untaxed reserves relate to taxable profits where the tax liability is deferred to later periods.

<sup>2</sup> During 2008, the Group carried out a review of its deferred tax balances resulting in a reclassification of a deferred tax liability of \$284m from property, plant and equipment to intangible assets as at 31 December 2007 (\$328m as at 1 January 2007). <sup>3</sup> The deferred tax liability of \$2,498m relates to MedImmune and other acquisitions.

### Unrecognised deferred tax assets

Deferred tax assets of \$104m have not been recognised in respect of deductible temporary differences (2008: \$80m; 2007: \$106m) because it is not probable that future taxable profit will be available against which the Group can utilise the benefits therefrom.

# 5 Earnings per \$0.25 Ordinary Share

	2009	2008	2007
Profit for the financial year attributable to equity holders (\$m)	7,521	6,101	5,595
Basic earnings per Ordinary Share	\$5.19	\$4.20	\$3.74
Diluted earnings per Ordinary Share	\$5.19	\$4.20	\$3.73
Weighted average number of Ordinary Shares in issue for basic earnings (millions)	1,448	1,453	1,495
Dilutive impact of share options outstanding (millions)	2	-	3
Diluted weighted average number of Ordinary Shares in issue (millions)	1,450	1,453	1,498

There are no options, warrants or rights outstanding in respect of unissued shares except for employee share option schemes. The number of options outstanding and the weighted average exercise price of these options is shown in Note 24. The earnings figures used in the calculations above are post-tax.

# **6 Segment information**

AstraZeneca is engaged in a single business activity of pharmaceuticals and 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 Senior Executive Team (SET) is AstraZeneca's chief operating decision making body (as defined by IFRS 8). All significant operating decisions are taken by SET. 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. Resources are allocated on a group-wide basis according to need. In particular, capital expenditure, in-licensing, and research and 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.

### **Geographic areas**

The tables below show information by geographic area and, for revenue and property, plant and equipment, material countries. The figures show the revenue, operating profit and profit before tax made by companies located in that area/country, together with segment assets, segment assets acquired, net operating assets and property, plant and equipment owned by the same companies; export sales and the related profit are included in the area/country from which those sales were made.

	2009	2008	2007
	\$m	\$m	\$m
UK			
External	1,809	1,910	1,981
Intra-Group	9,056	8,460	6,506
	10,865	10,370	8,487
Continental Europe			
Belgium	353	380	387
France	1,880	1,945	1,806
Germany	1,197	1,225	1,164
Italy	1,012	1,145	1,111
Spain	742	832	840
Sweden	1,070	1,135	985
Others	2,622	2,696	2,291
Intra-Group	4,944	3,895	4,123
	13,820	13,253	12,707
The Americas			
Canada	1,188	1,269	1,145
US	14,994	13,657	13,404
Others	1,113	1,155	872
Intra-Group	1,962	1,169	786
	19,257	17,250	16,207
Asia, Africa & Australasia			
Australia	790	763	631
Japan	2,214	1,861	1,585
China	811	627	403
Others	1,009	1,001	954
Intra-Group	80	78	56
	4,904	4,330	3,629
Continuing operations	48,846	45,203	41,030
Intra-Group eliminations	(16,042)	(13,602)	(11,471)
	32,804	31,601	29,559

Export sales from the UK totalled \$9,864m for the year ended 31 December 2009 (2008: \$9,439m; 2007: \$7,546m). Intra-Group pricing is determined on an arm's-length basis.

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# **6 Segment information continued**

	Operating profit			Profit before tax			
Profit from	2009 \$m	2008 \$m	2007 \$m	2009 \$m	2008 \$m	2007 \$m	
UK	3,124	2,907	2,060	2,813	2,612	1,828	
Continental Europe	4,809	3,136	2,894	4,821	3,233	2,964	
The Americas	3,265	2,705	2,734	2,832	2,440	2,781	
Asia, Africa & Australasia	345	396	406	341	396	410	
Continuing operations	11,543	9,144	8,094	10,807	8,681	7,983	

		Non-current assets <sup>1</sup>				Total assets
	2009 \$m	2008 \$m	2007 \$m	2009 \$m	2008 \$m	2007 \$m
UK	3,810	3,524	4,808	17,092	9,870	12,574
Continental Europe	3,966	3,674	4,709	6,706	6,275	7,400
The Americas	21,354	21,762	19,887	28,397	28,290	25,775
Asia, Africa & Australasia	476	436	427	2,725	2,515	2,239
Continuing operations	29,606	29,396	29,831	54,920	46,950	47,988

	Assets acquired <sup>2</sup>			Ν	let operating assets <sup>3</sup>	
	2009 \$m	2008 \$m	2007 \$m	2009 \$m	2008 \$m	2007 \$m
UK	537	440	929	4,473	4,234	5,043
Continental Europe	643	295	624	4,094	3,683	4,972
The Americas	711	3,252	17,858	19,186	21,033	19,742
Asia, Africa & Australasia	79	67	48	1,707	1,732	1,510
Continuing operations	1,970	4,054	19,459	29,460	30,682	31,267

<sup>1</sup> Non-current assets exclude deferred tax assets and derivative financial instruments.

<sup>3</sup> 'Net operating assets' exclude short-term investments, cash, short-term borrowings, loans, retirement benefit obligations and non-operating receivables and payables.

		Property, plant and		
	2009 \$m	2008 \$m	2007 \$m	
UK	1,901	1,750	2,490	
Sweden	1,700	1,722	2,204	
US	2,386	2,200	1,915	
Rest of the world	1,320	1,371	1,689	
Continuing operations	7,307	7,043	8,298	

## **Geographic markets**

The table below shows revenue in each geographic market in which customers are located.

	2009 \$m	2008 \$m	2007 \$m
UK	1,057	994	1,003
Continental Europe	9,286	9,937	9,138
The Americas	17,096	15,945	15,459
Asia, Africa & Australasia	5,365	4,725	3,959
Continuing operations	32,804	31,601	29,559

Revenue is recognised at the point of delivery, which is usually when title passes to the wholesaler. Transactions with two wholesalers individually represented greater than 10% of total revenue (2008: 2, 2007: 2). The value of these transactions, recorded as revenue was \$4,319m and \$4,228m (2008: \$3,936m and \$3,900m, 2007: \$4,101m and \$4,236m).

# 7 Property, plant and equipment

				Total property,
	Land and	Plant and	Assets in course	plant and
	buildings \$m	equipment \$m	of construction \$m	equipment \$m
Cost				
At 1 January 2007	5,082	9,363	463	14,908
Capital expenditure	53	304	812	1,169
Additions through business combinations	302	122	176	600
Transfer of assets into use	151	470	(621)	
Disposals and other movements	(23)	(555)	(16)	(594)
Exchange adjustments	254	470	28	752
At 31 December 2007	5,819	10,174	842	16,835
Capital expenditure	49	239	825	1,113
Transfer of assets into use	275	404	(679)	_
Disposals and other movements	(123)	(558)	(25)	(706)
Exchange adjustments	(803)	(1,725)	(100)	(2,628)
At 31 December 2008	5,217	8,534	863	14,614
Capital expenditure	8	209	750	967
Transfer of assets into use	218	388	(606)	_
Disposals and other movements	(400)	(937)	(20)	(1,357)
Exchange adjustments	293	609	42	944
At 31 December 2009	5,336	8,803	1,029	15,168
Depreciation				
At 1 January 2007	1,656	5,799	-	7,455
Charge for year	227	849	-	1,076
Impairment	39	65	2	106
Disposals and other movements	(3)	(498)	(1)	(502)
Exchange adjustments	96	306	-	402
At 31 December 2007	2,015	6,521	1	8,537
Charge for year	247	812	-	1,059
Impairment	91	32	-	123
Disposals and other movements	(120)	(529)	(2)	(651)
Exchange adjustments	(303)	(1,192)	(2)	(1,497)
At 31 December 2008	1,930	5,644	(3)	7,571
Charge for year	219	674	-	893
Impairment	44	6	-	50
Disposals and other movements	(343)	(859)	(4)	(1,206)
Exchange adjustments	117	434	2	553
At 31 December 2009	1,967	5,899	(5)	7,861
Net book value				
At 31 December 2007	3,804	3,653	841	8,298
At 31 December 2008	3,287	2,890	866	7,043
At 31 December 2009	3,369	2,904	1,034	7,307

Impairment charges in 2009 are due to the productivity initiatives in the global supply chain in Italy and research and development in Canada. These costs were recognised in cost of sales and research and development respectively.

Impairment charges in 2008 were due to the productivity initiatives in the global supply chain in France and research and development in Canada. These costs were recognised in cost of sales and research and development respectively.

Impairment charges in 2007 were due to the productivity initiatives in the global supply chain in Germany and the write-down of business support assets. These costs were recognised in cost of sales and general and administrative expenses respectively.

	2009 \$m	2008 \$m	2007 \$m
The net book value of land and buildings comprised:			
Freeholds	3,369	3,287	3,804

Total property.

# 8 Goodwill

	2009 \$m	2008 \$m	2007 \$m
Cost			
At 1 January	10,211	10,225	1,430
Additions through business combinations	-	-	8,757
Exchange adjustments	17	(14)	38
At 31 December	10,228	10,211	10,225
Amortisation and impairment losses			
At 1 January	337	341	333
Exchange adjustments	2	(4)	8
At 31 December	339	337	341
Net book value at 31 December	9,889	9,874	9,884

For the purpose of impairment testing of goodwill, the Group is regarded as a single cash-generating unit.

The recoverable amount is based on value in use using discounted risk-adjusted projections of the Group's pre-tax cash flows over 10 years, a period reflecting the average patent-protected lives of our current products. The projections include assumptions about product launches, competition from rival products and pricing policy as well as the possibility of generics entering the market. In setting these assumptions we consider our past experience, external sources of information (including information on expected increases and ageing of the populations in our established markets and the expanding patient population in newer markets), our knowledge of competitor activity and our assessment of future changes in the pharmaceutical industry. The 10-year period is covered by internal budgets and forecasts. Given that internal budgets and forecasts are prepared for all projections, no general growth rates are used to extrapolate internal budgets and forecasts for the purposes of determining value in use. No terminal value is included as these cash flows are more than sufficient to establish that an impairment does not exist.

In arriving at value in use, we disaggregate our projected pre-tax cash flows into groups reflecting similar risks and tax effects. For each group of cash flows we use an appropriate discount rate reflecting those risks and tax effects. In arriving at the appropriate discount rate for each group of cash flows, we adjust AstraZeneca's post-tax weighted average cost of capital (7.6% for 2009, 7.6% for 2008) to reflect the impact of relevant industry risks, the time value of money and tax effects. The weighted average pre-tax discount rate we used was approximately 11% (11% for 2008).

As a further check, we compare our market capitalisation to the book value of our net assets and this indicates significant surplus at 31 December 2009 (and 31 December 2008).

## No goodwill impairment was identified.

The Group has also performed sensitivity analysis calculations on the projections used and discount rate applied. The Directors have concluded that, given the significant headroom that exists, and the results of the sensitivity analysis performed, there is no significant risk that reasonable changes in any key assumptions would cause the carrying value of goodwill to exceed its value in use.

# 9 Intangible assets

9 Intaligible assets				
	Product, marketing and distribution rights	Other intangibles	Software development costs	Total
	and distribution rights \$m	\$m	\$m	\$m
Cost				
At 1 January 2007	4,173	910	786	5,869
Additions – through business combinations	6,946	1,477	-	8,423
Additions – separately acquired	299	33	178	510
Disposals	(52)	(82)	-	(134)
Exchange adjustments	183	47	12	242
At 31 December 2007	11,549	2,385	976	14,910
Additions – separately acquired	2,743	20	178	2,941
Disposals	_	(33)	(30)	(63)
Exchange adjustments	(770)	(197)	(133)	(1,100)
At 31 December 2008	13,522	2,175	991	16,688
Additions – separately acquired	764	46	193	1,003
Disposals	(200)	(1)	-	(201)
Exchange adjustments	267	84	28	379
At 31 December 2009	14,353	2,304	1,212	17,869
Amortisation and impairment losses				
At 1 January 2007	1,859	443	460	2,762
Amortisation for year	364	112	78	554
Disposals	(52)	(81)	-	(133)
Impairment	98	22	-	120
Exchange adjustments	104	32	4	140
At 31 December 2007	2,373	528	542	3,443
Amortisation for year	529	182	96	807
Disposals	-	(9)	(10)	(19)
Impairment	516	91	24	631
Exchange adjustments	(357)	(104)	(36)	(497)
At 31 December 2008	3,061	688	616	4,365
Amortisation for year	481	162	86	729
Disposals	(67)	-	-	(67)
Impairment	93	273	49	415
Exchange adjustments	159	25	17	201
At 31 December 2009	3,727	1,148	768	5,643
Net book value				
At 31 December 2007	9,176	1,857	434	11,467
At 31 December 2008	10,461	1,487	375	12,323
At 31 December 2009	10,626	1,156	444	12,226

Other intangibles consist mainly of licensing and rights to contractual income streams.

Amortisation charges are recognised in profit as follows:

	Product, marketing		Software	
	and distribution rights	and distribution rights Other intangibles development	development costs	Total
	\$m	\$m	\$m	\$m
Year ended 31 December 2007				
Selling, general and administrative costs	364	27	78	469
Other operating income and expense	-	85	-	85
	364	112	78	554
Year ended 31 December 2008				
Cost of sales	39	-	-	39
Research and development	10	-	-	10
Selling, general and administrative costs	480	35	96	611
Other operating income and expense	-	147	-	147
	529	182	96	807
Year ended 31 December 2009				
Cost of sales	48	-	-	48
Selling, general and administrative costs	433	27	86	546
Other operating income and expense	-	135	-	135
	481	162	86	729

## 9 Intangible assets continued

Impairment charges are recognised in profit as follows:

	Product, marketing	Product, marketing		
	and distribution rights	Other intangibles	development cost	Total
	\$m	\$m	\$m	\$m
Year ended 31 December 2007				
Research and development	98	22	-	120
Year ended 31 December 2008				
Cost of sales	115	-	-	115
Research and development	144	-	-	144
Selling, general and administrative costs	257	-	24	281
Other operating income and expense	-	91	-	91
	516	91	24	631
Year ended 31 December 2009		· · ·		
Research and development	93	7	-	100
Selling, general and administrative costs	-	1	49	50
Other operating income and expense	-	265	-	265
	93	273	49	415

# Amortisation and impairment charges

The write down in value of the intangible assets in relation to these income streams was determined based on value in use calculations using discounted risk-adjusted projections of the products' expected cash flows over a period reflecting the patent-protected lives of the individual products. The full period of projections is covered by internal budgets and forecasts. In arriving at the appropriate discount rate to use for each product, we adjust AstraZeneca's post-tax weighted average cost of capital (7.6% for 2009; 7.6% in 2008) to reflect the impact of risks and tax effects specific to the individual products. The weighted average pre-tax discount rate we used was approximately 14% (2008: 14%).

The 2009 impairment of product marketing and distribution rights results from the termination of development projects during the year. The 2009 impairment of other intangibles results from a reassessment of the future royalties expected to be received relating to the HPV cervical cancer vaccine and a reassessment of other future licensing and contractual income expected to be earned within our biologics business.

The 2008 impairment of product, marketing and distribution rights results, in part, from the settlement of the *Pulmicort Respules* patent litigation with Teva (\$115m) and the 'at risk' launch of a generic competitor to *Ethyol* (\$257m). The 2008 impairment of other intangibles results from a reassessment of the future royalties expected to be received relating to the HPV cervical cancer vaccine. These impairment charges were determined using value in use calculations applying the same considerations as above. The post-tax weighted average cost of capital was 7.6%. The remaining \$144m impairment of product, marketing and distribution rights results from the termination of projects in development during the year.

The impairment in 2007 was in relation to the termination of a product in development acquired with Medlmmune and four collaboration agreements.

## **Significant assets**

	Description	Carrying value \$m	Remaining amortisation period
Intangible assets arising from joint venture with Merck <sup>1</sup>	Product, marketing and distribution rights	227	4 and 8 years
Advance payment <sup>1</sup>	Product, marketing and distribution rights	516	9 years
Partial retirement (non-refundable deposit) <sup>1</sup>	Product, marketing and distribution rights	1,656	Not amortised
Partial retirement <sup>1</sup>	Product, marketing and distribution rights	792	12-18 years
Intangible assets arising from the acquisition of CAT <sup>2</sup>	Product, marketing and distribution rights	409	6 and 11 years
Intangible assets arising from the acquisition of KuDOS <sup>2</sup>	Product, marketing and distribution rights	285	Not amortised
RSV franchise assets arising from the acquisition of MedImmune <sup>3</sup>	Product, marketing and distribution rights	4,884	16-22 years
Intangible assets arising from the acquisition of MedImmune <sup>3</sup>	Licensing and contractual income	720	2-10 years
Intangible assets arising from the acquisition of MedImmune <sup>3</sup>	Product, marketing and distribution rights	637	22 years
Intangible assets arising from the collaboration with BMS <sup>4</sup>	Product, marketing and distribution rights	416	13-14 years

<sup>1</sup> These assets are associated with the restructuring of the joint venture with Merck & Co., Inc. Further information can be found in Note 25.

<sup>2</sup> Assets in development are not amortised but are tested annually for impairment.

<sup>3</sup> An allocation of the cost of these assets to Therapy Area is given in Note 22.

<sup>4</sup> These assets arise from the collaboration agreement with BMS for Onglyza<sup>™</sup>.

## **10 Other investments**

2009	2008	2007
\$m	\$m	\$m
184	156	182
184	156	182
18	51	31
1,466	54	60
1,484	105	91
	\$m 184 184 18 18 1,466	\$m         \$m           184         156           184         156           184         51           1,466         54

Impairment charges of \$18m in respect of available for sale securities are included in other operating income and expense in profit (2008: \$25m; 2007: \$18m).

## **11 Inventories**

	2009	2008	2007
	\$m	\$m	\$m
Raw materials and consumables	445	409	579
Inventories in process	726	631	806
Finished goods and goods for re-sale	579	596	734
	1,750	1,636	2,119

Inventory write-offs in the year amounted to \$83m (2008: \$51m; 2007: \$95m).

## 12 Trade and other receivables

	2009	2008	2007
	\$m	\$m	\$m
Amounts due within one year			
Trade receivables	5,863	5,657	5,415
Less: Amounts provided for doubtful debts (Note 16)	(81)	(99)	(89)
	5,782	5,558	5,326
Other receivables	1,170	978	593
	580	552	510
	7,532	7,088	6,429
Amounts due after more than one year			
Other receivables	27	44	54
Prepayments and accrued income	150	129	185
Other receivables	177	173	239
	7,709	7,261	6,668
Provision for doubtful debts			
Balance at beginning of year	99	89	52
Income statement (credit)/charge	(20)	23	34
Amounts utilised, exchange and other movements	2	(13)	3
Balance at end of year	81	99	89

## 13 Cash and cash equivalents

	2009 \$m	2008 \$m	2007 \$m
Cash at bank and in hand	1,077	1,039	1,403
Short term deposits	8,841	3,247	4,464
Cash and cash equivalents	9,918	4,286	5,867
Unsecured bank overdrafts	(90)	(163)	(140)
Cash and cash equivalents in the cash flow statement	9,828	4,123	5,727

The Group's insurance subsidiaries hold cash and short term investments totalling \$173m (2008: \$400m; 2007: \$347m), of which \$49m (2008: \$278m; 2007: \$257m) is required to meet insurance solvency requirements and which, as a result, is not readily available for the general purposes of the Group.

#### 14 Interest-bearing loans and borrowings

·	-	Repayment	2009	2008	2007
		dates	\$m	\$m	\$m
Current liabilities					
Bank overdrafts		On demand	90	163	140
Floating rate note	US dollars	2009	_	650	-
4.625% Non-callable bond	Euros	2010	1,073	-	-
5.625% Non-callable bond	Euros	2010	717	-	-
Other loans		Within one year	46	180	4,140
			1,926	993	4,280
Non-current liabilities					
Floating rate note	US dollars	2009	-	-	649
4.625% Non-callable bond	Euros	2010	_	1,053	1,099
5.625% Non-callable bond	Euros	2010	-	702	-
5.4% Callable bond	US dollars	2012	1,805	1,823	1,765
5.4% Callable bond	US dollars	2014	821	789	767
5.125% Non-callable bond	Euros	2015	1,072	1,051	1,099
5.9% Callable bond	US dollars	2017	1,818	1,896	1,768
7% Guaranteed debentures	US dollars	2023	346	324	323
5.75% Non-callable bond	Pounds sterling	2031	558	501	691
6.45% Callable bond	US dollars	2037	2,717	2,716	2,715
			9,137	10,855	10,876

All loans and borrowings above are unsecured.

#### 15 Financial risk management objectives and policies

The Group's principal financial instruments, other than derivatives, comprise bank overdrafts, loans, current and non-current investments, cash and short-term deposits. The main purpose of these financial instruments is to manage the Group's funding and liquidity requirements. The Group has other financial assets and liabilities such as trade receivables and trade payables, which arise directly from its operations.

The principal financial risks to which the Group is exposed are those of liquidity, interest rate, foreign currency and credit. Each of these is managed in accordance with Board-approved policies. These policies are set out below.

The Group uses foreign currency borrowings, foreign currency forwards and options, interest rate swaps and forward rate agreements for the purpose of hedging its foreign currency and interest rate risks. The Group may designate certain financial instruments as either fair-value hedges or net investment hedges in accordance with IAS 39. Key controls applied to transactions in derivative financial instruments are: to use only instruments where good market liquidity exists, to revalue all financial instruments regularly using current market rates and to sell options only to offset previously purchased options. The Group does not use derivative financial instruments for speculative purposes.

#### **Capital management**

The capital structure of the Group consists of shareholders' equity (Note 20), debt (Note 14) and cash (Note 13). For the foreseeable future, the Board will maintain a capital structure that supports the Group's strategic objectives through:

- > Managing funding and liquidity risk.
- > Optimising shareholder return.
- > Maintaining a strong investment-grade credit rating.

Funding and liquidity risk are reviewed regularly by the Board and managed in accordance with policies described below.

The Board's distribution policy comprises both a regular cash dividend and subject to business needs, a share re-purchase component. The Board regularly reviews its shareholders' return strategy, and in 2009 adopted a progressive dividend policy, whereby the Board intends to maintain or grow the dividend each year, targeting an average dividend cover of 2 times (ie a payout ratio of 50%), based on reported earnings, (before restructuring costs). In addition, after providing for business investment, funding the progressive dividend policy and meeting debt service obligations, the Board will regularly assess the opportunity to return cash in excess of these requirements to shareholders through share re-purchases.

The Group's net debt position (loans and borrowings net of cash and cash equivalents, current investments and derivative financial instruments) has reduced from \$7,174m at the beginning of the year to a net funds position of \$535m at 31 December 2009 as a result of strong net operating cash in flows. The Group's policy is to manage its debt level so as to maintain a strong investment-grade credit rating. The Group's current long-term credit rating is A1 by Moody's and AA- by Standard and Poor's, both with a stable outlook.

## 15 Financial risk management objectives and policies continued Liquidity risk

The Board reviews the Group's ongoing liquidity risks annually as part of the planning process and on an *ad hoc* basis. The Board considers short-term requirements against available sources of funding taking into account forecast cash flow. The Group manages liquidity risk by maintaining access to a number of sources of funding which are sufficient to meet anticipated funding requirements. Specifically, the Group uses US commercial paper, committed bank facilities and cash resources to manage short-term liquidity and manages long-term liquidity by raising funds through the capital markets.

In addition to cash and cash equivalents of \$9,918m, fixed deposits of \$1,466m less overdrafts of \$90m at 31 December 2009, the Group has committed bank facilities of \$4.25bn available to manage liquidity. At 31 December 2009, the Group has issued \$3,420m under an EMTN programme, and \$7,507m under a SEC-registered programme. The Company regularly monitors the credit standing of the banking group and currently does not anticipate any issue with drawing on the committed facilities should this be necessary. The committed facilities consist of \$3.6bn maturing in October 2012 and \$0.65bn maturing between October and December 2010 and were undrawn at 31 December 2009.

#### Market risk

#### Interest rate risk

The Group maintains a mix of fixed and floating rate debt. The portion of fixed rate debt was approved by the Board and any variation requires Board approval. A significant portion of the long-term debt entered into in 2007 in order to finance the acquisition of MedImmune has been held at fixed rates of interest. The Group uses interest rate swaps and forward rate agreements to manage this mix.

At 31 December 2009, the Group held interest rate swaps with a notional value of \$2.5bn, converting the 5.4% callable bond maturing in 2014, and the 7% guaranteed debentures payable in 2023 to floating rates and partially converting the 5.4% callable bond maturing in 2012 and the 5.9% callable bond maturing in 2017 to floating rates. No new interest rate swaps were entered into during 2009. At 31 December 2009 swaps with a notional value of \$1.5bn were designated as fair-value hedges and swaps with a notional value of \$1.0bn related to debt designated as fair value through profit or loss. Designated hedges are expected to be effective and therefore the impact of ineffectiveness on profit is not expected to be material. The accounting treatment for fair-value hedges and debt designated as fair value through profit or loss is disclosed in the Accounting Policies section from page 128.

The majority of the Group's cash balances are held with third party fund managers with floating rates of interest being earned.

#### Foreign currency risk

The US dollar is the Group's most significant currency. As a consequence, the Group results are presented in US dollars and exposures are managed against US dollars accordingly.

#### Translational

Approximately 54% of Group external sales in 2009 were denominated in currencies other than the US dollar, while a significant proportion of manufacturing and research and development costs were denominated in sterling and Swedish krona. Surplus cash generated by business units is substantially converted to, and held centrally in US dollars. As a result, operating profit and total cash flow in US dollars will be affected by movements in exchange rates.

This currency exposure is managed centrally based on forecast cash flows for the currencies of Swedish krona, sterling, euro, Australian dollar, Canadian dollar and Japanese yen. The impact of movements in exchange rates is mitigated significantly by the correlations which exist between the major currencies to which the Group is exposed and the US dollar. Monitoring of currency exposures and correlations is undertaken on a regular basis and hedging is subject to pre-execution approval.

Where there is non-US dollar debt and an underlying net investment of that amount in the same currency, the Group applies net investment hedging. The €500m January 2010 bond and the €750m November 2010 bond were issued in non-US dollar currencies to match investors' appetite but currency swaps were transacted to convert them into fixed-rate US dollar instruments. As at 31 December 2009, after currency swaps, 5.0% of interest-bearing loans and borrowings were denominated in sterling and 9.7% of interest-bearing loans and borrowings were denominated in sterling and 9.7% of interest-bearing loans and borrowings were denominated as net investment hedges are recognised in other comprehensive income to the extent that the hedge is effective. Any ineffectiveness is taken to profit. Exchange differences on foreign currency borrowings not designated in a hedge relationship are taken to profit.

#### Transactional

The transaction exposures that arise from non-local currency sales and purchases by subsidiaries are, where practicable, fully hedged using forward foreign exchange contracts. In addition, the Group's external dividend, which is paid principally in sterling and Swedish krona, is fully hedged from announcement to payment date. Foreign exchange gains and losses on forward contracts transacted for transactional hedging are taken to profit.

#### **Credit risk**

The Group is exposed to credit risk on financial assets, such as cash balances (including fixed deposits and cash and cash equivalents), derivative instruments, trade and other receivables. The Group is also exposed in its net asset position to its own credit risk in respect of the 2023 debentures and 2014 bonds which are accounted for at fair value through profit and loss.

## 15 Financial risk management objectives and policies continued

## Trade and other receivables

Trade receivable exposures are managed locally in the operating units where they arise and credit limits are set as deemed appropriate for the customer. The Group is exposed to customers ranging from government-backed agencies and large private wholesalers to privately owned pharmacies, and the underlying local economic and sovereign risks vary throughout the world. Where appropriate, the Group endeavours to minimise risks by the use of trade finance instruments such as letters of credit and insurance. The Group establishes an allowance for impairment that represents its estimate of incurred losses in respect of specific trade and other receivables where it is deemed that a receivable may not be recoverable. When the debt is deemed irrecoverable, the allowance account is written off against the underlying receivable. The maximum exposure to credit risk for trade receivables and concentrations of credit risk are disclosed in Note 16.

#### **Other financial assets**

The Group may hold significant cash balances as part of its normal operations, with the amount of cash held at any point reflecting the level of cash flow generated by the business and the timing of the use of that cash. The majority of excess cash is centralised within the group treasury entity and is subject to counterparty risk on the principal invested. This risk is mitigated though a policy of prioritising security and liquidity over return, and as such cash is only invested in high credit quality investments. Counterparty limits are set according to the assessed risk of each counterparty and exposures are monitored against these limits on a regular basis. The majority of the Group's cash is invested in US Treasury bills, US Treasury funds, AAA-rated liquidity funds and short-term bank deposits.

The most significant concentration of financial credit risk at 31 December 2009 was \$4,636m invested in US Treasury funds and \$3,699m in US Treasury bills, which each bear credit exposure to the US government. There were no other significant concentrations of financial credit risk at the reporting date. All financial derivatives are transacted with commercial banks, in line with standard market practice. During the year the Group has entered into agreements with some bank counterparties whereby the parties agree to post cash collateral for the benefit of the other equivalent to the market valuation of the derivative positions above a predetermined threshold. The carrying value of such cash collateral held by the Group at 31 December 2009 was \$2m. The maximum exposure to credit risk is represented by the carrying amount of each financial asset, including derivative financial instruments recorded, in the Statement of Financial Position.

#### 16 Financial instruments

#### **Derivative financial instruments**

Set out below is a summary of the derivative financial instruments included in the Statement of Financial Position at 31 December 2009, 31 December 2008 and 31 December 2007.

	Non-current assets \$m	Current assets \$m	Current liabilities \$m	Non-current liabilities \$m	Total \$m
	•			· · · · · · · · · · · · · · · · · · ·	
Designated in a fair-value hedge	135	-	-	-	135
Related to instruments designated at fair value through profit or loss	127	-	-	-	127
Other derivatives	-	24	(90)	-	(66)
31 December 2009	262	24	(90)	-	196
	Non-current assets	Current assets	Current liabilities	Non-current liabilities	Total
	\$m	\$m	\$m	\$m	\$m
Designated in a fair-value hedge	229	-	-	-	229
Related to instruments designated at fair value through profit or loss	220	-	-	-	220
Other derivatives	-	-	(95)	(71)	(166)
31 December 2008	449	-	(95)	(71)	283
	Non-current assets	Current assets	Current liabilities	Non-current liabilities	Total
	\$m	\$m	\$m	\$m	\$m
Designated in a fair-value hedge	49	-	-	-	49
Related to instruments designated at fair value through profit or loss	68	-	-	-	68
Other derivatives	-	-	(31)	-	(31)
31 December 2007	117	-	(31)	-	86

To conform to the current basis of presentation, the Consolidated Statements of Financial Position at 31 December 2008 and 31 December 2007 have been adjusted to reflect changes to the classification of derivative financial instruments at those dates. The adjustments have increased total assets at 31 December 2008 by \$166m and at 31 December 2007 by \$31m and have decreased current assets at 31 December 2008 by \$283m and at 31 December 2007 by \$86m. The adjustments have had no effect on net assets or net income for the year.

### Fair values of financial assets and financial liabilities

Set out below is a comparison by category of carrying values and fair values of all the Group's financial assets and financial liabilities at 31 December 2009, 31 December 2008 and 31 December 2007. None of the financial assets or financial liabilities have been reclassified during the year.

		Instruments	Other					
	Instruments in a hedge relationship <sup>1</sup>	designated at fair value <sup>2</sup>	derivatives at fair value <sup>3</sup>	Available for sale	Held for trading	Amortised cost	Total carrying value	Fair value
	sm	\$m	\$m	\$m	\$m	\$m	sm	\$m
2009								
Cash and cash equivalents	-	-	-	-	-	9,918	9,918	9,918
Overdrafts	-	-	-	-	-	(90)	(90)	(90)
Loans due within one year	-	-	-	-	-	(1,836)	(1,836)	(1,867)
Loans due after more than one year	(1,629)	(1,167)	-	-	-	(6,341)	(9,137)	(9,832)
Derivative financial instruments	135	127	(66)	-	-	-	196	196
Other investments	-	-	-	184	18	1,466	1,668	1,668
Other financial assets	-	-	-	-	-	6,979	6,979	6,979
Other financial liabilities	-	-	-	-	-	(8,872)	(8,872)	(8,872)
2008								
Cash and cash equivalents	-	-	-	-	-	4,286	4,286	4,286
Overdrafts	-	-	-	-	-	(163)	(163)	(163)
Loans due within one year	-	-	-	-	-	(830)	(830)	(830)
Loans due after more than one year	(1,727)	(1,113)	-	-	-	(8,015)	(10,855)	(11,238)
Derivative financial instruments	229	220	(166)	-	-	_	283	283
Other investments	-	-	-	156	50	54	260	260
Other financial assets	-	-	-	-	-	6,580	6,580	6,580
Other financial liabilities	-	-	-	-	-	(7,239)	(7,239)	(7,239)
2007								
Cash and cash equivalents	-	-	-	-	-	5,867	5,867	5,867
Overdrafts	-	-	-	-	-	(140)	(140)	(140)
Loans due within one year	-	-	-	-	-	(4,140)	(4,140)	(4,140)
Loans due after more than one year	(1,544)	(1,090)	-	-	-	(8,242)	(10,876)	(11,235)
Derivative financial instruments	49	68	(31)	-	-	_	86	86
Other investments	_	-	-	182	31	60	273	273
Other financial assets	-	-	-	-	-	5,973	5,973	5,973
Other financial liabilities	-	-	-	-	-	(7,057)	(7,057)	(7,057)

<sup>1</sup> Includes borrowings and derivatives designated as hedged items in fair-value hedge relationships with respect to interest rate risk.

<sup>2</sup> Includes borrowings designated at fair value through profit or loss and related derivatives.

<sup>3</sup> Derivatives not designated in hedge relationships or related to financial instruments designated at fair value through profit or loss.

Other financial assets represent trade and other receivables (Note 12) excluding prepayments and accrued income. Other financial liabilities represent trade and other payables (Note 17) excluding deferred income.

Credit risk decreased the fair value of the bonds designated as fair value through profit or loss by \$145m for the year and increased the fair value by \$35m since designation. Changes in credit risk had no material effect on any other financial assets and liabilities recognised at fair value in the Financial Statements. The change in fair value attributable to changes in credit risk is calculated as the change in fair value not attributable to market risk.

The methods and assumptions used to estimate the fair values of financial instruments together with their carrying values are as follows:

- > Cash and overdrafts held on the Statement of Financial Position at amortised costs. Fair value approximates to carrying value.
- > Loans due within one year and after more than one year the fair value of fixed-rate publicly traded debt is based on year-end quoted market prices; the fair value of floating rate debt is nominal value, as mark to market differences would be minimal given the frequency of resets. The carrying value of loans designated at fair value through profit or loss is the fair value. For loans designated in a fair-value hedge relationship, carrying value is initially measured at fair value and remeasured for fair-value changes in respect of the hedged risk at each reporting date. All other loans are held at amortised cost.
- > Derivative financial instruments consists of interest rate swaps (included in designated as fair value through profit or loss if related to debt designated at fair value, or instruments in a hedge relationship as a fair-value hedge or other derivatives), forward foreign exchange contracts and foreign currency option contracts (included in other derivatives). All derivatives are held at fair value.
  - Interest rate swaps the fair value is estimated using appropriate zero coupon curve valuation techniques to discount future contractual cash flows based on rates current at year end.
  - Forward foreign exchange contracts the majority of contracts for existing transactions had maturities of six months or less from year end.
     The fair value of forward foreign exchange contracts is estimated by discounting the future contractual cash flows using appropriate yield curves based on market forward foreign exchange rates at the year end.
  - Foreign currency option contracts the fair value of option contracts is estimated using Black-Scholes valuation techniques.

- > Other investments held on the Statement of Financial Position at fair value. These include equity securities held on the Statement of Financial Position as other investments (Note 10). The fair value of listed investments is based on year end quoted market prices. For unlisted investments, carrying values approximate fair value.
- > Other financial assets and other financial liabilities held on the Statement of Financial Position at amortised costs with carrying value being a reasonable approximation of fair value.

The interest rates used to discount future cash flows, where applicable, are based on market swap curves at the reporting date, and were as follows:

	2009	2008	2007
Derivatives	2.0% to 4.6%	3.8% to 4.6%	4.3% to 5.1%
Loans and borrowings	2.0% to 4.6%	3.8% to 4.6%	4.3% to 5.1%

#### Fair value hierarchy

The table below analyses financial instruments carried at fair value, by valuation method. The different levels have been defined as follows:

> Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.

- > Level 2: inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (ie, as prices) or indirectly (ie, derived from prices).
- > Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

	Level 1 \$m	Level 2 \$m	Level 3 \$m	Total \$m
31 December 2009				
Equity securities available for sale	41	-	143	184
Equity securities held for trading	18	-	-	18
Derivative assets	-	286	-	286
Assets	59	286	143	488
Borrowing designated at fair value through profit or loss	(1,167)	-	-	(1,167)
Derivative liabilities	-	(90)	-	(90)
Liabilities	(1,167)	(90)	-	(1,257)

Equity securities available for sale which are analysed at Level 3 represent investments in private biotech companies. The fair values of these are approximated as cost. Hence, value is adjusted only for permanent impairment and for no other movement.

#### Net gains and losses on financial assets and financial liabilities

	2009 \$m	2008 \$m	2007 \$m
Included in operating profit			
Gains/(losses) on forward foreign exchange contracts	114	(399)	(59)
(Losses)/gains on receivables and payables	(141)	391	74
Losses on investments designated at fair value through profit or loss	_	_	(1)
Losses on available for sale current investments	(18)	(25)	(21)
	(45)	(33)	(7)
Included in finance income and expense			
Interest and fair value adjustments in respect of debt designated at fair value through profit or loss, net of derivatives	(169)	87	(22)
Interest and changes in carrying values of debt designated as hedged items, net of derivatives	(35)	(64)	(28)
Interest and fair value changes on fixed and short-term deposits and equity securities	43	140	344
Interest on debt, overdrafts and commercial paper held at amortised cost	(501)	(609)	(436)
Exchange gains/(losses) on financial assets and liabilities	31	(12)	(3)
	(631)	(458)	(145)
Included in other comprehensive income			
Foreign exchange differences on borrowings forming net investment hedges	(68)	291	(40)
Gain/(loss) on cash flow hedge in connection with debt issue	1	1	(21)
Available for sale gains/(losses) taken to equity	2	2	(9)
	(65)	294	(70)

\$95m fair value losses on interest rate fair value hedging instruments and \$97m fair value gains on the related hedged items have been included within interest and changes in carrying values of debt designated as hedged items, net of derivatives. All fair value hedge relationships were effective during the year. The accounting treatment for fair value hedges is disclosed in the Accounting Policies.

\$94m fair value losses on derivatives related to debt instruments designated at fair value through profit or loss and \$53m fair value losses on debt instruments designated at fair value through profit or loss have been included within interest and fair value adjustments in respect of debt designated at fair value through profit or loss, net of derivatives. The accounting treatment for debt designated at fair value through profit or loss is disclosed in the Accounting Policies section from page 128. The loss on cash flow hedge in connection with debt issue included in other comprehensive income relates to the amortisation of a loss on a cash flow hedge of a prospective debt issue which was taken directly to reserves in 2007. The total loss is being amortised through profit over the remaining life of the underlying debt instrument.

Ineffectiveness on the net investment hedge taken to profit was \$nil (2008: \$nil; 2007: \$nil). The accounting treatment for net investment hedges is disclosed in the Accounting Policies section from page 128.

#### Liquidity risk

The maturity profile of the anticipated future contractual cash flows including interest in relation to the Group's financial liabilities, on an undiscounted basis and which, therefore, differs from both the carrying value and fair value, is as follows:

31 December 2009	136	10,927	8,872	19,935	(262)	90	(172)	19,763
Effect of discounting, fair values and issue costs	-	209	-	209	(262)	1	(261)	(52)
Effect of interest	(3)	(7,467)	-	(7,470)	739	-	739	(6,731)
	139	18,185	8,872	27,196	(739)	89	(650)	26,546
In more than five years	-	12,209	-	12,209	(239)	-	(239)	11,970
In four to five years	-	405	-	405	(64)	-	(64)	341
In three to four years	-	429	-	429	(86)	-	(86)	343
In two to three years	-	2,246	-	2,246	(116)	-	(116)	2,130
In one to two years	-	523	185	708	(117)	-	(117)	591
Within one year	139	2,373	8,687	11,199	(117)	89	(28)	11,171
	and other Ioans \$m	Bonds \$m	and other payables \$m	financial instruments \$m	Interest rate swaps \$m	Currency swaps \$m	financial instruments \$m	Total \$m
	Bank overdrafts		Trade	Total non-derivative			Total derivative	

Barlin LotationTrade non-derivativeTrade financialInterest financialCurrency financialInterest financialCurrency financialInterest financialCurrency financialInterest financialCurrency financialInterestCurrency financialTotalSm </th <th>31 December 2008</th> <th>343</th> <th>11.505</th> <th>7.239</th> <th>19.087</th> <th>(449)</th> <th>71</th> <th>(378)</th> <th>18,709</th>	31 December 2008	343	11.505	7.239	19.087	(449)	71	(378)	18,709
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	Effect of discounting, fair values and issue costs	-	247	-	247	(449)	5	(444)	(197)
overdrafts and other loansTrade and othernon-derivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financial instrumentsderivative financialWithin one year3451,2717,1788,794(60)(60)8,734In one to two years-2,335612,396(60)6662,402In two to three years-465-465(59)(59)406In four to five years-2,241-2,241(59)-(59)2,182In more than five years-424-424(46)-(46)378In more than five years-12,478-12,478(163)-(163)12,315	Effect of interest	(2)	(7,956)	-	(7,958)	447	-	447	(7,511)
overdrafts and otherTrade and othernon-derivative financialderivative financialioansBonds \$mpayablesinstrumentsCurrency rate swapsinstrumentsTotal\$m\$m\$m\$m\$m\$m\$m\$m\$mWithin one year3451,2717,1788,794(60)(60)8,734In one to two years-2,335612,396(60)6662,402In three to four years-465-465(59)(59)406In four to five years-2,241-2,241(59)-(59)2,182In four to five years-424-424(46)-(46)378		345	19,214	7,239	26,798	(447)	66	(381)	26,417
overdrafts and otherTrade and othernon-derivative financialderivative financialloansBonds \$mpayablesinstruments \$mCurrency financialinstruments \$mTotal%m\$m\$m\$m\$m\$m\$m\$m\$m\$m\$mWithin one year3451,2717,1788,794(60)-(60)8,734In one to two years-2,335612,396(60)6662,402In two to three years-465-465(59)-(59)406In three to four years-2,241-2,241(59)-(59)2,182	In more than five years	-	12,478	-	12,478	(163)	-	(163)	12,315
overdrafts and otherTrade and othernon-derivative financialderivative financialloansBonds \$mBonds \$msminstrumentsCurrency financialTotal swapsVithin one year3451,2717,1788,794(60)-(60)8,734In one to two years-2,335612,396(60)6662,402In two to three years-465-465(59)-(59)406	In four to five years	-	424	-	424	(46)	-	(46)	378
overdrafts and otherTrade and othernon-derivative financialderivative financialand other loansBonds \$mBonds \$minstruments \$mInterest \$mCurrency \$mfinancial instrumentsWithin one year3451,2717,1788,794(60)-(60)8,734In one to two years-2,335612,396(60)6662,402	In three to four years	-	2,241	-	2,241	(59)	-	(59)	2,182
overdrafts         Trade and other         non-derivative         derivative           and other         and other         and other         financial         Interest         Currency         financial           loans         Bonds         payables         instruments         rate swaps         swaps         instruments         Total           \$m           Within one year         345         1,271         7,178         8,794         (60)         -         (60)         8,734	In two to three years	-	465	-	465	(59)	-	(59)	406
overdrafts Trade non-derivative derivative and other and other financial Interest Currency financial Ioans Bonds payables instruments rate swaps swaps instruments Total \$m \$m \$m \$m \$m \$m \$m \$m \$m m	In one to two years	-	2,335	61	2,396	(60)	66	6	2,402
overdrafts Trade non-derivative derivative and other and other financial Interest Currency financial Ioans Bonds payables instruments rate swaps swaps instruments Total	Within one year	345	1,271	7,178	8,794	(60)	-	(60)	8,734
		and other loans		and other payables	financial instruments	rate swaps	swaps	financial instruments	

31 December 2007	4,280	10,876	7,057	22,213	(117)	-	(117)	22,096
Effect of discounting, fair values and issue costs	-	33	-	33	(117)	-	(117)	(84)
Effect of interest	(25)	(8,857)	-	(8,882)	25	-	25	(8,857)
	4,305	19,700	7,057	31,062	(25)	-	(25)	31,037
In more than five years	-	13,356	-	13,356	(25)	-	(25)	13,331
In four to five years	-	2,255	-	2,255	-	-	-	2,255
In three to four years	-	532	-	532	-	-	-	532
In two to three years	-	1,679	-	1,679	-	-	-	1,679
In one to two years	-	1,259	89	1,348	-	-	-	1,348
Within one year	4,305	619	6,968	11,892	-	-	-	11,892
	overdrafts and other loans \$m	Bonds \$m	Trade and other payables \$m	non-derivative financial instruments \$m	Interest rate swaps \$m	Currency swaps \$m	derivative financial instruments \$m	Total \$m
	Bank			Total			Total	

Where interest payments are on a floating-rate basis it is assumed that rates will remain unchanged from the last business day of each year ended 31 December. For details of how liquidity risk is managed and for details of cash and cash equivalents, fixed deposits and committed bank facilities available to manage liquidity risk refer to Note 15.

It is not expected that the cash flows in the maturity profile could occur significantly earlier or at significantly different amounts.

### 16 Financial instruments continued Market risk

#### Interest rate risk

The interest rate profile of the Group's interest-bearing financial instruments, as at 31 December 2009, 31 December 2008 and 31 December 2007 is set out below. In the case of non-current financial liabilities, the classification includes the impact of interest rate swaps which convert the debt to floating rate.

			2009			2008			2007
	Total \$m	Fixed rate \$m	Floating rate \$m	Total \$m	Fixed rate \$m	Floating rate \$m	Total \$m	Fixed rate \$m	Floating rate \$m
Financial liabilities									
Interest-bearing loans and borrowings									
Current	1,926	1,790	136	993	-	993	4,280	-	4,280
Non-current	9,137	6,340	2,797	10,855	8,015	2,840	10,876	7,594	3,282
	11,063	8,130	2,933	11,848	8,015	3,833	15,156	7,594	7,562
Financial assets									
Fixed deposits	1,466	-	1,466	54	-	54	60	-	60
Cash and cash equivalents	9,918	-	9,918	4,286	-	4,286	5,867	-	5,867
	11,384	_	11,384	4,340	-	4,340	5,927	-	5,927

In addition to the financial assets above, there are \$7,376m (2008: \$7,070m; 2007: \$6,272m) of other current and non-current asset investments and other financial assets on which no interest is received.

#### Foreign currency risk

#### Translational

In 2009, the US Dollar was generally stronger than in the prior year against our six principal currency exposures: sterling (GBP), Swedish krona (SEK), euro (EUR), Australian dollar (AUD), Japanese yen (JPY) and Canadian dollar (CAD). The weakness of our cost currencies sterling and Swedish krona relative to the euro which is our main non-US dollar income currency has resulted in a small net benefit for the Group. During the year a series of option-based currency hedges were executed to protect the Group from adverse exchange rate movements and all matured during the period without being exercised. The cost of executing these hedges is recorded through profit.

#### Transactional

100% of the Group's major transactional currency exposures on working capital balances, which typically extend for up to three months, are hedged, where practicable, using forward foreign exchange contracts against individual Group companies' reporting currency.

The table below sets out the principal foreign exchange contracts outstanding at 31 December 2009, 31 December 2008 and 31 December 2007 along with the underlying gross exposure as defined above.

	GBP	SEK	EUR	AUD	JPY	CAD
2009	\$m	\$m	\$m	\$m	\$m	\$m
Gross exposure	(124)	(811)	556	75	197	43
Forward exchange contracts	124	811	(556)	(75)	(197)	(43)
Net exposure	-	-	-	-	-	-
2008						
Gross exposure	(676)	(444)	505	57	166	49
Forward exchange contracts	690	445	(512)	(52)	(166)	(24)
Net exposure	14	1	(7)	5	-	25
2007						
Gross exposure	(536)	(476)	627	24	168	57
Forward exchange contracts	530	494	(627)	(24)	(168)	(57)
Net exposure	(6)	18	-	_	-	-

#### 16 Financial instruments continued Sensitivity analysis

The sensitivity analysis set out below summarises the sensitivity of the market value of our financial instruments to hypothetical changes in market rates and prices. The range of variables chosen for the sensitivity analysis reflects our view of changes which are reasonably possible over a one-year period. Market values are the present value of future cash flows based on market rates and prices at the valuation date. For long-term debt, an increase in interest rates results in a decline in the fair value of debt.

The sensitivity analysis assumes an instantaneous 100 basis point change in interest rates in all currencies from their levels at 31 December 2009, with all other variables held constant. Based on the composition of our long-term debt portfolio as at 31 December 2009, a 1% increase in interest rates would result in an additional \$32m in interest expense being incurred per year. The exchange rate sensitivity analysis assumes an instantaneous 10% change in foreign currency exchange rates from their levels at 31 December 2009, with all other variables held constant. The +10% case assumes a 10% strengthening of the US dollar against all other currencies and the -10% case assumes a 10% weakening of the US dollar.

Each incremental 10% movement in foreign currency exchange rates would have approximately the same effect as the initial 10% detailed in the table below.

#### 31 December 2009

		Interest rates		Exchange rates
	+1%	-1%	+10%	-10%
Increase/(decrease) in fair value of financial instruments	602	(709)	137	(137)
Impact on profit: gain/(loss)	-	-	(134)	134
Impact on equity: gain/(loss)	-	-	271	(271)

#### 31 December 2008

		Interest rates		Exchange rates
	+1%	-1%	+10%	-10%
Increase/(decrease) in fair value of financial instruments	587	(706)	217	(217)
Impact on profit: gain/(loss)	-	-	(57)	57
Impact on equity: gain/(loss)	-	-	274	(274)

## 31 December 2007

		Interest rates		Exchange rates		
	+1%	-1%	+10%	-10%		
Increase/(decrease) in fair value of financial instruments	666	(779)	165	(165)		
Impact on profit: gain/(loss)	-	-	(37)	37		
Impact on equity: gain/(loss)	-	-	202	(202)		

There has been no change in the methods and assumptions used in preparing the above sensitivity analysis over the three-year period.

#### **Credit risk**

The carrying amount of financial assets, being cash and cash equivalents, derivative assets, other investments and other financial assets (consisting of trade and other receivables) represent the maximum credit exposure.

The maximum exposure to credit risk for trade receivables at the reporting date by geographic region was:

	2009 \$m	2008 \$m	2007 \$m
US	2,229	2,032	1,961
UK	482	459	425
Sweden	245	226	260
Euro zone countries	762	833	901
Other European countries	295	257	247
Japan	950	955	771
Other countries	819	796	761
	5,782	5,558	5,326

In the US, sales to three wholesalers accounted for approximately 81% of US sales (2008: three wholesalers accounted for approximately 81%; 2007: three wholesalers accounted for approximately 82%).

The ageing of trade receivables at the reporting date was:

	2009	2008	2007
	\$m	\$m	\$m
Not past due	5,542	5,262	4,930
Overdue but renegotiated	-	3	120
Past due 0-90 days	65	106	79
Past due 90-180 days	75	60	99
Past due > 180 days	100	127	98
	5,782	5,558	5,326
	2009	2008	2007
	\$m	\$m	\$m
Movements in provisions for trade receivables			
Balance at beginning of year	99	89	52
Income statement (credit)/charge	(20)	23	34
Amounts utilised, exchange and other movements	2	(13)	3
Balance at end of year	81	99	89

The allowance for impairment has been calculated based on past experience and is in relation to specific customers. Given the profile of our customers, including large wholesalers and government-backed agencies, no further credit risk has been identified with the trade receivables not past due other than those balances for which an allowance has been made.

## 17 Trade and other payables

	2009 \$m	2008 \$m	2007 \$m
Current liabilities			
Trade payables	2,316	1,940	1,983
Value added and payroll taxes and social security	342	371	434
Rebates and chargebacks	2,618	1,963	1,514
Other payables	1,038	1,026	865
Accruals	2,373	1,878	2,172
	8,687	7,178	6,968
Non-current liabilities			
Other payables	244	149	229

Included in other payables are amounts totalling \$259m (2008: \$227m; 2007: \$209m) to meet insurance obligations of the Group's insurance subsidiaries. These amounts are net of intra-group set-off.

## 18 Provisions for liabilities and charges

	Severance	Environmental	Employee benefits	Legal	Other provisions	Total
	\$m	\$m	\$m	\$m	\$m	\$m
At 1 January 2007	31	95	109	-	131	366
Charge for year	620	48	4	25	33	730
Cash paid	(25)	(32)	(23)	-	(25)	(105)
Exchange and other movements	17	-	10	-	2	29
At 31 December 2007	643	111	100	25	141	1,020
Charge/(credit) for year	469	37	(23)	-	164	647
Cash paid	(405)	(39)	(1)	-	(12)	(457)
Exchange and other movements	(88)	21	8	-	(9)	(68)
At 31 December 2008	619	130	84	25	284	1,142
Charge for year	309	6	12	636	101	1,064
Cash paid	(341)	(23)	-	(13)	(34)	(411)
Reversals	(89)	_	-	-	(28)	(117)
Exchange and other movements	13	(1)	(1)	_	(3)	8
At 31 December 2009	511	112	95	648	320	1,686

	2009 \$m	2008 \$m	2007 \$m
Due within one year	1,209	600	387
Due after more than one year	477	542	633
	1,686	1,142	1,020

#### 18 Provisions for liabilities and charges continued

AstraZeneca is undergoing a global restructuring initiative which involves rationalisation of the Global Supply Chain, European Sales and Marketing, Information Services and Business Support infrastructure and Research and Development. Employee costs in connection with the initiatives are recognised in severance provisions. This is a three-year programme expected to be substantially completed by the end of 2010.

Details of the environmental and legal provisions are provided in Note 25.

Employee benefit provisions include the executive deferred bonus plan. Further details are included in Note 24.

Other provisions comprise amounts relating to specific legal and constructive obligations and disputes.

No provision has been released or applied for any purpose other than that for which it was established.

#### **19 Capital and reserves**

	2009	2008	2007
Cumulative translation differences included within retained earnings	\$m	\$m	\$m
Balance at beginning of year	1,323	2,414	1,945
Foreign exchange arising on consolidation	388	(1,355)	489
Exchange adjustments on goodwill (recorded against other reserves)	13	(27)	20
Foreign exchange on borrowings	(68)	291	(40)
Net exchange movement in retained earnings	333	(1,091)	469
Balance at end of year	1,656	1,323	2,414

#### **Other reserves**

The other reserves arose from the cancellation of £1,255m of share premium account by the Company in 1993 and the redenomination of share capital (\$157m) in 1999. The reserves are available for writing off goodwill arising on consolidation and, subject to guarantees given to preserve creditors as at the date of the court order, are available for distribution.

#### **Retained earnings**

The cumulative amount of goodwill written off directly to reserves resulting from acquisitions, net of disposals, amounted to \$667m (2008: \$654m; 2007: \$681m) using year end rates of exchange. At 31 December 2009, 24,178 shares, at a cost of \$1m, have been deducted from retained earnings (2008: nil shares, at a cost of \$nil; 2007: nil shares, at a cost of \$nil).

There are no significant statutory or contractual restrictions on the distribution of current profits of subsidiaries, joint ventures or associates; undistributed profits of prior years are, in the main, permanently employed in the businesses of these companies. The undistributed income of AstraZeneca companies overseas might be liable to overseas taxes and/or UK taxation (after allowing for double taxation relief) if they were to be distributed as dividends (see Note 4).

#### 20 Share capital of the Company

	Authorised		Allotted, called-up	o and fully paid
	2009 \$m	2009 \$m	2008 \$m	2007 \$m
Issued Ordinary Shares (\$0.25 each)	363	363	362	364
Unissued Ordinary Shares (\$0.25 each)	237	_	-	_
Redeemable Preference Shares (£1 each – £50,000)	_	_	-	-
	600	363	362	364

The total authorised number of Ordinary Shares at 31 December 2009 was 2,400,000,000, of which 1,450,958,562 Ordinary Shares were in issue.

The Redeemable Preference Shares carry limited class voting rights and no dividend rights. This class of shares is capable of redemption at par at the option of the Company on the giving of seven days' written notice to the registered holder of the shares.

The movements in the number of Ordinary Shares during the year can be summarised as follows:

		No. of shares (million)
	2009	2008
At 1 January	1,447	1,457
Issues of shares	4	4
Re-purchase of shares	-	(14)
At 31 December	1,451	1,447

## 20 Share capital of the Company continued Share re-purchases

During the year, the Company did not re-purchase nor cancel any Ordinary Shares (2008: 13,597,940 Ordinary Shares at an average price of 2397 pence per share).

#### Share schemes

A total of 3,477,014 Ordinary Shares were issued during the year in respect of share schemes (2008: 4,078,635 Ordinary Shares). Details of movements in the number of Ordinary Shares under option are shown in Note 24; details of options granted to Directors are shown in the Directors' Remuneration Report from page 101.

#### Shares held by subsidiaries

No shares in the Company were held by subsidiaries in any year.

#### 21 Dividends to shareholders

	2009	2008	2007	2009	2008	2007
	Per share	Per share	Per share	\$m	\$m	\$m
Final	\$1.500	\$1.350	\$1.230	2,171	1,967	1,885
Interim	\$0.590	\$0.550	\$0.520	855	800	773
	\$2.090	\$1.900	\$1.750	3,026	2,767	2,658

The second interim dividend, to be confirmed as final, is \$1.71 per share and \$2,481m in total. This will be payable on 15 March 2010.

On payment of the dividends, exchange gains of \$17m (2008: gains of \$28m; 2007: gains of \$17m) arose. These exchange gains and losses are included in Note 3.

#### 22 Acquisitions of business operations

There were no acquisitions made during either the year ended 31 December 2009, or the year ended 31 December 2008.

Details with regard to acquisitions made during the year ended 31 December 2007 are set out below:

#### MedImmune

On 1 June 2007, AstraZeneca announced the successful tender offer for all the outstanding shares of common stock of Medlmmune, a world-leading biotechnology company with proven biologics discovery and development strength, pipeline and leading biomanufacturing capability. At that date, approximately 96.0% of the outstanding shares were successfully tendered; the remaining shares were acquired by 18 June 2007. The financial results of Medlmmune have been consolidated into the Group's results from 1 June 2007.

Cash consideration of \$13.9bn was paid for the outstanding shares. After taking account of the cash and investments acquired, together with the settlement of Medlmmune's convertible debt and outstanding share options, the total cash paid to acquire Medlmmune was \$15.6bn.

In most business acquisitions, there is a part of the cost that is not capable of being attributed in accounting terms to identifiable assets and liabilities acquired and is therefore recognised as goodwill. In the case of the acquisition of Medlmmune, this goodwill is underpinned by a number of elements, which individually cannot be quantified. Most significant amongst these is the premium attributable to a pre-existing, well positioned business in the innovation-intensive, high-growth biologics market with a highly skilled workforce and established reputation. Other important elements include buyer-specific synergies, potential additional indications for identified products and the core technological capabilities and knowledge base of the company.

MedImmune contributed \$714m of turnover in the year of acquisition. After amortisation, net investments/interest costs (including interest costs of external financing of \$446m) and tax, the loss attributable to MedImmune in the year of acquisition was \$410m. If the acquisition had taken effect at the beginning of the reporting period (1 January 2007), on a pro forma basis the revenue, profit before tax and profit after tax of the combined Group for 2007 would have been \$30,127m, \$7,576m and \$5,351m, respectively. Basic and diluted earnings per share for the combined Group in 2007 would have been \$3.56 and \$3.55, respectively. This pro forma information has been prepared taking into account amortisation, interest costs and related tax effects but does not purport to represent the results of the combined Group that actually would have occurred had the acquisition taken place on 1 January 2007 and should not be taken to be representative of future results.

## 22 Acquisitions of business operations continued

	Fair value			
	Book value	adjustment	Fair value	
	\$m	\$m	\$m	
Non-current assets				
Intangible assets	193	7,882	8,075	
Property, plant and equipment	523	70	593	
Other	550	(17)	533	
	1,266	7,935	9,201	
Current assets	1,439	115	1,554	
Current liabilities	(326)	39	(287)	
Additional obligations related to convertible debt and share options	-	(1,724)	(1,724)	
Non-current liabilities				
Interest-bearing loans and borrowings	(1,165)	-	(1,165)	
Other payables	(73)	-	(73)	
Deferred tax assets/(liabilities)	314	(2,694)	(2,380)	
	(924)	(2,694)	(3,618)	
Total assets acquired	1,455	3,671	5,126	
Goodwill	·		8,757	
Total consideration for outstanding shares			13,883	
Additional payments related to convertible debt, share options and other acquisition obligations			1,770	
Total consideration			15,653	

The total consideration for outstanding shares includes \$29m of directly attributable costs.

The intangible assets acquired included: (a) product, marketing and distribution rights relating to currently marketed products or franchises (principally in respect of the *Synagis* and motavizumab RSV franchise, *FluMist* and *Ethyol*); (b) product marketing and distribution rights relating to products in development (principally motavizumab); and (c) distribution rights relating to out-licensed products (principally the HPV cervical cancer vaccine). The combined acquisitions fair value of \$8,075m comprised \$6,570m relating to the Infection Therapy Area, \$1,425m relating to the Oncology Therapy Area and \$80m relating to the Respiratory & Inflammation Therapy Area. The carrying value of these assets is summarised in Note 9.

#### Other acquisitions

		Fair value		
	Book value	adjustment	Fair value	
	\$m	\$m	\$m	
Non-current assets				
Intangible assets	-	347	347	
Property, plant and equipment	7	-	7	
	7	347	354	
Current assets	12	-	12	
Current liabilities	(19)	-	(19)	
Non-current liabilities				
Other payables	(9)	-	(9)	
Deferred tax liabilities	_	(118)	(118)	
	(9)	(118)	(127)	
Total assets acquired	(9)	229	220	
Goodwill			-	
Total consideration			220	

The total consideration includes \$3m of directly attributable costs.

## 22 Acquisitions of business operations continued

### Arrow Therapeutics Limited

On 28 February 2007, the Company acquired 100% of the issued share capital of Arrow Therapeutics Limited for cash consideration of \$147m. Arrow Therapeutics Limited is a UK biotechnology company, focused on the discovery and development of anti-viral therapies. The acquisition provides a widely recognised expert group and technology platform in an area of research that complements internal capabilities in the Therapy Area of infection and anti-bacterials.

Arrow Therapeutics Limited had revenue of \$nil and a loss of \$26m for 2007 of which \$nil of revenue and \$17m of loss related to the period between acquisition and 31 December 2007.

#### Atlantis Components Inc.

On 10 October 2007, a Company subsidiary, Astra Tech AB, acquired 100% of the issued share capital of Atlantis Components Inc. for cash consideration of \$71m.

Atlantis Components Inc. is a US dental business whose principal activity is the design and manufacture of bespoke dental implant abutments. The intangible asset acquired is the specialist CAD/CAM technology used to design and manufacture customised dental implant abutments. The acquisition further strengthens Astra Tech AB's product portfolio in the field of dental implants.

The revenue and loss in 2007, for both the period since acquisition and full year, are immaterial.

#### **Cash flows**

	Medlmmune \$m	Other \$m	Total \$m
Total consideration	15,653	220	15,873
Cash and cash equivalents included in undertaking acquired	(979)	(3)	(982)
Net cash consideration	14,674	217	14,891

#### 23 Post-retirement benefits Pensions

## Background

The Company and most of its subsidiaries offer retirement plans which cover the majority of employees in the Group. Many of these plans are 'defined contribution', where the Company contribution and resulting charge is fixed at a set level or is a set percentage of employees' pay. However, several plans, mainly in the UK, the US and Sweden, are 'defined benefit', where benefits are based on employees' length of service and average final salary (typically averaged over one, three or five years). The major defined benefit plans, apart from the collectively bargained Swedish plan (which is still open to employees born before 1979), have been closed to new entrants since 2000.

The major defined benefit plans are funded through legally separate, fiduciary-administered funds. The cash funding of the plans, which may from time to time involve special payments, is designed, in consultation with independent qualified actuaries, to ensure that the assets together with future contributions should be sufficient to meet future obligations. The funding is monitored rigorously by the Company and appropriate fiduciaries specifically with reference to the Company's credit rating, market capitalisation and cash flows.

#### Post-retirement scheme deficit

The assets and obligations of the defined benefit schemes operated by the Group at 31 December 2009, as calculated in accordance with IAS 19 are shown below. The fair values of the schemes' assets are not intended to be realised in the short term and may be subject to significant change before they are realised. The present value of the schemes' obligations is derived from cash flow projections over long periods and is therefore inherently uncertain.

		Value at 31 December 2009			Value at 31 I	December 2008
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Scheme assets						
Equities	2,309	1,241	3,550	1,461	960	2,421
Bonds	2,279	903	3,182	1,935	772	2,707
Others	265	258	523	439	281	720
Total fair value of assets	4,853	2,402	7,255	3,835	2,013	5,848
Present value of scheme obligations	(7,055)	(3,591)	(10,646)	(5,029)	(3,591)	(8,620)
Past service cost not yet recognised	-	37	37	-	40	40
Deficit in the scheme as recognised in the Statement of Financial Position	(2,202)	(1,152)	(3,354)	(1,194)	(1,538)	(2,732)

## 23 Post-retirement benefits continued

#### Financing Principles

96.9% of the Group's defined benefit obligations at 31 December 2009 are in schemes within the UK, the US, Sweden or Germany. In these countries the pension obligations are funded with reference to the following financing principles:

- > The Group has a fundamental belief in funding the benefits it promises to employees.
- > The Group considers its pension arrangements in the context of its broader capital structure. In general it does not believe in committing excessive capital for funding whilst it has better uses of capital within the business nor does it wish to generate surpluses.
- > The pension funds are not part of the Group's core business. Pension funds may take rewarded risks with the investments underlying the funding, subject to adequate controls and the expected rewards outweighing the risks.
- > The Group recognises that deciding to hold certain investments may cause volatility in the funding position. The Group would not wish to amend its contribution level for relatively small deviations from its preferred funding level, because it is expected that there will be short-term volatility, but it is prepared to react appropriately to more significant deviations.
- > In the event that local regulations require an additional level of financing, the Group would consider the use of alternative methods of providing this that do not require immediate cash funding but help mitigate exposure of the pension arrangement to the credit risk of the Group.

These principles are appropriate to AstraZeneca's business at the present date; should circumstances change they may require review.

The Company has developed a funding framework to implement these principles. This determines the cash contributions payable to the pension funds, but does not affect the IAS 19 liabilities. To reduce the risk of committing excess capital to pension funds, liabilities are based on the expected return on the actual pension assets, rather than a corporate bond yield. At present this puts a different value on the liabilities than IAS 19.

#### UK

With regard to the Group's UK defined benefit fund, the above principles are modified in light of the UK regulatory requirements and resulting discussions with the Pension Fund Trustee. The most recent full actuarial valuation was carried out at 31 March 2008.

Under the agreed funding principles for the UK, cash contributions will be paid to the fund to target a level of assets in excess of the current expected cost of providing benefits. In addition, the Company will make contributions to an escrow account which will be held outside of the pension fund. The escrow account assets will be payable to the fund in agreed circumstances, for example, in the event of the Company and Trustee agreeing a change to the current long term investment strategy.

The market value of the fund's assets at the valuation date was £2,994m (\$5,951m equivalent), representing 87% of the fund's actuarially assessed liabilities as valued in accordance with the fund's technical provisions. The escrow fund held an additional £33m at the valuation date. During 2009, it was agreed to fund the shortfall by making a transfer of current escrow assets to the fund and by establishing a new funding schedule, making regular payments over seven years of about £42m per annum to the escrow and £132m per annum to the fund. This includes the contributions required to meet the benefits accruing of about £60m per annum. In addition, £90m per annum is being paid to the escrow for two years until the next valuation to cover the losses on the fund's investments since the valuation date as a result of the market downturn.

Under the agreed funding principles, the key assumptions as at 31 March 2008 for contributions to both the fund and escrow account are as follows: long-term UK price inflation set at 3.5% pa, salary increases at 3.5% pa, pension increases at 3.5% pa and investment returns at 7.1% pa (pre-retirement) and 5.96% pa (post-retirement).

On 28 January 2010, AstraZeneca announced that from 1 February 2010 the Company would commence consultation with its UK employees' representatives on proposals regarding changes affecting the Group's UK pension scheme. The Company does not propose to close the defined benefit fund to existing members, but proposes to freeze pensionable pay at its 30 June 2010 level. Employees who choose to leave the defined benefit fund will be offered funding which they may contribute to a new Group Self Invested Personal Pension Plan. Should the proposals proceed, implementation is planned from 1 July 2010, following which a review of the funding implications will be completed.

#### Rest of Group

The IAS 19 positions as at 31 December 2009 are shown below for each of the other countries with significant defined benefit plans. These plans account for 91% of the Group's defined benefit obligations outside of the UK. In principle, these plans are funded in line with the financing principles and contributions paid as prescribed by the funding framework.

- > The US defined benefits programme was actuarially revalued at 31 December 2009, when plan obligations were \$1,834m and plan assets were \$1,412m. This includes obligations in respect of the non-qualified plan which is largely unfunded.
- > The Swedish defined benefits programme was actuarially revalued at 31 December 2009, when plan obligations were estimated to amount to \$1,191m and plan assets were \$687m.
- > The German defined benefits programme was actuarially revalued at 31 December 2009, when plan obligations amounted to \$237m and plan assets were \$27m.

On current bases, it is expected that contributions (excluding those in respect of past service cost) during the year ended 31 December 2010 to the four main countries will be \$311m.

## 23 Post-retirement benefits continued

### Post-retirement benefits other than pensions

In the US, and to a lesser extent in certain other countries, AstraZeneca's employment practices include the provision of healthcare and life assurance benefits for retired employees. As at 31 December 2009, some 3,944 retired employees and covered dependants currently benefit from these provisions and some 12,658 current employees will be eligible on their retirement. AstraZeneca accrues for the present value of such retiree obligations over the working life of the employee. In practice these benefits will be funded with reference to the Financing Principles.

The cost of post-retirement benefits other than pensions for the Group in 2009 was \$19m (2008: \$21m; 2007: \$26m). Plan assets were \$285m and plan obligations were \$418m at 31 December 2009. These benefit plans have been included in the disclosure of post-retirement benefits under IAS 19.

#### **Financial assumptions**

Qualified independent actuaries have updated the actuarial valuations under IAS 19 of the major defined benefit schemes operated by the Group to 31 December 2009. The assumptions used by the actuaries are chosen from a range of possible actuarial assumptions which, due to the long-term nature of the scheme, may not necessarily be borne out in practice. These assumptions were as follows:

	2009			2008
	UK	Rest of Group	UK	Rest of Group
Inflation assumption	3.5%	2.3%	2.8%	2.2%
Rate of increase in salaries	4.5%	3.4%	3.8%	3.4%
Rate of increase in pensions in payment	3.5%	0.9%	2.8%	0.8%
Discount rate	5.5%	5.0%	6.2%	4.6%
Long-term rate of return expected at 31 December				
Equities	8.0%	8.1%	7.9%	7.7%
Bonds	5.5%	5.2%	5.2%	4.9%
Others	6.5%	4.8%	6.0%	3.5%
Rate of increase in medical costs	10.0%	10.0%	10.0%	10.0%

The expected return on assets is determined with reference to the expected long-term level of dividends, interest and other returns derived from the plan assets, together with realised and unrealised gains or losses on the plan assets, less any costs of administering the plan, less any tax payable by the plan. The expected returns are based on long-term market expectations and analysed on a regular basis to ensure that any sustained movements in underlying markets are reflected.

#### **Demographic assumptions**

The mortality assumptions are based on country-specific mortality tables. These are compared to actual AstraZeneca experience and adjusted where sufficient data is available. Additional allowance for future improvements in life expectancy is included for all major schemes where there is credible data to support this continuing trend.

The table below illustrates life expectancy assumptions at age 65 for male members retiring in 2009 and members expected to retire in 2029.

	Life expectancy assumption for a male me			
Country	2009	2029	2008	2028
UK	23.8	25.8	23.8	25.8
US	19.6	21.1	19.6	21.1
Sweden	20.4	22.4	20.4	22.4
Germany	17.7	20.5	17.7	20.5

#### Sensitivity of medical cost assumptions

	Effect of change in medical cost assumption increase/(decrease)				
	2009			2008	
	+1%	-1%	+1%	-1%	
Current service and interest cost of net periodic post-employment medical costs (\$m)	4	(3)	4	(3)	
Accumulated post-employment benefit obligation for medical costs (\$m)	32	(28)	28	(28)	

## 23 Post-retirement benefits continued Actuarial gains and losses

	2009	2008	2007	2006	2005
UK					
Present value of obligations (\$m)	(7,055)	(5,029)	(7,644)	(7,352)	(6,309)
Fair value of plan assets (\$m)	4,853	3,835	6,310	6,078	5,314
Deficit in the scheme (\$m)	(2,202)	(1,194)	(1,334)	(1,274)	(995)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	293	(1,185)	(185)	(259)	636
Percentage of scheme assets	6.0%	30.9%	2.9%	4.3%	12.0%
Scheme obligations					
Amount (\$m)	(1,218)	972	114	71	(539)
Percentage of scheme obligations	17.3%	19.3%	1.5%	1.0%	8.5%
Rest of Group					
Present value of obligations (\$m)	(3,591)	(3,591)	(3,348)	(3,109)	(2,995)
Fair value of plan assets (\$m)	2,402	2,013	2,644	2,493	2,284
Deficit in the scheme (\$m)	(1,189)	(1,578)	(704)	(616)	(711)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	180	(700)	(24)	55	63
Percentage of scheme assets	7.5%	34.8%	0.9%	2.2%	2.8%
Scheme obligations					
Amount (\$m)	176	(319)	(18)	25	(195)
Percentage of scheme obligations	4.9%	8.9%	0.5%	0.8%	6.5%
Total					
Present value of obligations (\$m)	(10,646)	(8,620)	(10,992)	(10,461)	(9,304)
Fair value of plan assets (\$m)	7,255	5,848	8,954	8,571	7,598
Deficit in the scheme (\$m)	(3,391)	(2,772)	(2,038)	(1,890)	(1,706)
Experience adjustments on:		· · · · ·			<u>_</u>
Scheme assets					
Amount (\$m)	473	(1,885)	(209)	(204)	699
Percentage of scheme assets	6.5%	32.2%	2.3%	2.4%	9.2%
Scheme obligations					
Amount (\$m)	(1,042)	653	96	96	(734)
Percentage of scheme obligations	9.8%	7.6%	0.9%	0.9%	7.9%

## The obligation arises from the following plans:

		2009		2008
	UK \$m	Rest of Group \$m	UK \$m	Rest of Group \$m
Funded	(7,026)	(3,159)	(5,004)	(3,025)
Unfunded	(29)	(432)	(25)	(566)
Total	(7,055)	(3,591)	(5,029)	(3,591)

## 23 Post-retirement benefits continued

## Statement of Comprehensive Income disclosures

The amounts that have been charged to the Consolidated Statement of Comprehensive Income, in respect of defined benefit schemes for the year ended 31 December 2009 are set out below:

			2009			2008
—	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Operating profit						
Current service cost	(96)	(126)	(222)	(146)	(107)	(253)
Past service cost	(53)	(24)	(77)	(86)	(28)	(114)
Settlements and curtailments	-	-	-	19	28	47
Total charge to operating profit	(149)	(150)	(299)	(213)	(107)	(320)
Finance expense						
Expected return on post-retirement scheme assets	261	127	388	398	187	585
Interest on post-retirement scheme obligations	(330)	(163)	(493)	(416)	(172)	(588)
Net return	(69)	(36)	(105)	(18)	15	(3)
Charge before taxation	(218)	(186)	(404)	(231)	(92)	(323)
Other comprehensive income						
Difference between the actual return and the expected return on the post-retirement schemes' assets	293	180	473	(1,185)	(700)	(1,885)
Experience gains/(losses) arising on the post-retirement schemes' obligations	105	(67)	38	78	4	82
Changes in assumptions underlying the present value of the post-retirement schemes' obligations	(1,323)	243	(1,080)	894	(323)	571
Actuarial (losses)/gains recognised	(925)	356	(569)	(213)	(1,019)	(1,232)

#### Movement in post-retirement scheme obligations

	:					2008
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Present value of obligation in schemes at beginning of year	(5,029)	(3,591)	(8,620)	(7,644)	(3,348)	(10,992)
Current service cost	(96)	(126)	(222)	(146)	(107)	(253)
Past service cost	(53)	(21)	(74)	(86)	(28)	(114)
Participant contributions	(31)	(3)	(34)	(43)	(3)	(46)
Benefits paid	295	200	495	375	112	487
Other finance expense	(330)	(163)	(493)	(416)	(172)	(588)
Expenses	6	-	6	8	-	8
Actuarial (loss)/gain	(1,218)	176	(1,042)	972	(319)	653
Settlements and curtailments	-	-	-	19	28	47
Exchange	(599)	(63)	(662)	1,932	246	2,178
Present value of obligations in schemes at end of year	(7,055)	(3,591)	(10,646)	(5,029)	(3,591)	(8,620)

### Fair value of scheme assets

	2009					2008
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
At beginning of year	3,835	2,013	5,848	6,310	2,644	8,954
Expected return on plan assets	261	127	388	398	187	585
Expenses	(6)	-	(6)	(8)	-	(8)
Actuarial gains/(losses)	293	180	473	(1,185)	(700)	(1,885)
Exchange	430	17	447	(1,583)	(161)	(1,744)
Employer contributions	304	262	566	235	152	387
Participant contributions	31	3	34	43	3	46
Benefits paid	(295)	(200)	(495)	(375)	(112)	(487)
At end of year	4,853	2,402	7,255	3,835	2,013	5,848

The actual return on the plan assets was a gain of \$861m (2008: loss of \$1,300m; 2007: gain of \$364m).

Included in total assets and obligations for the UK is \$363m in respect of members' defined contribution sections of the scheme. Costs in respect of the defined contribution sections of the scheme during the year were \$234m (2008: \$226m; 2007: \$191m).

## 23 Post-retirement benefits continued

## Transactions with pension schemes

During the year, the Group made loans to the UK and Swedish pension schemes to enable these schemes to manage their short-term liquidity requirements. The maximum balance outstanding in the year was \$9m and the amount outstanding at 31 December 2009 was \$5m.

#### Reserves

Included within the retained earnings reserve is the actuarial reserve. Movements on this reserve are as follows:

	2009 \$m	2008 \$m	2007 \$m
At 1 January	(1,371)	(479)	(401)
Actuarial losses	(569)	(1,232)	(113)
Deferred tax	140	340	35
At 31 December	(1,800)	(1,371)	(479)

The cumulative amount of actuarial losses before deferred tax recognised in other comprehensive income is \$2,436m (2008: \$1,867m; 2007: \$635m).

#### 24 Employee costs and share option plans for employees

#### **Employee costs**

The average number of people, to the nearest hundred, employed by the Group is set out in the table below. In accordance with the Companies Act 2006, this includes part-time employees.

Employees	2009	2008	2007
UK	10,600	11,000	11,800
Continental Europe	21,200	23,100	25,600
The Americas	19,800	20,900	20,200
Asia, Africa & Australasia	12,300	11,100	10,300
Continuing operations	63,900	66,100	67,900

Geographical distribution described in the table above is by location of legal entity employing staff. Certain staff will spend some or all of their activity in a different location.

The number of people employed by the Group at the end of 2009 was 62,700 (2008: 65,000; 2007: 67,400).

The costs incurred during the year in respect of these employees were:

	2009 \$m	2008 \$m	2007 \$m
Salaries	4,713	5,080	5,217
Social security costs	644	743	858
Pension costs	516	497	449
Other employment costs	560	596	584
	6,433	6,916	7,108

Severance costs of \$285m are not included above (2008: \$546m; 2007: \$724m).

The Directors believe that, together with the basic salary system, the Group's employee incentive schemes provide competitive and marketrelated packages to motivate employees. They should also align the interests of employees with those of shareholders, as a whole, through long-term share ownership in the Company. The Group's current UK, Swedish and US schemes are described below; other arrangements apply elsewhere.

#### **Bonus plans**

#### The AstraZeneca UK Performance Bonus Plan

Employees of participating AstraZeneca UK companies are invited to participate in this bonus plan, which rewards strong individual performance. Bonuses are paid partly in the form of Ordinary Shares in the Company (under the Her Majesty's Revenue & Customs (HMRC)-approved AstraZeneca All-Employee Share Plan and up to a maximum annual value of £3,000) and partly in cash. A tax-efficient share retention scheme, under which employees leave their bonus shares in trust for three to five years, forms part of the All-Employee Share Plan. The Company also offers UK employees the opportunity to buy Partnership Shares (Ordinary Shares) under the All-Employee Share Plan. Employees may invest up to £1,500 over a 12-month accumulation period and purchase Partnership Shares in the Company with the total proceeds at the end of the period. The purchase price for the shares is the lower of the price at the beginning or the end of the 12-month period. A tax-efficient share retention scheme is also available in respect of Partnership Shares. At the Company's AGM in 2002, shareholders approved the issue of new shares for the purposes of the All-Employee Share Plan.

#### 24 Employee costs and share option plans for employees continued

#### The AstraZeneca Executive Annual Bonus Scheme

This scheme is a performance bonus scheme for Directors and senior employees who do not participate in the AstraZeneca UK Performance Bonus Plan. Annual bonuses are paid in cash and reflect both corporate and individual performance measures. The Remuneration Committee has discretion to reduce or withhold bonuses if business performance falls sufficiently short of expectations in any year such as to make the payment of bonuses inappropriate.

#### The AstraZeneca Deferred Bonus Plan

This plan was introduced in 2006 and is used to defer a portion of the bonus earned under the AstraZeneca Executive Annual Bonus Scheme into Ordinary Shares in the Company for a period of three years. The plan currently operates only in respect of Executive Directors and members of the Senior Executive Team (SET). Awards of shares under this plan are typically made in February each year, the first award having been made in February 2006.

#### Sweden

In Sweden an all-employee performance bonus plan is in operation, which rewards strong individual performance. Bonuses are paid 50% into a fund investing in AstraZeneca equities and 50% in cash. The AstraZeneca Executive Annual Bonus Scheme, the AstraZeneca Share Option Plan and the AstraZeneca Performance Share Plan all operate in respect of relevant AstraZeneca employees in Sweden.

#### US

In the US, there are two all-employee short-term or annual performance bonus plans in operation to differentiate and reward strong individual performance. Annual bonuses are paid in cash. There are also two senior staff long-term incentive schemes, under which approximately 450 participants may be eligible for awards granted as either AstraZeneca ADSs or stock appreciation rights related to AstraZeneca ADSs. AstraZeneca ADSs necessary to satisfy the awards are purchased in the market or funded via a share trust. The AstraZeneca Share Option Plan, the AstraZeneca Pharmaceuticals LP Executive Performance Share Plan, the AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan operate in respect of relevant employees in the US.

#### Share plans

#### The AstraZeneca Performance Share Plan

This plan was approved by shareholders in 2005 for a period of 10 years. Generally, awards can be granted at any time, but not during a close period of the Company. The first grant of awards was made in June 2005. The main grant of awards in 2009 under the plan was in March, at the same time as options were granted under the AstraZeneca Share Option Plan, with a further smaller grant in August. Awards granted under the plan vest after three years subject to a performance condition. For awards in 2009 to Executive Directors and members of the Senior Executive Team (SET) the performance condition relates to the performance of the Company's total shareholder return (TSR) compared with that of a selected peer group of other pharmaceutical companies.

For awards to all other participants in 2009, except employees of MedImmune, the performance condition is equally weighted between the TSR condition described above and a three-year earnings per share (EPS) target. A separate performance condition applies to employees of MedImmune linked to the achievement of MedImmune business targets. The Remuneration Committee has responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated, including agreeing performance targets and which employees should be invited to participate. A fuller description of this plan can be found on page 108 in the Directors' Remuneration Report.

## The AstraZeneca Pharmaceuticals LP Executive Performance Share Plan

This plan was introduced in 2007 and is used to grant awards of performance shares to selected US employees under broadly the same terms as awards are made under the AstraZeneca Performance Share Plan. The only grant of awards in 2009 under the plan was in March. Awards granted under the plan vest after three years subject to a performance condition. For awards in 2009 to all participants, except employees of MedImmune, the performance condition is equally weighted between the performance of the Company's total shareholder return (TSR) compared with that of a selected peer group of other pharmaceutical companies and a three-year earnings per share (EPS) target. A separate performance condition applies to employees of MedImmune linked to the achievement of MedImmune business targets. The Remuneration Committee has responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated, including agreeing performance targets and which employees should be invited to participate.

#### The AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan

This plan was introduced in 2007 and provides for the grant of restricted stock unit (RSU) awards to selected employees (predominantly in the US). The RSU Plan is used in conjunction with the AstraZeneca Share Option Plan to provide a mix of RSUs and share options. The only grant of awards in 2009 under the plan was in March. Awards typically vest on the third anniversary of the date of grant and are contingent on continued employment with the Company. The Remuneration Committee has responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated.

#### The MedImmune, Inc. 2008 Restricted Stock Unit Award Plan

This plan was introduced in 2008 and provides for the grant of RSU awards to selected employees of MedImmune. This plan is used in conjunction with the AstraZeneca Share Option Plan to provide a mix of RSUs and share options. The only grant of awards in 2009 under the plan was in March. Awards typically vest on the third anniversary of the date of grant and are contingent on continued employment with the Company. The Remuneration Committee has responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated.

## 24 Employee costs and share option plans for employees continued

#### The AstraZeneca Restricted Share Plan

This plan was introduced in 2008 and provides for the grant of restricted share awards to key employees, excluding Executive Directors. Awards are made on an ad hoc basis with variable vesting dates. The plan has been used twice in 2009 to make awards to twelve employees. The Remuneration Committee has responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated.

## AstraZeneca Performance Share Plan

	Shares	WAFV <sup>1</sup>
	'000'	pence
Shares awarded in June 2005	312	1121
Shares awarded in March 2006	280	1486
Shares awarded in May 2006	19	1424
Shares awarded in March 2007	1,611	1372
Shares awarded in August 2007	68	1217
Shares awarded in November 2007	16	1105
Shares awarded in March 2008	1,338	941
Shares awarded in August 2008	14	1326
Shares awarded in March 2009	1,190	1140
Shares awarded in August 2009	8	1424

#### AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan

	Units '000	WAFV <sup>1</sup> \$
Units awarded in March 2007	755	26.90
Units awarded in November 2007	270	21.56
Units awarded in March 2008	1,313	18.88
Units awarded in March 2009	1,283	16.70

#### AstraZeneca Pharmaceuticals LP Executive Performance Share Plan

	Shares '000	WAFV1 \$
Shares awarded in March 2007	38	25.86
Shares awarded in March 2008	2,094	18.88
Shares awarded in August 2008	20	24.46
Shares awarded in March 2009	2,288	16.70
Shares awarded in August 2009	6	23.18

#### MedImmune, Inc. 2008 Restricted Stock Unit Award Plan

	Units	WAFV <sup>1</sup>
	'000	\$
Units awarded in March 2008	130	18.88
Units awarded in March 2009	177	16.70

#### **AstraZeneca Restricted Share Plan**

	Shares	WAFV <sup>1</sup>
	'000	pence
Shares awarded in March 2008	51	941
Shares awarded in May 2008	35	2210
	Units	WAFV <sup>1</sup>
	'000	\$
Units awarded in August 2009	9	23.22
Units awarded in September 2009	22	22.31
· · · · · · · · · · · · · · · · · · ·		-

<sup>1</sup> Weighted average fair value.

The fair values were determined using a modified version of the binomial model. This method incorporated expected dividends but no other features into the measurements of fair value.

The charge for share-based payments in respect of the AstraZeneca Performance Share Plan, the US incentive share schemes and restricted stock unit award plan is \$81m (2008: \$53m; 2007: \$31m). The plans are equity-settled.

#### Share option plans

At 31 December 2009, there were options outstanding under the Zeneca 1994 Executive Share Option Scheme, the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca Share Option Plan.

## 24 Employee costs and share option plans for employees continued

## (1) Summary of the AstraZeneca Share Option Plan

This is a share option plan for employees of participating AstraZeneca Group companies which was approved by shareholders at the Company's AGM in 2000. The first grant of options occurred in August 2000. The main grant of options in 2009 under the plan was in March, with a further smaller grant in August. The Remuneration Committee sets the policy for the Company's operation of the plan and, in accordance with the rules of the plan, conducted a review of the plan in 2004.

#### Eligibility

Any AstraZeneca employee may be recommended from time to time for the grant of an option. The Remuneration Committee sets the policy for the Company's operation of the plan including as regards which employees will be eligible to participate.

#### Grant of options

Options may be granted at any time other than during a close period. The grant of options is supervised by the Remuneration Committee, which is comprised wholly of Non-Executive Directors. No payment is required for the grant of an option. Options are not transferable. Options may be granted over AstraZeneca Ordinary Shares or ADSs.

#### Acquisition price

The price per Ordinary Share payable upon the exercise of an option will not be less than an amount equal to the average of the middle-market closing price for an Ordinary Share or ADS of the Company on the London or New York Stock Exchange on the three consecutive dealing days immediately before the date of grant (or as otherwise agreed with HM Revenue & Customs). Where the option is an option to subscribe, the price payable upon exercise cannot be less than the nominal value of an Ordinary Share of the Company.

#### Exercise of options

An option will normally be exercisable between three and 10 years following its grant provided any relevant performance condition has been satisfied. Options may be satisfied by the issue of new Ordinary Shares or by existing Ordinary Shares purchased in the market. The Remuneration Committee sets the policy for the Company's operation of the plan including as regards whether any performance target(s) will apply to the grant and/or exercise of each eligible employee's option. Options normally lapse on cessation of employment. Exercise is, however, permitted for a limited period following cessation of employment either for reasons of injury or disability, redundancy or retirement, or at the discretion of the Remuneration Committee, and on an amalgamation, take-over or winding-up of the Company.

#### (2) Summary of the AstraZeneca Savings-Related Share Option Plan (SAYE Scheme)

The AstraZeneca Savings-Related Share Option Plan was approved by shareholders in 2003 for a period of 10 years. The first grant of options under this plan was made in September 2003.

#### Eligibility

UK-resident employees of participating AstraZeneca companies are automatically eligible to participate.

#### Grant of options

Invitations to apply for options may be issued within six weeks after the announcement by the Company of its results for any period and at other times in circumstances considered to be exceptional by the Directors. No invitations may be issued later than 10 years after the approval of the scheme by shareholders. Options may only be granted to employees who enter into HM Revenue & Customs-approved savings contracts with the savings body nominated by the Company, under which monthly savings of a fixed amount (currently not less than £5 nor more than £250) are made over a period of three or five years. The number of Ordinary Shares over which an option is granted will be such that the total amount payable on its exercise will be the proceeds on maturity of the related savings contract. No payment will be required for the grant of an option. Options are not transferable.

#### Individual participation

Monthly savings by an employee under all savings contracts linked to options granted under any Save As You Earn scheme may not exceed £250 or such lower amounts as may be determined by the Directors.

#### Acquisition price

The price per Ordinary Share payable upon the exercise of an option will not normally be less than the higher of:

- (a) 90% of the arithmetical average of the middle-market quotations for an Ordinary Share on the London Stock Exchange on three consecutive dealing days shortly before the date on which invitations to apply for options are issued (provided that no such day may fall before the Company last announced its results for any period) or such other dealing day or days falling within the six-week period for the issue of invitations, as the Directors may decide; and
- (b) the nominal value of an Ordinary Share (unless the option is expressed to relate only to existing Ordinary Shares).

#### Exercise of options

An option will normally be exercisable only for six months commencing on the third or fifth anniversary of the commencement of the related savings contract. Options are satisfied by the issue of new Ordinary Shares. Options normally lapse on cessation of employment. Exercise is, however, permitted for a limited period (irrespective of the period during which the option has been held) following cessation of employment in certain compassionate circumstances and/or where an option has been held for more than three years (except on dismissal for misconduct) and/or on an amalgamation, take-over or winding-up of the Company.

## 24 Employee costs and share option plans for employees continued

### (3) Summary of the Zeneca 1994 Executive Share Option Scheme (1994 Scheme)

The Zeneca 1994 Executive Share Option Scheme was introduced in 1994. The last date for the grant of options was 16 March 2000 and the scheme has been replaced by the AstraZeneca Share Option Plan. Options granted under the 1994 Scheme are normally exercisable between three and 10 years following grant, provided the relevant performance condition has been satisfied. Options are satisfied by the issue of new Ordinary Shares. The performance condition applicable to the 1994 Scheme was that earnings per share must have grown by at least the increase in the UK Retail Price Index over three years plus 3% per annum. Satisfaction of this condition was tested annually by reference to the audited financial statements. All options granted under the 1994 Scheme have become exercisable, the performance conditions having been satisfied.

Options '000         WAEP' pence         Options '000         WAEP' pence         Options pence         Options '000           Movements during 2007         7,312         2737         -         -         1,074           Options granted         (2,770)         2648         (321)         2426         (1,327)           Options forfeited         (1,706)         2745         (95)         2603         (238)           Weighted average fair value of options granted during the year         682         -         -         483           Options curstanding         42,560         2451         1,490         2364         2,720           Movements during 2008         -         -         483         -         -         483           Options exercised         (2,577)         2204         (99)         2620         (675)           Options outstanding         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404         -         -         453           Options outstanding         52,568         2978         1,285         2934         2,140           Movements during 2009         -         -         -         351	WAEP <sup>1</sup> pence
Movements during 2007         -         -         1,074           Options granted         7,312         2737         -         -         1,074           Options exercised         (2,770)         2648         (321)         2426         (1,327)           Options forfeited         (1,706)         2745         (95)         2603         (238)           Weighted average fair value of options granted during the year         682         -         -         -         483           At 31 December 2007	pence
Options granted         7,312         2737         -         -         1,074           Options exercised         (2,770)         2648         (321)         2426         (1,327)           Options forfeited         (1,706)         2745         (95)         2603         (238)           Weighted average fair value of options granted during the year         682         -         -         -         483           Options outstanding         42,560         2451         1,490         2364         2,720           Movements during 2008         -         -         -         483           Options granted         14,858         1887         -         -         483           Options granted         (2,577)         2204         (99)         2620         (675)           Options forfeited         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404         -         -         4143           At 31 December 2008         -         -         -         351         -         -           Options outstanding         52,568         2978         1,285         2934         2,140         -	
Options exercised         (2,770)         2648         (321)         2426         (1,327)           Options forfeited         (1,706)         2745         (95)         2603         (238)           Weighted average fair value of options granted during the year         682         682         682         682           At 31 December 2007         Options outstanding         42,560         2451         1,490         2364         2,720           Movements during 2008         0         2,577         2204         (99)         2620         (675)           Options sercised         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404         404         404         404           At 31 December 2008         0ptions outstanding         52,568         2978         1,285         2934         2,140           Movements during 2009         0ptions granted         15,246         2281         -         -         351           Options granted         15,246         2281         -         -         351         2010         2680         260         2680         2680         2680         2680         2680         2680         2680	
Options forfeited         (1,706)         2745         (95)         2603         (238)           Weighted average fair value of options granted during the year         682	2164
Weighted average fair value of options granted during the year         682           At 31 December 2007         682           Options outstanding         42,560         2451         1,490         2364         2,720           Movements during 2008           -         -         483           Options granted         14,858         1887         -         -         483           Options exercised         (2,577)         2204         (99)         2620         (675)           Options forfeited         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404         404         404         404           At 31 December 2008         Options outstanding         52,568         2978         1,285         2934         2,140           Movements during 2009         Use 15,246         2281         -         -         351           Options exercised         (2,275)         2213         (317)         2670         (286)           Options forfeited         (3,141)         2604         (51)         2688         (169)	1785
At 31 December 2007         Options outstanding       42,560       2451       1,490       2364       2,720         Movements during 2008	2528
Options outstanding         42,560         2451         1,490         2364         2,720           Movements during 2008	616
Movements during 2008         Image: Constraint of the second	
Options granted         14,858         1887         -         -         483           Options exercised         (2,577)         2204         (99)         2620         (675)           Options forfeited         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404         - </td <td>2226</td>	2226
Options exercised         (2,577)         2204         (99)         2620         (675)           Options forfeited         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404         404         4131         December 2008         2620         (675)           Options outstanding         52,568         2978         1,285         2934         2,140           Movements during 2009         Units and the service of the service o	
Options forfeited         (2,273)         2622         (106)         2594         (388)           Weighted average fair value of options granted during the year         404	2398
Weighted average fair value of options granted during the year     404       At 31 December 2008     404       Options outstanding     52,568     2978     1,285     2934     2,140       Movements during 2009     0     2281     -     -     351       Options exercised     (2,275)     2213     (317)     2670     (286)       Options forfeited     (3,141)     2604     (51)     2688     (169)	2062
At 31 December 2008           Options outstanding         52,568         2978         1,285         2934         2,140           Movements during 2009	2291
Options outstanding         52,568         2978         1,285         2934         2,140           Movements during 2009                 2,140           Options granted         15,246         2281         -         -         351                        351	499
Movements during 2009           Options granted         15,246         2281         -         -         351           Options exercised         (2,275)         2213         (317)         2670         (286)           Options forfeited         (3,141)         2604         (51)         2688         (169)	
Options granted         15,246         2281         -         -         351           Options exercised         (2,275)         2213         (317)         2670         (286)           Options forfeited         (3,141)         2604         (51)         2688         (169)	2304
Options exercised         (2,275)         2213         (317)         2670         (286)           Options forfeited         (3,141)         2604         (51)         2688         (169)	
Options forfeited         (3,141)         2604         (51)         2688         (169)	2563
	2258
Weighted average fair value of options granted during the year 423	2340
	425
At 31 December 2009	
Options outstanding         62,398         2601         917         2734         2,036	2349
Range of exercise prices 1882 to 3934 2714	2164 to 3001
Weighted average remaining contractual life 2,240 days 75 days 1,	86 days
Options exercisable         29,376         2737         917         2714         105	2658

<sup>1</sup>Weighted average exercise price.

The fair value of options is estimated at the date of grant using the Black-Scholes option pricing model. The following table gives the assumptions applied to the options granted in the respective periods shown. Expectations of early exercise are incorporated into the model.

	2009	2008	2007
Average share price (pence)	2651	2295	2599
Weighted average exercise price (pence)			
AstraZeneca Share Option Plan	2281	1887	2737
SAYE schemes	2563	2398	2164
Expected volatility (%)	25.0	25.0	25.0
Dividend yield (%)	4.0	3.4	2.6
Risk-free interest rate (%)	3.7	4.3	4.8
Expected lives: AstraZeneca Share Option Plan (years)	6.0	6.0	6.0
Expected lives: SAYE schemes (years)	4.2	4.0	4.3

The expected volatility is based on the historic volatility (calculated based on the weighted average remaining life of the share options) adjusted for any expected changes to future volatility due to publicly available information.

No other features of options granted were incorporated into the measurement of fair value.

The charge for share-based payments in respect of share options is \$105m (2008: \$125m; 2007: \$124m) which is comprised entirely of equity-settled transactions.

#### 25 Commitments and contingent liabilities

	2009 \$m	2008 \$m	2007 \$m
Commitments			
Contracts placed for future capital expenditure not provided for in these accounts	739	332	571

Included in the above total are contracts related to certain product purchase and licence agreements with contingent consideration, the amounts of which are variable depending upon particular 'milestone' achievements. Sales of the products to which these milestones relate could give rise to additional payments, contingent upon the sale levels achieved. AstraZeneca generally has the right to terminate these agreements at no cost. Guarantees and contingencies arising in the ordinary course of business, for which no security has been given, are not expected to result in any material financial loss.

#### Arrangements with Merck

#### Introduction

In 1982, Astra AB set up a joint venture with Merck & Co., Inc. (now Merck Sharp & Dohme Corp., a subsidiary of the new Merck & Co., Inc. that resulted from the merger with Schering-Plough) (Merck) for the purposes of selling, marketing and distributing certain Astra products in the US. In 1998, this joint venture was restructured (Restructuring). Under the agreements relating to the Restructuring (Agreements), a US limited partnership (Partnership) was formed, in which Merck is the limited partner and AstraZeneca is the general partner, and AstraZeneca obtained control of the joint venture's business subject to certain limited partner and other rights held by Merck and its affiliates. These rights provide Merck with safeguards over the activities of the Partnership and place limitations on AstraZeneca's commercial freedom to operate. The Agreements provided for:

- > A payment to Merck in the event of a business combination between Astra and a third party in order for Merck to relinquish certain claims to that third party's products.
- > Annual contingent payments.
- > Termination arrangements which cause Merck to relinquish its interests in AstraZeneca's products and activities in stages, some of which are mandatory and others optional.

These elements are discussed in further detail below, together with a summary of their accounting treatments.

#### Payment in the event of a business combination

On the merger of Astra and Zeneca, a one-time lump sum payment of \$809m was triggered. As a result of this payment, Merck relinquished any claims it may have had to Zeneca products.

This payment was expensed at the point of merger since it caused no incremental benefits over the prior years' aggregate Astra and Zeneca performance to accrue to the merged AstraZeneca entity.

#### Annual contingent payments

AstraZeneca makes ongoing payments to Merck based on sales of certain of its products in the US (the 'contingent payments' on the 'agreement products'). As a result of the merger of Astra and Zeneca in 1999, these contingent payments (excluding those in respect of *Prilosec* and *Nexium*) could not be less than annual minimum sums between 2002 and 2007 ranging from \$125m to \$225m. AstraZeneca's payments exceeded the minimum level in all years.

AstraZeneca will continue to make contingent payments to Merck until at least 2012. Contingent payments (excluding those in respect of *Prilosec* and *Nexium* will cease in 2010 if AstraZeneca exercises the First Option (as discussed under First Option below); contingent payments in respect of *Prilosec* and *Nexium* will cease in 2012 if AstraZeneca exercises the Second Option at that time (as discussed under Second Option below).

The annual contingent payments on agreement products are expensed as incurred.

#### Termination arrangements

The Agreements provided for arrangements and payments under which, subject to the exercise of certain options, the rights and interests in AstraZeneca's activities and products held by Merck immediately prior to the merger would be terminated, including details of:

- > the Advance Payment;
- > the Partial Retirement;
- > the True-Up;
- > the Loan Note Receivable;
- > the First Option;
- > the Second Option.

#### Advance Payment

The merger between Astra and Zeneca in 1999 triggered the first step in the termination arrangements. Merck relinquished all rights, including contingent payments on future sales, to potential Astra products with no existing or pending US patents at the time of the merger. As a result, AstraZeneca now has rights to such products and is relieved of potential obligations to Merck and restrictions in respect of those products (including annual contingent payments), affording AstraZeneca substantial freedom to exploit the products as it sees fit.

#### 25 Commitments and contingent liabilities continued

At the time of the merger, the Advance Payment was paid. It was calculated as the then net present value of \$2.8bn discounted from 2008 to the date of merger at a rate of 13% per annum and amounted to \$967m. It was subject to a true-up in 2008 (as discussed under True-Up below).

#### **Partial Retirement**

In March 2008, there was a partial retirement of Merck's limited partnership interest by payment to Merck of an amount calculated as a multiple of the average annual contingent payments from 2005 to 2007 on the relevant products, plus \$750m. The payment was \$4,271m. The amount payable under the Partial Retirement was estimated to be \$4.3bn in the 2007 Financial Statements.

Upon the Partial Retirement, Merck's rights in respect of certain of the agreement products ended. The products covered by the Partial Retirement include *Toprol-XL*, *Pulmicort*, *Rhinocort* and *Symbicort*.

#### True-Up

In 2008, in accordance with the Agreements, there was a True-Up of the Advance Payment. The True-Up amount was based on a multiple of the average annual contingent payments from 2005 to 2007 in respect of all the agreement products with the exception of *Prilosec* and *Nexium* (subject to a minimum of \$6.6bn), plus other defined amounts (totalling \$912m). In accordance with the Agreements, the calculated amount was then reduced by the Appraised Value (as discussed under "First Option" below), the Partial Retirement and the Advance Payment (at its undiscounted amount of \$2.8bn). This True-Up amount was settled in an amount equal to \$241m owed by Merck to AstraZeneca. The amount payable under the True-Up was estimated to be \$0.2bn in the 2007 Financial Statements, payable by Merck to AstraZeneca.

#### Loan Note Receivable

Included in the assets and liabilities covered by the Restructuring was a loan note receivable by AstraZeneca from Merck with a face value of \$1.38bn. In 2008, at the same time as the settlement of the Partial Retirement and the True-Up, Merck settled the loan note receivable by paying AstraZeneca \$1.38bn.

If Merck had exercised the First Option in 2008, the net minimum payment that would have been made to Merck would have been \$3.3bn, being the minimum combined payments of \$4.7bn specified in the Agreements on the Partial Retirement, the True-Up and First Option, less the repayment of the loan note of \$1.38bn. In accounting for the Restructuring in 1998, the loan note was included in the determination of the fair values of the assets and liabilities to be acquired. At that time, the loan note was ascribed a fair value of zero on acquisition and on the balance sheet, because it was estimated that the net minimum payment of \$3.3bn equated to the fair value of the rights to be acquired under the Partial Retirement, True-Up and First Option.

#### **First Option**

In accordance with the Agreements, in 2008 a calculation was made of the Appraised Value, being the net present value of the future contingent payments in respect of all agreement products not covered by the Partial Retirement, other than *Prilosec* and *Nexium*. The Appraised Value was calculated in 2008 as \$647m.

Payment of the Appraised Value to Merck in March 2008 would have taken place only if Merck had exercised the First Option in 2008. Merck did not exercise this option. AstraZeneca may exercise the First Option in the first two months of 2010 for a sum equal to the 2008 Appraised Value. If AstraZeneca exercises the First Option, it expects to consummate this option in April 2010.

Upon consummation of the First Option, Merck will relinquish its rights over the agreement products not covered by the Partial Retirement, other than *Nexium* and *Prilosec* and the right to receive contingent payments in respect of felodipine AG (Merck's continuing contingent payment interest in respect of the authorised generic version of felodipine is the result of Ranbaxy Pharmaceuticals, Inc. becoming the exclusive US distributor of the authorised generic version of felodipine, which arrangement is expected to end in June 2011). Products covered by the First Option include *Entocort, Atacand, Plendil* and certain compounds still in development including *Brilinta*, AZD3355, AZD6765 and AZD2327. If AstraZeneca does not exercise the First Option, the contingent payment arrangements in respect of these agreement products will continue (as will AstraZeneca's other obligations and restrictions in respect of these products) and the Appraised Value will not be paid.

#### Second Option

Provided that the First Option is exercised, AstraZeneca may exercise a Second Option to repurchase Merck's interests in *Prilosec* and *Nexium* in the US. This option is exercisable by AstraZeneca in 2012, or in 2017, or if combined annual sales of the two products fall below a minimum amount. AstraZeneca's consummation of the Second Option will end the contingent payments in respect of *Prilosec* and *Nexium* and will effectively end AstraZeneca's relationship with, and obligations to, Merck (other than some residual manufacturing arrangements). The exercise price for the Second Option is the net present value of the future annual contingent payments on *Prilosec* and *Nexium* as determined at the time of exercise. If the Second Option is consummated, Merck will then have relinquished all its interests in the Partnership and the agreement products, including rights to contingent payments. The exercise price of the Second Option cannot be determined at this time.

#### Accounting treatment of termination arrangements

AstraZeneca considers that the termination arrangements described above represent the acquisition, in stages, of Merck's interests in the Partnership and agreement products (including Merck's rights to contingent payments) and depend, in part, on the exercise of the First and Second Options. The effects will only be reflected in the financial statements as these stages are reached. If and when all such payments are made, AstraZeneca will have unencumbered discretion in its operations in the US market.

#### 25 Commitments and contingent liabilities continued

AstraZeneca anticipates that the benefits that accrue under all of the termination arrangements arise:

- > Currently, from the substantial freedom over products acquired or discovered post-merger.
- > On occurrence of each stage of such arrangements, from enhanced contributions from, and substantial freedom over, those products that have already been launched (for example, *Pulmicort*, *Symbicort*, *Rhinocort* and *Atacand*), and those that are in development.
- > Economic benefits include relief from contingent payments, anticipated cost savings from cessation of manufacturing arrangements and other cost efficiencies, together with the strategic advantages of increased freedom to operate.

The Advance Payment has been accounted for as an intangible asset and is being amortised over 20 years. This approach reflects the fact that, under the Agreements, AstraZeneca has acquired rights relieving it of potential obligations and restrictions in respect of Astra products with no existing or pending patents at the time of merger. Although these rights apply in perpetuity, the period of amortisation of 20 years has been chosen to reflect the typical timescale of development and marketing of a product.

The net payment made in 2008, consisting of the Partial Retirement of \$4.271bn less the True-Up of \$241m and loan note receivable of \$1.38bn, in total \$2.6bn, has been capitalised as intangible assets.

Part of the net payment made in 2008 resulted in AstraZeneca acquiring Merck's interests in certain AstraZeneca products, including *Pulmicort*, *Rhinocort*, *Symbicort* and *Toprol-XL*. Consequently AstraZeneca no longer has to make contingent payments on these products to Merck and has obtained the ability to fully exploit these products and to fully exploit other opportunities in the Respiratory therapy area that AstraZeneca was previously prevented from doing by Merck's interests in these products. Intangible assets aggregating \$994m have been recognised in respect of these acquired product rights and these are being amortised over various periods, giving rise to an annual expense of approximately \$60m going forward.

The balance of the net payment made in 2008 represents a payment on account for the product rights that will be acquired in the event that the First and Second Options are exercised by AstraZeneca. Intangible assets aggregating \$1.656bn were recognised in 2008. This balance will not be subject to amortisation until each of the options is exercised and the related product rights are acquired. If the First Option is not exercised, all the payments on account will be expensed immediately. If after the First Option is exercised but it becomes probable that the Second Option will not be exercised, the payments on account for the product rights to be acquired under the Second Option will be expensed immediately.

#### **Environmental costs and liabilities**

The Group's expenditure on environmental protection, including both capital and revenue items, relates to costs which are necessary for implementing internal systems and programmes and meeting legal and regulatory requirements for processes and products.

They are an integral part of normal ongoing expenditure for carrying out the Group's research, manufacturing and commercial operations and are not separated from overall operating and development costs. There are no known changes in legal, regulatory or other requirements resulting in material changes to the levels of expenditure for 2007, 2008 or 2009.

In addition to expenditure for meeting current and foreseen environmental protection requirements, the Group incurs costs in investigating and cleaning up land and groundwater contamination. In particular, AstraZeneca has environmental liabilities at some currently or formerly owned, leased and third party sites.

In the US, Zeneca Inc., and/or its indemnitees, have been named as potentially responsible parties (PRPs) or defendants at approximately 19 sites where Zeneca Inc. is likely to incur future investigation, remediation or operation and maintenance costs under federal or state, statutory or common law environmental liability allocation schemes (together, US Environmental Consequences). Similarly, Stauffer Management Company LLC (SMC), which was established in 1987 to own and manage certain assets of Stauffer Chemical Company acquired that year, and/or its indemnitees, have been named as PRPs or defendants at approximately 28 sites where SMC is likely to incur US Environmental Consequences. Outside the US, AstraZeneca has given indemnities to third parties in respect of approximately 22 sites. These environmental liabilities arise from legacy operations that are not part of the Group's current pharmaceuticals business and, at most of these sites, remediation, where required, is either completed or nearing completion.

AstraZeneca has made provisions for the estimated costs of future environmental investigation, remediation and operation and maintenance activity beyond normal ongoing expenditure for maintaining the Group's R&D and manufacturing capacity and product ranges where a present obligation exists, it is probable that such costs will be incurred and they can be estimated reliably. With respect to such estimated future costs, there were provisions at 31 December 2009 in the aggregate of \$101m, which mainly relate to the US. These provisions do not include possible additional costs that are not currently probable. Where we are jointly liable or otherwise have cost sharing agreements with third parties, we reflect only our share of the obligation. Where the liability is insured in part or in whole by insurance or other arrangements for reimbursement, an asset is recognised to the extent that this recovery is virtually certain.

It is possible that AstraZeneca could incur future environmental costs beyond the extent of our current provisions. The extent of such possible, additional costs is inherently difficult to estimate due to a number of factors, including: (1) the nature and extent of claims that may be asserted in the future; (2) whether AstraZeneca has or will have any legal obligation with respect to asserted or unasserted claims; (3) the type of remedial action, if any, that may be selected at sites where the remedy is presently not known; (4) the potential for recoveries from or allocation of liability to third parties; and (5) the length of time that the environmental investigation, remediation and liability allocation process can take. Notwithstanding and subject to the foregoing, it is estimated that potential additional loss for future environmental investigation, remediation and remedial operation and maintenance activity above and beyond our provisions could be, in aggregate, in the order of \$10-25m, which relates solely to the US.

## 25 Commitments and contingent liabilities continued Legal proceedings

AstraZeneca is involved in various legal proceedings considered typical to its businesses, including actual or threatened litigation and/or actual or potential government investigations relating to employment, product liability, commercial disputes, pricing, sales and marketing practices, infringement of intellectual property rights, the validity of certain patents and anti-trust laws. The more significant matters are discussed below.

Most of the claims involve highly complex issues. Often, these issues are subject to substantial uncertainties and therefore the probability of a loss, if any, being sustained and an estimate of the amount of any loss is difficult to ascertain. Consequently, for a majority of these claims, 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 to the nature and facts of the cases.

With respect to each of the legal proceedings described below, other than those for which provision has been made, we are unable to make estimates of the possible loss or range of possible losses at this stage, other than as set forth herein. We also do not believe that disclosure of the amount sought by plaintiffs, if that is known, would be meaningful with respect to those legal proceedings. This is due to a number of factors including: the stage of the proceedings (in many cases trial dates have not been set) and the overall length and extent of pre-trial discovery; the entitlement of the parties to an action to appeal a decision; clarity as to theories of liability, damages and governing law; uncertainties in timing of litigation; and the possible need for further legal proceedings to establish the appropriate amount of damages, if any.

However, although there can be no assurance regarding the outcome of any of the legal proceedings referred to in this Note 25, based on management's current and considered view of each situation, we do not currently expect them to have a material adverse effect on our financial position. This position could of course change over time, not least because of the factors referred to above.

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 other similar forms of relief), or where a loss is probable and we are able to make a reasonable estimate of the loss, we indicate the loss absorbed or the amount of the provision accrued. AstraZeneca is defending its interests in various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices and in respect of which the Company has made provisions in aggregate of \$636m during 2009. \$524m of this has been made in respect of the US Attorney's Office's investigation into sales and marketing practices involving *Seroquel* and \$112m relates to average wholesale price litigation. The current status of these matters is described below. These provisions constitute our best estimate at this time of the losses expected for these matters.

Where it is considered that the Group is more likely than not to prevail, legal costs involved in defending the claim are charged to profit as they are incurred.

Where it is considered that the Group has a valid contract which provides the right to reimbursement (from insurance or otherwise) of legal costs and/or all or part of any loss incurred or for which a provision has been established, we consider recovery to be virtually certain and, the best estimate of the amount expected to be received is recognised as an asset.

Assessments as to whether or not to recognise provisions or assets and of the amounts concerned usually involve a series of complex judgements about future events and can rely heavily on estimates and assumptions. AstraZeneca believes that the provisions recorded are adequate based on currently available information and that the insurance recoveries recorded will be received. However, given the inherent uncertainties involved in assessing the outcomes of these cases and in estimating the amount of the potential losses and the associated insurance recoveries, we could in future periods incur judgments or insurance settlements that could have a material adverse effect on our results in any particular period.

Intellectual property claims include challenges to the Group's patents on various products or processes and assertions of non-infringement of patents. A loss in any of these cases could result in loss of patent protection on the related product. The consequences of any such loss could be a significant decrease in sales of the product, which could materially affect the future results of the Group. The lawsuits pending against companies that have filed ANDAs in the US, seeking to market generic forms of products sold by the Group prior to the expiry of the applicable patents covering these products, typically include allegations of non-infringement, invalidity and unenforceability of these patents. In the event that the Group is not successful in these actions or the statutory 30-month stay expires before a ruling is obtained, the companies involved will also have the ability, subject to FDA approval, to introduce generic versions of the product concerned.

#### Accolate (zafirlukast)

#### Patent litigation – US

In May 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Dr. Reddy's Laboratories, Ltd and Dr. Reddy's Laboratories, Inc. (together DRL) that it had submitted an ANDA seeking FDA approval to market *Accolate* before expiration of AstraZeneca's FDA-listed patents. AstraZeneca lists seven patents referencing *Accolate* in the FDA's Orange Book. DRL did not challenge two listed patents, US Patent Nos. 4,859,692 and 5,583,152, which both expire in September 2010. As a result, DRL cannot market its zafirlukast product before the patents expire in 2010. DRL's notice-letter challenged the five remaining listed patents alleging non-infringement, invalidity or unenforceability. In June 2008, AstraZeneca commenced patent infringement litigation against DRL in the United States District Court for the District of New Jersey for infringement of three of the five remaining listed patents, US Patent Nos. 5,319,097 (the '097 patent), 5,482,963 (the '963 patent) and 6,143,775 (the '775 patent). The remaining two patents listed in the FDA's Orange Book have expiration dates in December 2011 and March 2014. In mid-2009, the parties agreed to dismiss without prejudice all claims and counterclaims based on the '097 and '775 patents. The matter proceeds in discovery based only on the '963 patent. The parties have submitted claim construction briefing.

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

## 25 Commitments and contingent liabilities continued *Arimidex* (anastrozole)

## Patent litigation - Canada

In July 2009, AstraZeneca Canada Inc. (AstraZeneca Canada) received a Notice of Allegation from Mylan Pharmaceuticals ULC (trading under the name Genpharm ULC) (Mylan ULC) in respect of Canadian Patent No. 1,337,420 (the '420 patent) listed on the Canadian Patent Register for *Arimidex*. Mylan ULC alleges, among other things, that the '420 patent is invalid and/or its product does not infringe the '420 patent. In September 2009, AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Mylan ULC for its anastrozole tablets until the expiration of the '420 patent. The matter proceeds.

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

#### Atacand (candesartan cilexetil)

### Patent litigation – Canada

In April 2009, 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 was not infringed and was not properly listed on the Canadian Patent Register.

In May 2009, AstraZeneca Canada filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a NOC to Sandoz 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 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 suspend 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

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 an ANDA seeking FDA approval to market a generic version of *Atacand HCT*, a combination product containing candesartan cilexetil and hydrochlorothiazide in 32/12.5, 32/25 and 16/12.5mg dose forms. Matrix is a subsidiary of Mylan, Inc. AstraZeneca then listed five patents referencing *Atacand HCT* in the FDA's Orange Book. Matrix's notice alleged 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 ANDA seeking FDA approval to market a generic version of *Atacand HCT* in 32/12.5, 32/25 and 16/12.5mg dose forms. AstraZeneca now lists six unexpired patents in the FDA's 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*. 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 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.

## 25 Commitments and contingent liabilities continued Crestor (rosuvastatin)

#### Patent litigation – US

AstraZeneca lists three patents referencing Crestor in the FDA's Orange Book: US Patent No. RE 37,314 covering the active ingredient (the '314 patent), US Patent No. 6,316,460 covering formulations (the '460 patent), and US Patent No. 6,858,618 covering medical use (the '618 patent). Since 2007, AstraZeneca has received Paragraph IV Certification notice-letters from nine generic drug companies. The companies each notified AstraZeneca that it had submitted an ANDA for approval to market 5, 10, 20 and 40mg rosuvastatin calcium tablets prior to the expiration of one or more of AstraZeneca's three FDA Orange Book-listed patents. AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, 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 parents or subsidiaries of eight of these companies for infringement of the patent covering rosuvastatin calcium, the active ingredient in Crestor tablets. AstraZeneca did not file patent infringement actions against one company, Glenmark Pharmaceuticals Inc. USA, because it did not seek approval to market products before the 2016 expiration date of the patent covering the active ingredient.

The parties filed various jurisdictional motions, which Magistrate Judge Leonard Stark decided in a Report and Recommendation Regarding Motions to Dismiss. In January 2009, the Court adopted the magistrate's report and recommendations deciding the defendants' various jurisdictional motions directed to parent and subsidiary entities.

In May 2009, the magistrate issued his Report and Recommendation Regarding Claim Construction, which set out his recommendations for claim construction of the '314 patent claims. In May 2009, Mylan Pharmaceuticals Inc (Mylan Pharma) and Par Pharmaceutical, Inc. (Par) filed objections to the Report. In October 2009, Judge Joseph Farnan overruled the objections of Mylan Pharma and Par to the Report and adopted Magistrate Judge Leonard Stark's recommendations for claim construction of the '314 patent claims.

After completion of fact-discovery, 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. The parties also filed evidentiary motions. 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, 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 the '314 patent.

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

In October 2008, Teva Pharmaceuticals Industries Ltd. (Teva Pharmaceuticals) filed a patent infringement lawsuit against AstraZeneca Pharmaceuticals LP, the Company, AstraZeneca UK Limited and IPR Pharmaceuticals, Inc. in the Eastern District of Pennsylvania, alleging that Crestor infringed one of its formulation patents – Patent No. RE 39,502 (the '502 patent). In January 2009, the Company and AstraZeneca UK Limited moved for dismissal on jurisdictional grounds. By agreement, Teva Pharmaceuticals voluntarily dismissed its claims against the Company and AstraZeneca UK Limited without prejudice. In March 2009, AstraZeneca moved to transfer the case to the US District Court, District of Delaware. In April 2009, AstraZeneca also moved to strike Teva Pharmaceutical's jury demand. Both motions were denied. In September 2009, AstraZeneca filed a Motion for Summary Judgment of Invalidity Due to Prior Invention. In September 2009, Teva Pharmaceuticals filed a reissue application with the US Patent and Trademark Office with respect to the '502 patent. In October 2009, Teva Pharmaceuticals filed a motion to stay the litigation in its entirety during the pendency of the reissue prosecution in the US Patent and Trademark Office. AstraZeneca opposed Teva Pharmaceutical's motion, arguing that the summary judgment motion should be fully briefed and decided prior to any stay of the litigation. On 14 January 2010, the Court denied Teva Pharmaceutical's motion for a stay and ordered it to respond to AstraZeneca's summary judgment motion.

#### Patent litigation - Canada

In September 2008, AstraZeneca Canada received a Notice of Allegation from Novopharm Limited (Novopharm) in respect of Canadian Patents Nos. 2,072,945 (the '945 patent) and 2,313,783 (the '783 patent) listed on the Canadian Patent Register for Crestor. AstraZeneca responded by commencing a court application in October 2008 under the Patented Medicines (Notice of Compliance) Regulations, seeking an order prohibiting the Minister of Health from issuing a NOC to Novopharm until after expiry of the patents.

In November 2008, AstraZeneca Canada received a Notice of Allegation from Apotex Inc. (Apotex) in respect of the '945 and '783 patents. AstraZeneca Canada responded by commencing a court application in December 2008 under the Patented Medicines (Notice of Compliance) Regulations, seeking an order prohibiting the Minister of Health from issuing a NOC to Apotex until after expiry of the patents.

In addition to the NOC proceedings currently pending against Novopharm and 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 '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.

#### 25 Commitments and contingent liabilities continued

In April 2009, AstraZeneca Canada received a Notice of Allegation from Cobalt Pharmaceuticals, Inc. (Cobalt) in respect of the '783 patent and the '945 patent. Cobalt claims that the '945 patent is not infringed and invalid; and that the '783 patent is not infringed and invalid.

In May 2009, AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a 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, AstraZeneca Canada received a Notice of Allegation from Sandoz Canada with respect to the '945 and '783 patents. Sandoz Canada claims that the '945 patent is invalid and that the '783 patent is not infringed and invalid. In July 2009, AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a NOC to Sandoz Canada for its 5, 10, 20 and 40mg rosuvastatin calcium tablets until the expiration of the '945 and '783 patents.

In August 2009, AstraZeneca Canada received a Notice of Allegation from ratiopharm Inc. (ratiopharm) with respect to the '945 and '783 patents. 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.

As a consequence of AstraZeneca Canada's legal actions seeking prohibition orders, none of Novopharm, Apotex, Cobalt, Sandoz Canada or ratiopharm can obtain a NOC for its rosuvastatin calcium tablets until the earlier of the disposition of the respective court application in its favour or, unless a Prohibition Order is granted, 24 months after the date on which the respective court application was commenced (assuming its regulatory submission is approvable by that date).

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

#### Entocort EC (budesonide)

AstraZeneca lists two patents in the FDA's Orange Book referencing *Entocort EC*. In 2008, in response to Paragraph IV Certification noticeletters from Barr Laboratories and Mylan Pharma 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 the 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)

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 was dismissed in its entirety. Plaintiffs appealed this decision and the Second Circuit Court of Appeals summarily affirmed the trial court's dismissal of the action. Plaintiffs have not appealed the Second Circuit Court of Appeals' decision. This litigation is therefore concluded.

#### Faslodex (fulvestrant)

AstraZeneca lists two patents in the FDA's Orange Book referencing *Faslodex*: US Patent No. 6,774,122 (the '122 patent) and US Patent No. 7,456,160 (the '160 patent), both of which expire in 2021. 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 to the FDA seeking approval to market generic fulvestrant injection 50 mg/ml, and alleging the invalidity and unenforceability of the patents listed in the FDA's Orange Book with respect to *Faslodex*. In January 2010, AstraZeneca filed a lawsuit against Teva Parenteral, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals in the US District Court for the District of Delaware for infringement of the '122 and '160 patents.

#### Iressa (gefitinib)

Between 2004 and 2008, seven claims were filed against AstraZeneca KK in Japan, in the Osaka and Tokyo District Courts. In six of the claims, it is alleged that *Iressa* caused a fatal incidence of interstitial lung disease (ILD) in a Japanese patient. In the seventh claim, it is alleged that *Iressa* caused a non-fatal incidence of ILD. AstraZeneca KK believes the claims are without merit and is defending all the cases.

#### Losec/Prilosec (omeprazole)

#### Patent litigation - US

From 2001 to 2005, as previously reported more fully, 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 Pharma), 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 Pharma). The basis for these proceedings included that conduct of these companies would infringe US Patent Nos. 4,786,505 (the '505 patent) and 4,853,230 (the '230 patent) formulation patents relating to omeprazole.

In 2003, Mylan Pharma commenced commercial sale of Esteve's generic omeprazole product. In 2003 and 2004, Lek, Apotex Group and Teva Pharma (distributing Impax's product) commenced commercial sales of generic omeprazole products. AstraZeneca made claims for damages against each selling defendant, as well as damages claims against Andrx. Anti-trust counterclaims were filed by many generic defendants. Several anti-trust counterclaims, as well as several AstraZeneca claims, proceed in the US District Court for the Southern District of New York.

#### 25 Commitments and contingent liabilities continued

From April to June 2006, a consolidated bench trial on patent liability issues occurred in the District Court, involving defendants, Mylan Pharma, Esteve, Lek, Apotex Group and Impax. In May 2007, the Court upheld both formulation patents covering *Prilosec*. The Court found that the generic omeprazole formulations of Impax and Apotex Group infringed AstraZeneca's patents. The Court also found that the generic products sold by Lek, Mylan Pharma and Esteve did not infringe AstraZeneca's patents. AstraZeneca appealed the Mylan Pharma/Esteve decision to the US Court of Appeals for the Federal Circuit. In June 2008, the Federal Circuit upheld the ruling that Mylan Pharma/Esteve did not infringe. In September 2008, the Federal Circuit upheld that the generic omeprazole formulations of Impax and Apotex Group infringed AstraZeneca's patents of Impax and Apotex Group infringed AstraZeneca's patents appealed the mylan Pharma/Esteve did not infringe. In September 2008, the Federal Circuit upheld that the generic omeprazole formulations of Impax and Apotex Group infringed AstraZeneca's patents-in-suit. In January 2010, AstraZeneca settled with Impax and Teva Pharma, who market 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.

#### Patent litigation - Canada

AstraZeneca continues to be involved in proceedings in Canada involving various patents relating to omeprazole capsules and omeprazole magnesium tablets. Apotex launched a generic omeprazole capsule product in Canada in January 2004.

In January 2006, AstraZeneca Canada Inc. was served with a claim in the Federal Court of Canada for payment of an undetermined sum based on damages allegedly suffered by Apotex due to the delay from January 2002 to January 2004 in the issuance to Apotex of a NOC for its 20mg omeprazole capsule product. AstraZeneca believes the claim is without merit and is defending it, as well as continuing to vigorously pursue its already pending patent infringement action against Apotex.

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

#### European Commission case

In June 2005, the Commission notified the Company and AstraZeneca AB of its Decision to impose fines totalling €60m on the companies for infringement of European competition law (Article 82 of the EC Treaty (now Article 102 TFEU) and Article 54 of the EEA Agreement). The Commission alleges that the companies abused their dominant positions in the periods between 1993 and 2000 by making a pattern of misleading representations before the patent offices and/or courts in Belgium, Denmark, Germany, the Netherlands, Norway and the UK in regard to obtaining supplementary protection certificates for omeprazole; and by requesting the surrender of market authorisations for omeprazole capsules in Denmark, Norway and Sweden, combined with withdrawal of omeprazole capsules from these countries and the launch of omeprazole MUPS (tablets). AstraZeneca does not accept the Commission's decision and has appealed it to the Court of First Instance (now referred to, following the Treaty of Lisbon, as the General Court). AstraZeneca denies that it had a dominant position or that it was engaged in the behaviours as characterised by the Commission. In the meantime, the fine was fully provided for in the half-year results in 2005 through a charge to operating profit of \$75m. Because it is further alleged by the Commission that these activities had the effect of hindering the entry of the generic version of *Losec* and parallel trade, it is possible that third parties could seek damages for alleged losses arising from this matter. Any such claims would be vigorously resisted.

The oral hearing in the above appeal to the General Court took place in November 2008 and AstraZeneca expects the appeal judgment to be handed down in 2010.

#### Nexium (esomeprazole magnesium)

### Sales and marketing practices

AstraZeneca entities have been sued in various state and federal courts in the US in purported representative class actions involving the marketing of *Nexium*. These actions generally allege that AstraZeneca's promotion and advertising of *Nexium* to physicians and consumers was unfair, unlawful and deceptive, particularly as the promotion relates to comparisons of *Nexium* with *Prilosec*. They also allege that AstraZeneca's conduct relating to the pricing of *Nexium* was unfair, unlawful and deceptive. The plaintiffs allege claims under various state consumer protection, unfair practices and false advertising laws. The plaintiffs in these cases seek remedies that include restitution, disgorgement of profits, damages, punitive damages, injunctive relief, attorneys' fees and costs of suit.

The first action was brought in 2004 in California state court on behalf of a class of California consumers and third-party payers. Lawsuits making substantially similar allegations were later filed in 2004 and 2005 in state courts in Arkansas, Florida, Massachusetts and Delaware, and in Delaware federal court.

The Florida and Arkansas cases have been dismissed at the trial court level and both of these dismissals have been affirmed on appeal. In March 2009, the California court granted AstraZeneca's motions for summary judgment and denied plaintiffs' motion for class certification. That decision has been appealed. 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.

The case in 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. The Delaware state case has been stayed pending the outcome of the federal case.

#### 25 Commitments and contingent liabilities continued Patent litigation - US

In April 2008, AstraZeneca entered into a settlement agreement and consent judgment with Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited (together Ranbaxy) to settle the Ranbaxy ANDA patent litigation. Ranbaxy was the first to file a Paragraph IV Certification notice-letter in respect of Nexium patents listed in the FDA's Orange Book. The settlement agreement allows Ranbaxy to commence sales of a generic version of Nexium under a license from AstraZeneca on 27 May 2014.

AstraZeneca received a Paragraph IV Certification notice-letter in January 2006 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 wilful patent infringement litigation in the US District Court for the District of New Jersey against IVAX Group, its parent Teva Pharmaceuticals, 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 patentsat-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 settlement with Ranbaxy. 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 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 2008, AstraZeneca, IVAX Group and DRL filed declaratory judgment suits in US District Court, District of New Jersey alleging non-infringement and/or invalidity for patents that were not previously included in the ongoing Nexium patent infringement litigations. In January 2010, as part of the above referenced settlement, the IVAX Group declaratory judgment actions were dismissed. The declaratory judgment actions involving DRL proceed. No trial date has been set for the DRL actions.

In December 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz stating that Sandoz had submitted an ANDA for approval to market 20 and 40mg esomeprazole magnesium delayed-release capsules. In January 2009, AstraZeneca commenced patent infringement litigation in US District Court. In July 2009, the Court stayed the Sandoz patent infringement litigation until after trial in the above referenced DRL patent infringement litigation. No trial date has been set in the Sandoz patent infringement litigation.

In September 2009, AstraZeneca received a Paragraph IV Certification notice-letter from Lupin Limited (Lupin) stating that Lupin had submitted an ANDA for approval to market 20 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) stating that Sun had submitted an ANDA 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

AstraZeneca Canada received several notices of allegation from Apotex in late 2007 in respect of patents listed on the Canadian Patent Register 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 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.

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 is considering its options.

#### 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 to exclusive marketing rights for Nexium through 2012. AstraZeneca is awaiting trial decision on the merits.

#### Patent litigation - EU

During 2009, marketing authorisations for generic products containing 20 and 40 mg 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.

#### 25 Commitments and contingent liabilities continued

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*. The oral proceedings were held in court in Denmark in December 2009. 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 equal to or greater than 99.8% enantiomeric excess in Denmark. Sandoz A/S may appeal this decision to the Eastern High Court of Denmark within four weeks. An appeal will not suspend the effect on the injunction, and the injunction will be in force during an appeal process.

In Portugal, AstraZeneca filed a request in August 2009 with the Lisbon Administrative Court of First Instance seeking a preliminary injunction and initiating a main action in the administrative courts. AstraZeneca has filed the request to seek a suspension of the effect of decisions taken by administrative bodies in Portugal to grant Sandoz Farmacêutica Limitada marketing authorisations for generic esomeprazole magnesium. 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 in 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 in 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 patent 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, 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

In 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 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 equal to or greater than 99.8% enantiomeric excess. Hexal AG and Teva Pharmaceuticals filed Notices of Opposition against the grant of Esomeprazole Magnesium Patent in July 2009.

#### Federal Trade Commission (FTC) inquiry

In July 2008, AstraZeneca received a Civil Investigative Demand from the Federal Trade Commission seeking information regarding the *Nexium* patent litigation settlement with Ranbaxy. AstraZeneca is co-operating fully with the request.

#### Prilosec OTC (omeprazole magnesium)

#### Patent litigation - US

In June 2007, AstraZeneca received a Paragraph IV Certification notice-letter from DRL stating that DRL had submitted an ANDA seeking FDA approval to market a 20mg delayed release omeprazole magnesium capsule for the OTC market (AstraZeneca's OTC product is marketed by Proctor & Gamble Co.) before the expiration of the patents listed in the FDA's Orange Book in reference to the *Prilosec* OTC product. In July 2007, AstraZeneca commenced patent infringement litigation in the US District Court for the Southern District of New York against DRL. In March 2009, the Court granted DRL's motion for summary judgment of non-infringement of the two patents-in-suit. 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.

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

# **25** Commitments and contingent liabilities continued *Pulmicort Respules* (budesonide inhalation suspension) Patent litigation – US

In March 2008, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Breath Ltd. (now owned by Watson Pharmaceuticals, hereinafter Watson) for patent infringement. The lawsuit is the result of an ANDA filed by Watson with the FDA concerning Watson's intent to market a generic version of AstraZeneca's *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents. The basis for AstraZeneca's complaint is that the action by Watson of filing an ANDA infringes certain of AstraZeneca's patents directed to *Pulmicort Respules* and their use. The Watson litigation proceeds.

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 April 2009, on AstraZeneca's motion, the Court issued a Temporary Restraining Order barring Apotex Group from launching its generic version of *Pulmicort Respules* until further order of the Court. In April 2009, the Court commenced a hearing to determine whether to continue the injunction. 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 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 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 Pharma's generic copies of *Pulmicort Respules*, Teva Pharma was granted an exclusive license to market its generic product on or after 15 December 2009. Teva Pharma 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

The US Attorney's Office in Philadelphia, working with a number of states as part of the National Medicaid Fraud Control Unit, has been 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 two sealed *qui tam* (whistleblower) lawsuits filed under the False Claims Act. During the investigation, the government also raised allegations related to selected physicians who participated in clinical studies involving *Seroquel*. In September 2009, AstraZeneca reached an agreement in principle with the US Attorney's Office to resolve the investigation, subject to the negotiation and finalisation of appropriate implementing agreements, including civil settlement agreements and a corporate integrity agreement. This agreement will involve AstraZeneca paying \$524m, including interest, and a provision for this amount has been made in 2009.

There are also a number of additional active investigations involving *Seroquel* sales and marketing practices led by state Attorneys General which include investigations relating to *Seroquel* off-label issues and which purport to cover issues in addition to the respective states' participation in the National Medicaid Fraud Control Unit. Over 40 states, as part of the National Association of Attorneys General, are participating in a joint investigation and several states may also have individual investigations.

Some states are separately suing AstraZeneca. In February 2007, the Commonwealth of Pennsylvania filed suit against AstraZeneca, Eli Lilly & Company (Lilly), and Janssen Pharmaceutica Inc. (Janssen) claiming damages incurred by the Commonwealth as a result of alleged off-label promotion of atypical anti-psychotics by the three manufacturers. The lawsuit is filed in state court in Philadelphia and seeks to recover the cost to the Pennsylvania Medicaid programme and other state-funded health insurance programmes for prescriptions written as a result of the alleged off-label promotion and also seeks compensation for costs incurred by the state for the treatment of Medicaid and other public assistance beneficiaries who allegedly developed diabetes, hyperglycaemia and other conditions as a result of using *Seroquel* without adequate warning. In December 2007, the Court granted the defendants' motion to sever the claims against AstraZeneca and Janssen from those against Lilly and directed the Commonwealth to file separate complaints against the two severed defendants, which the Commonwealth did in January 2008. In December 2008, the Court granted AstraZeneca's motion to dismiss all but two counts of the complaint including dismissal of the Commonwealth's claims alleging violations of the Pennsylvania Medicaid False Claims Act.

Similar lawsuits were filed by the State of Montana in February 2008, the State of Arkansas in May 2008, the State of South Carolina in January 2009 and the State of New Mexico in February 2009. These suits generally seek compensation for costs incurred by the state for the treatment of Medicaid and other public assistance beneficiaries who allegedly developed diabetes, hyperglycaemia 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 programmes for prescriptions that relate to so-called non-medically accepted indications of *Seroquel*. The lawsuits further seek various fines and penalties.

AstraZeneca believes these claims to be without merit and intends to vigorously defend against them. The suits are in various stages of litigation, but the Pennsylvania and Arkansas suits are furthest along and are in the discovery phase.

#### 25 Commitments and contingent liabilities continued

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. The lawsuit was filed in the federal District Court in New Jersey and alleged that AstraZeneca promoted *Seroquel* for off-label uses and misled class members into believing that *Seroquel* was superior to other, lower-cost alternative medicines. Two similar class action lawsuits were filed in June and July 2007 in the New Jersey and Pennsylvania federal courts. In December 2007, the three lawsuits were transferred to the Middle District of Florida by the US Judicial Panel on Multi-District Litigation (MDL). In November 2008, the MDL Court granted AstraZeneca's motion and dismissed these cases in their entirety with prejudice, and the plaintiffs appealed. AstraZeneca intends to vigorously defend against the appeal, which is scheduled to be heard by the Eleventh Circuit Court of Appeals in February 2010.

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* prescriptions and the medical care of PEBTF members allegedly injured from *Seroquel* use. In October 2008, AstraZeneca removed this lawsuit to federal court and immediately requested that it be transferred to the *Seroquel* MDL. 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

In August 2003, Susan Zehel-Miller filed a putative class action against the Company and AstraZeneca Pharmaceuticals LP on behalf of 'all persons in the US who purchased and/or used *Seroquel*'. Among other things, the class action alleged that AstraZeneca failed to provide adequate warnings in connection with an alleged association between *Seroquel* and the onset of diabetes. In 2004, the US District Court for the Middle District of Florida denied class certification and the case was ultimately dismissed. Two additional putative class actions raising similar allegations have likewise been dismissed. There are no other US class actions relating to *Seroquel*; however, four putative class actions raising substantially similar allegations 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.

AstraZeneca Pharmaceuticals LP, either alone or in conjunction with one or more affiliates, has been sued in numerous individual personal injury actions involving *Seroquel*. In most of these cases, the nature of the plaintiffs' alleged injuries is not clear from the complaint and, in most cases, little or no factual information regarding the alleged injury has been provided in the complaint. However, the plaintiffs generally contend that they developed diabetes and/or other related injuries as a result of taking *Seroquel* and/or other atypical anti-psychotic medications.

As of 4 December 2009, AstraZeneca was defending 10,399 served or answered lawsuits 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 an 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 Lilly, Janssen 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 in 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.

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.

#### 25 Commitments and contingent liabilities continued

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 \$656m (2008: \$512m) have been incurred in connection with *Seroquel*-related product liability claims. The first \$39m is not covered by insurance. At 31 December 2009 AstraZeneca has recorded an insurance receivable of \$521m (2008: \$426m) 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 above the \$521m recorded as an insurance receivable 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

As previously reported, in 2005 and into 2006, AstraZeneca received Paragraph IV Certification notice-letters from Teva Pharmaceuticals USA Inc. (Teva) stating that Teva had submitted an ANDA and amendments for approval to market and sell quetiapine fumarate tablets prior to the expiration of the patent covering *Seroquel* tablets. AstraZeneca filed lawsuits directed to Teva's ANDA, as amended, in the US District Court for the District of New Jersey for patent infringement.

AstraZeneca received a similar Paragraph IV Certification notice-letter in March 2007 from Sandoz stating that Sandoz had submitted an ANDA for approval to market a generic version of AstraZeneca's quetiapine fumarate 25mg tablets prior to the expiration of AstraZeneca's listed patent. Sandoz's notice-letter alleged non-infringement and patent invalidity. AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Sandoz alleging patent infringement.

Teva and Sandoz thereafter conceded that their respective ANDA products infringe AstraZeneca's patent covering *Seroquel* and that the patent is valid, leaving only allegations of unenforceability relating to inequitable conduct.

In July 2008, the Court entered its Final Judgment in AstraZeneca's favour on all claims and defences in respect of infringement, validity, and enforceability of AstraZeneca's patent. Teva and Sandoz appealed the judgment to the Federal Circuit Court of Appeals.

In February 2009, during the pendency of the appeal, AstraZeneca received another Paragraph IV Certification notice-letter from Sandoz directed to the remaining approved *Seroquel* dosage amounts. AstraZeneca sued Sandoz in US District Court for the District of New Jersey alleging patent infringement in March 2009. The Court stayed the new action against Sandoz pending the outcome of the appeal.

In September 2009, the Court of Appeals for the Federal Circuit affirmed the District Court's judgment against Teva 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 and Sandoz 'exceptional' under 35 U.S.C. § 285, thereby allowing recovery of attorneys' fees from each non-prevailing party.

#### 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 - EU

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 injunctions 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 a definitive decision on the merits in the main actions.

#### 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 July 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Handa Pharmaceuticals, LLC (Handa) stating that it had submitted an ANDA seeking approval to market generic versions of 200 and 300mg *Seroquel XR* tablets before the expiration of AstraZeneca's two listed patents covering *Seroquel XR*. Handa's notice-letter alleged non-infringement, invalidity and unenforceability. Later in July 2008, AstraZeneca received a similar notice-letter from Handa stating that it had submitted an amendment to its ANDA for 200 and 300mg tablets adding a request for approval to market a generic version of 400mg *Seroquel XR* tablets before the expiration of AstraZeneca's two listed patents covering *Seroquel XR*.

In July 2008, AstraZeneca filed a lawsuit in US District Court, District of New Jersey, against Handa and a currently unknown, associated entity alleging infringement of AstraZeneca's '288 and '437 patents covering *Seroquel XR* 200, 300 and 400mg tablets. The filing of this lawsuit triggered 30-month stays of FDA final approval for Handa's ANDA products.

In September 2008, AstraZeneca received a Paragraph IV Certification notice-letter from Accord Healthcare Inc. (Accord) advising that it had submitted an ANDA seeking approval to market generic versions of 200, 300 and 400mg *Seroquel XR* tablets before expiration of AstraZeneca's patent covering the *Seroquel XR* formulation. Accord is a subsidiary of Intas Pharmaceutical Limited (Intas). Later in September 2008, AstraZeneca filed a lawsuit in US District Court, District of New Jersey, against Accord, Intas and related entities, alleging infringement of the '437 patent. The filing of this lawsuit triggered a 30-month stay of FDA final approval for Accord's ANDA products.

In October and November 2008, AstraZeneca received, respectively, a third and fourth Paragraph IV Certification notice-letter from Handa advising that it had submitted an ANDA seeking approval to market generic versions of 50 and 150mg *Seroquel XR* tablets before expiration of AstraZeneca's patents covering the product. In October 2008, AstraZeneca filed a second lawsuit in US District Court, District of New Jersey, against Handa alleging infringement of AstraZeneca's patents covering the active ingredient and formulation of *Seroquel XR* 50mg tablets; and 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 50 and 150mg ANDA products.

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 200, 300 and 400mg *Seroquel XR* tablets before the expiration of AstraZeneca's two listed patents covering *Seroquel XR*. Biovail's notice-letter alleged non-infringement and invalidity in respect of AstraZeneca's patents. In January 2009, AstraZeneca filed a lawsuit in US District Court, District of New Jersey, against Biovail alleging infringement of AstraZeneca's '288 and '437 patents covering *Seroquel XR* 200, 300 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* tablets. The filing of this additional lawsuit triggered a 30-month stay of FDA final approval for Accord's 150mg ANDA product.

The matters respecting Handa, Accord and Biovail proceed in co-ordinated discovery.

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

#### Synagis (palivizumab)

In December 2008, MedImmune initiated patent litigation against PDL BioPharma, Inc. (PDL) in the US District Court for the Northern District of California. MedImmune seeks a declaratory judgment that the Queen patents (owned by PDL) are invalid and/or not infringed by either *Synagis* and/or motavizumab, and that no further royalties are owed under a patent licence MedImmune and PDL signed in 1997 (1997 Agreement). MedImmune has paid royalties on *Synagis* since 1998 under the 1997 Agreement. In February 2009, MedImmune amended its complaint to add a separate claim asserting that MedImmune is entitled under the 1997 Agreement's 'most favoured licensee' provision to more favourable royalty terms that PDL has granted to other Queen patent licensees. PDL has taken the position in the case that both *Synagis* and motavizumab infringe a single claim of the Queen patents, and on that basis that MedImmune owes royalties for both products. With respect to the 'most favoured licensee' dispute, PDL contends that MedImmune's rights under that provision have not been triggered by PDL's licensing activities with third parties. In December 2009, PDL purported to cancel the 1997 Agreement and to add counterclaims to the case. The proposed counterclaims assert that MedImmune underpaid royalties on ex-US sales of *Synagis* by Abbott Laboratories, Inc. prior to the purported termination of the 1997 Agreement and separately also that MedImmune is infringing sales of *Synagis* post-dating the purported cancellation of the 1997 Agreement. If the Court permits PDL to add the claim for infringement, PDL plans to seek actual and exemplary damages and an injunction. MedImmune has moved to strike the amended counterclaims. A hearing on that motion is set for 26 February 2010. The case is scheduled for trial on 14 June 2010.

#### Symbicort (budesonide/formoterol)

## Symbicort Maintenance and Reliever Therapy (Symbicort SMART)

In December 2008, oppositions were filed against European patent EP1 085 877 B1 covering the use of *Symbicort* for the as needed symptomatic relief of asthma in addition to regular maintenance treatment of chronic asthma. The opponents are Vectura Limited, ratiopharm GmbH, Generics (UK) Limited and Norton Healthcare Limited. A hearing date has not yet been set by the EPO Opposition Division.

### US patent term extension

In June 2008, the US Patent and Trademark Office issued a final determination that US Patent No. 5,674,860 was not eligible for patent term extension. AstraZeneca filed a request for reconsideration.

AstraZeneca will vigorously defend and enforce its remaining intellectual property portfolio protecting Symbicort, which has patent expiry dates up to 2019 in Europe.

#### Toprol-XL (metoprolol succinate)

Beginning in 2003, AstraZeneca initiated and prosecuted numerous patent infringement actions involving patents covering *Toprol-XL* tablets against KV Pharmaceutical Company (KV), Andrx Pharmaceuticals LLC (Andrx LLC) and Eon Labs Manufacturing Inc. (later acquired by Sandoz) in US District Courts for the Eastern District of Missouri and District of Delaware in response to notifications of intentions to market generic versions of *Toprol-XL* tablets. At the end of 2008, the patent litigations relating to *Toprol-XL* had been decided, resolved or settled.

In the first quarter of 2006, AstraZeneca was served with 14 complaints filed in the US District Courts in Delaware, Massachusetts and Florida against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB and Aktiebolaget Hässle. The complaints were putative class actions filed on behalf of both direct purchasers and indirect purchasers that allege that the AstraZeneca defendants attempted to illegally maintain monopoly power in the US over *Toprol-XL* in violation of the Sherman Act through the listing of invalid and unenforceable patents in the FDA's Orange Book and the enforcement of such patents through litigation against generic manufacturers seeking to market metoprolol succinate. The complaints seek treble damages based on alleged overcharges to the putative classes of plaintiffs. These 14 complaints were consolidated into two amended complaints in the US District Court in Delaware, one on behalf of direct purchasers, and one on behalf of indirect purchasers. The lawsuits are based upon a 2006 ruling by the US District Court for the Eastern District of Missouri in the consolidated patent litigation against KV, Andrx LLC and Sandoz, that the AstraZeneca patents relating to *Toprol-XL* are invalid and unenforceable. In 2006 AstraZeneca filed a motion seeking to dismiss or, in the alternative, stay the consolidated complaint in both anti-trust complaints and will vigorously defend the lawsuits.

#### Zestril (lisinopril)

In 1996, two of AstraZeneca's predecessor companies, Zeneca Limited and Zeneca Pharma Inc. (as licensees), Merck & Co., Inc. and Merck Frosst Canada Inc. (together Merck Group) commenced a patent infringement action in the Federal Court of Canada against Apotex, alleging infringement of Merck Group's lisinopril patent. Apotex sold a generic version of AstraZeneca's *Zestril* and Merck Group's Prinivil<sup>™</sup> tablets. Following a trial in early 2006, in April 2006 the Federal Court of Canada ruled in favour of AstraZeneca and Merck Group on the key issues and Apotex stopped selling lisinopril in May 2006. In October 2006, the Federal Court of Appeal in Canada upheld the lower court's decision and dismissed Apotex's appeal. The Supreme Court of Canada dismissed Apotex's leave to appeal in May 2007. AstraZeneca intends to pursue a reference proceeding in the Federal Court to quantify the damages related to the infringement by Apotex. Apotex re-commenced the sale of lisinopril in October 2007 after expiry of the relevant patent.

#### **Pain pump litigation**

Since February 2008, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Zeneca Holdings Inc., and/or the Company have been named as defendants and served with approximately 282 lawsuits, involving approximately 475 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 chrondrolysis. 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. 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, 13 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.

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 the Company, 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.

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.

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.

AstraZeneca intends to vigorously defend against this matter.

#### 25 Commitments and contingent liabilities continued Average Wholesale Price Litigation

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. During 2009, AstraZeneca made a total provision of \$112m in relation to certain sets of cases regarding these alleged practices.

The first set of cases was filed in December 2001 in the US District Court in Boston, Massachusetts on behalf of a putative class of plaintiffs and related only to the physician-administered *Zoladex* medication. Following the Massachusetts complaint, nearly identical class action suits were filed in two other states, which have been consolidated with the Massachusetts action for pre-trial purposes, pursuant to federal multi-district litigation (MDL) procedures. AstraZeneca and other manufacturers were later sued in similar lawsuits filed by the State Attorneys General of Alabama, Alaska, Arizona, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Mississippi, Montana, Nevada, Pennsylvania, Utah, and Wisconsin, as well as by multiple individual counties in the State of New York. The Attorney General lawsuits seek to recover alleged overpayments under Medicaid and other state-funded healthcare programmes for substantially all of AstraZeneca's medications. In several cases, the states are also suing to recover alleged overpayments by state residents. Several of these suits have also been consolidated with the Massachusetts action for pre-trial purposes, pursuant to federal MDL procedures. Private insurers and consumers filed putative state-wide class actions in Arizona and New Jersey alleging damages relating to private reimbursement of prescription drugs.

In the MDL action in January 2006, the District Court certified three classes of plaintiffs against a sub-group of defendants (the Track 1 manufacturer defendants) including AstraZeneca. For AstraZeneca, the three certified classes were: a nationwide class of consumers who made co-payments for *Zoladex* reimbursed under the Medicare Part B programme (Part B drugs) (Class 1); a Massachusetts-only class of third party payers, including insurance companies, union health and welfare benefit plans, and self-insured employers, who covered consumer co-payments for *Zoladex* (Class 2); and a Massachusetts-only class of third party payers and consumers who paid for *Zoladex* outside of the Medicare programme (Class 3). For all classes, the only AstraZeneca drug at issue is *Zoladex* (goserelin acetate implant).

In May 2007, AstraZeneca reached a settlement agreement resolving the Class 1 claims. 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. The administration of claims under this settlement continues.

In June 2007 and November 2007, the MDL Court issued decisions, after a bench trial, on liability and damages on Classes 2 and 3. The Court found AstraZeneca liable under the Massachusetts consumer protection statute for engaging in unfair and deceptive conduct in connection with the pricing of *Zoladex* during the period 1998 to 2003. The Court awarded double damages (with pre-judgment interest) of \$5.5m for Class 2, and single damages (with pre-judgment interest) of \$7.4m for Class 3, for a total of \$12.9m. The District Court could award post-judgment interest and attorneys' fees in addition to the judgment amount. AstraZeneca believes the decision 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, administration fees, and plaintiffs' attorney fees. The settlement is subject to final Court approval. AstraZeneca took a provision of \$13m with respect to this matter in 2009 and there is no material increase in reserve with respect to the settlement.

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 January 2009, the Court granted AstraZeneca's motion to stay the entry of the order pending its appeal of the Court's award relating to Massachusetts payers. 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 the *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 \$90m in 2009 in respect of this settlement.

The multiple Attorney General lawsuits pending against AstraZeneca and other manufacturers nationwide, which involve numerous drugs in addition to *Zoladex*, remain pending and are in various stages of discovery. Those matters with significant developments are noted below.

The average wholesale price case filed by the Alabama Attorney General was tried in Circuit Court in Montgomery, Alabama in February 2008. The trial resulted in a jury verdict against AstraZeneca on the State's claims of fraudulent concealment and misrepresentation, and an award of compensatory damages of \$40m and punitive damages of \$175m. In June 2008, the trial court held a hearing on AstraZeneca's request for post-trial relief and reduced the punitive damages award, as required by statute, to \$120m. AstraZeneca filed an appeal with the Alabama Supreme Court and in October 2009, the Supreme Court of Alabama overturned the trial court's judgment against AstraZeneca and rendered judgment in AstraZeneca's favour instead. In January 2010, the Alabama Supreme Court denied the State of Alabama's petition for reconsideration. No provision has been made in respect of this matter.

In October 2009, a Kentucky jury found AstraZeneca liable under the Commonwealth of Kentucky's Consumer Protection statute and Medicaid Fraud statute, and awarded \$14.72m in compensatory damages and \$100 in punitive damages for drugs reimbursed by the Commonwealth of Kentucky Medicaid Agency. In January 2010, the trial court rendered a decision awarding statutory penalties of \$5.4m. The court also awarded pre-judgment interest of 8% beginning in 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 May 2009, AstraZeneca reached a settlement to resolve the claims of the states of Nevada and Montana for an immaterial amount which has been provided. Those cases have now been dismissed with prejudice. 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 did not appeal this ruling, and so that case is final. 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 described in this section are denied and will be vigorously defended.

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

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. The 340B programme entitles hospitals and clinics that treat a substantial portion of uninsured patients to preferential drug pricing for outpatient drugs. A hearing on class certification was held in April 2009, and in May 2009 the court denied class certification without prejudice and established Bayer Corporation as a lead-track defendant for summary judgment and trial. AstraZeneca intends to vigorously defend these claims.

#### **Verus Pharmaceuticals Litigation**

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

#### Medco qui tam litigation

AstraZeneca has been named in a lawsuit filed in the Philadelphia federal court by a former Medco Health Systems employee, Karl Schumann, under the *qui tam* (whistleblower) provisions of the federal and certain state False Claims Acts. The action was initially filed in September 2003 but remained under seal until July 2009, at which time AstraZeneca was served with a copy of the amended complaint following the government's decision not to intervene in the case. The lawsuit seeks to recover, *inter alia*, alleged overpayments by federal and state governments for *Prilosec* and *Nexium* from 1996 to 2007. These overpayments are alleged to be the result of improper payments intended to influence the formulary status of *Prilosec* and *Nexium* at Medco and its customers. AstraZeneca has moved to dismiss the amended complaint and intends to vigorously defend this matter.

#### **Drug importation anti-trust litigation**

In August 2004, Californian retail pharmacy plaintiffs filed an action in the Superior Court of California alleging a conspiracy by AstraZeneca and approximately 15 other pharmaceutical manufacturer defendants to set the price of drugs sold in California at or above the Canadian sales price for those same drugs and otherwise restrict the importation of pharmaceuticals into the US. In July 2005, the Court overruled in part and sustained in part, without leave to amend, the defendants' motion to dismiss the plaintiffs' third amended complaint in these proceedings. The Court overruled the defendants' motion in respect of conspiracy claims but sustained the motion in respect of the California Unfair Competition Law claims. In December 2006, the Court granted the defendants' motion for summary judgment and the case was subsequently dismissed. Plaintiffs appealed that decision and the Court of Appeal of the State of California affirmed the lower Court's decision. Plaintiffs have appealed to the Supreme Court of California, which has decided to hear the appeal.

AstraZeneca denies the material allegations in the California action and is vigorously defending this matter.

#### Anti-trust

#### US secondary wholesalers

In July 2006, AstraZeneca Pharmaceuticals LP was named as a defendant, along with a number of other pharmaceutical manufacturers and wholesalers, in a complaint filed by RxUSA Wholesale, Inc. (RxUSA) in the US District Court for the Eastern District of New York. The complaint alleges that the defendants violated federal and state anti-trust laws by, amongst other things, allegedly refusing to deal with RxUSA and other 'secondary wholesalers' in the wholesale pharmaceutical industry. The plaintiff alleges a conspiracy among the manufacturers and seeks an injunction and treble damages. AstraZeneca vigorously denies the allegations and in November 2006 filed a motion to dismiss the complaint. In September 2009 the Court granted the defendants' motion to dismiss. Plaintiff is appealing the decision.

#### EU Commission Sector Inquiry

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. In the final report, published in July 2009 the Commission 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 co-operate fully with the request.

#### Other

For a description of other anti-trust-related litigation involving AstraZeneca, see the subsections entitled *Losec/Prilosec* (omeprazole), *Nexium* (esomeprazole) and *Toprol-XL* (metoprolol succinate) in this Note 25 to the Financial Statements.

#### Additional government investigations into drug marketing practices

As is true for most, if not all, major prescription pharmaceutical companies operating in the US, AstraZeneca is currently involved in multiple US federal and state investigations into drug marketing and pricing practices. In addition to the investigations described above, the US Attorney's Office (USAO) in Philadelphia is directing an investigation involving requests for documents and information relating to contracting and disease management programmes with one of the leading national Pharmacy Benefits Managers. AstraZeneca has been co-operating with this investigation and currently does not expect the government to take further action. The USAO in Boston is conducting an additional investigation with a leading provider of pharmacy services to long-term care facilities. According to a Court and a securities filing, that investigation may be the subject of one or more *qui tam* (whistleblower) complaints that were filed under the False Claims Act. We have been informed by the government that they do not intend to pursue the matter as to AstraZeneca.

In addition to the Attorney General investigations regarding *Seroquel* described above, the Delaware Attorney General's Office is investigating certain sales and marketing practices of AstraZeneca, which appear to focus on AstraZeneca's prior interactions with physicians in the State of Delaware. In addition, AstraZeneca is providing information in response to two informal requests for information relating to nominal pricing under the Medicaid rebate program, one from the US Department of Justice and one from the Attorney General of the State of Michigan.

It is not possible to predict the outcome of any of these investigations, which could include the payment of damages and the imposition of fines, penalties and administrative remedies.

#### **UK Serious Fraud Office (SFO) inquiry**

In 2007, AstraZeneca received from the SFO a request for documentation about its involvement in the UN Oil for Food programme in Iraq. AstraZeneca denies any allegation of illegal or unethical behaviour in its trading relationships with Iraq. AstraZeneca was informed in August 2009 that following a review of cases undertaken by the SFO, the SFO decided that no further action should be taken against the Company. AstraZeneca co-operated fully with the SFO throughout its investigation.

#### Other actual and potential government investigations

From time to time, AstraZeneca receives enquiries and requests for information from a number of governmental and/or other regulatory bodies relating to a range of issues (some, but not all, of which may relate directly to the business of AstraZeneca) and some of which are confidential in nature. AstraZeneca seeks to comply with these requests in an appropriate and timely manner and generally on the basis of legal advice received. The nature and scope of the investigation in relation to which such enquiries and requests for information have been received is not always known to AstraZeneca. Consequently, it is not always possible to determine whether such enquiries and investigations relate specifically to AstraZeneca or are merely a means of gathering factual information in the context of an unrelated third-party issue. In addition, in the ordinary course of business AstraZeneca self-reports matters which may result in government investigations.

#### **Congressional investigations**

In March 2009, AstraZeneca received and responded to an enquiry from the Senate Finance Committee about *Seroquel* clinical studies conducted in the 1990s. In addition, AstraZeneca has responded to enquires from the House Energy and Commerce Committee about heparinised saline, found to have been contaminated, that was manufactured in Australia and sold in Australia, New Zealand and Hong Kong in 2008.

#### Informal SEC inquiry

In October 2006, AstraZeneca received from the SEC a letter requesting documents related to its business activities in Croatia, Italy, Russia and Slovakia for the period 1 October 2003 to the present. The SEC's request generally seeks documents concerning any payments to doctors or government officials and related internal accounting controls. The request also seeks policies, correspondence, audits and other documents concerning compliance with the Foreign Corrupt Practices Act, as well as any allegations or communications with prosecutors' offices relating to corruption or bribery of doctors or government officials. AstraZeneca has produced documents in response to this request. It is not currently possible to predict the outcome of this inquiry.

#### **Employment-wage/hour litigation**

In September 2006, Marc Brody filed a putative class action lawsuit against AstraZeneca LP on behalf of himself and a class of approximately 844 pharmaceutical sales specialists employed by the Group in California during the period 19 September 2002 to present. The plaintiff alleges he and the proposed class members were unlawfully classified as exempt employees and denied overtime compensation and meal breaks

in violation of the California Labour Code. AstraZeneca removed this action to the US District Court for the Central District of California in October 2006. The plaintiff filed a first amended complaint in March 2007, for failure to provide meal and rest periods, failure to pay all wages earned each pay period, failure to provide accurate wage statements, failure to pay wages in a timely manner upon termination of employment, unfair competition and seeking civil penalties. AstraZeneca denies the allegations made by the plaintiff, asserting that the sales specialists are properly classified under various exemptions to the wage laws. The plaintiff's lawyers are also pursuing similar claims in lawsuits against most of the major pharmaceutical companies.

In separate lawsuits against AstraZeneca, the firms representing the Brody plaintiff filed additional state and wage-and-hour class actions. The first case currently captioned Baum v. AstraZeneca, LP was filed under the Pennsylvania Minimum Wage Act and Wage Payment Collection Law in the US District Court for the Western District of Pennsylvania on behalf of two plaintiffs and a putative class of approximately 473 sales specialists working in Pennsylvania during the period March 2004 to the present. The second case, Hummel v. AstraZeneca, was filed in the US District Court for the Southern District of New York on behalf of one plaintiff and a putative class of approximately 890 sales specialists working in the state of New York during the period June 2001 to the present, claiming the sales specialists were misclassified as exempt from overtime pay under New York labour law.

Additionally, in June 2007, the firms representing the Brody plaintiff filed a nationwide collective action based on federal wage-and-hour law (FLSA) in the US District Court for the District of Delaware, seeking unpaid overtime compensation and liquidated damages. The lawsuit had a potential class size of 8,300 current and former sales specialists employed by the Group in the US during the period June 2004 to the present. The parties have negotiated a stipulation of dismissal of this lawsuit and the action has been dismissed with prejudice. The plaintiff's counsel purportedly may file a new FLSA action with a different plaintiff in the future.

The US District Court for the Central District of California granted summary judgment in favour of AstraZeneca in the Brody lawsuit, dismissing all claims by plaintiff and finding the motion for class certification to be moot. Plaintiff Brody has filed a notice of appeal with the Ninth Circuit Court of Appeals in California. Briefing is scheduled to begin in January 2010. Additionally, the US District Court, Western District of Pennsylvania, granted summary judgment in favour of AstraZeneca in the Baum matter, dismissing all claims filed by plaintiff Baum and finding the motion for class certification to be moot. Plaintiff has filed an appeal with the Third Circuit Court of Appeals; the case has been fully briefed.

Finally, in Hummel v. AstraZeneca, the US District Court for the Southern District of New York granted AstraZeneca's motion for summary judgment and dismissed the case in September 2008. In October 2008, Hummel filed a notice of appeal to the prejudice in exchange for AstraZeneca's agreement to waive its costs. The Hummel case has been resolved and dismissed with prejudice.

#### Тах

Where tax exposures can be quantified, an accrual is made based on best estimates and management's judgement. Details of the movements in relation to material tax exposures are discussed below.

AstraZeneca faces a number of transfer pricing audits in jurisdictions around the world and, in some cases, is in dispute with the tax authorities. The issues under discussion are often complex and can require many years to resolve. Accruals for tax contingencies require management to make estimates and judgements with respect to the ultimate outcome of a tax audit, and actual results could vary from these estimates. The international tax environment presents increasingly challenging dynamics for the resolution of transfer pricing disputes. 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. Management considers that at present such corresponding relief will be available but given the challenges in the international tax environment will keep this aspect under careful review. The total net accrual included in the Financial Statements to cover the worldwide exposure to transfer pricing audits is \$2,327m, an increase of \$699m 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.

Included in the total net accrual are amounts in respect of the following transfer pricing arrangements:

- > AstraZeneca and 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.
- > AstraZeneca has applied for an advance pricing agreement in relation to intra-group transactions between the UK and the US which is being progressed through competent authority proceedings under the relevant double tax treaty.

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 \$575m (2008: \$400m); 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 \$565m (2008: \$365m). Interest is accrued as a tax expense.

### 26 Leases

Total rentals charged to profit were as follows:

	2009	2008	2007
	\$m	\$m	\$m
Operating leases	198	206	210

The future minimum lease payments under operating leases that have initial or remaining terms in excess of one year at 31 December 2009 were as follows:

	2009	2008	2007
	\$m	\$m	\$m
Obligations under leases comprise:			
No later than one year	132	101	103
Rentals due after more than one year:			
Later than five years	131	145	184
Later than one year and not later than five years	208	212	195
	339	357	379
	471	458	482
27 Statutory and other information			
	2009 \$m	2008 \$m	2007 \$m

	\$m	\$m	\$m
Fees payable to KPMG Audit Plc and its associates:			
Group audit fee	2.4	3.2	3.6
Fees payable to KPMG Audit Plc and its associates for other services:			
The audit of subsidiaries pursuant to legislation	6.6	7.1	6.1
Other services pursuant to legislation	2.9	3.3	3.6
Taxation	1.0	0.9	1.1
All other services	0.7	1.7	0.7
Fees payable to KPMG Audit Plc in respect of the Group's pension schemes:			
The audit of subsidiaries' pension schemes	0.5	0.6	0.6
	14.1	16.8	15.7

Other services pursuant to legislation includes fees of \$2.3m (2008: \$2.5m; 2007: \$2.7m) in respect of section 404 of the Sarbanes-Oxley Act.

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

All other services includes assurance services in relation to third party compliance with manufacturing and distribution agreements and advisory services supporting management in their development of competency and development frameworks for staff.

#### **Related party transactions**

The Group had no material related party transactions which might reasonably be expected to influence decisions made by the users of these Financial Statements.

#### Key management personnel compensation

Key management personnel are defined for the purpose of disclosure under IAS 24 'Related Party Disclosures' as the Board of Directors and the SET.

	2009 \$000	2008 \$000	2007 \$000
Short-term employee benefits	20,784	21,973	31,525
Post-employment benefits	2,080	2,290	2,072
Termination benefits	3,639	-	_
Share-based payments	12,547	13,210	11,515
	39,050	37,473	45,112

Short-term employee benefits in 2007 include one-off employee costs of \$11m in relation to the acquisition of MedImmune.

Total remuneration is included within employee costs (see Note 24).

#### Subsequent events

There were no material subsequent events.

# **Principal Subsidiaries**

At 31 December 2009	Country	Percentage of voting share capital held	Principal activity
UK			
AstraZeneca UK Limited	England	100	Research and development, manufacturing, marketing
AstraZeneca Treasury Limited	England	100	Treasury
Continental Europe			
NV AstraZeneca SA	Belgium	100	Marketing
AstraZeneca Dunkerque Production SCS	France	95	Manufacturing
AstraZeneca SAS	France	100	Research, manufacturing, marketing
AstraZeneca GmbH	Germany	100	Development, manufacturing, marketing
AstraZeneca Holding GmbH	Germany	100	Manufacturing, marketing
AstraZeneca SpA	Italy	100	Marketing
AstraZeneca Farmaceutica Spain SA	Spain	100	Marketing
AstraZeneca AB	Sweden	100	Research and development, manufacturing, marketing
AstraZeneca BV	The Netherlands	100	Marketing
The Americas			
AstraZeneca Canada Inc.	Canada	100	Research, marketing
AZ Reinsurance Limited	Cayman Islands	100	Insurance and reinsurance underwriting
IPR Pharmaceuticals Inc.	Puerto Rico	100	Development, manufacturing, marketing
AstraZeneca LP	US	99	Research and development, manufacturing, marketing
AstraZeneca Pharmaceuticals LP	US	100	Research and development, manufacturing, marketing
Zeneca Holdings Inc.	US	100	Manufacturing, marketing
MedImmune, LLC	US	100	Research and development, manufacturing, marketing
Asia, Africa & Australasia			
AstraZeneca Pty Limited	Australia	100	Development, manufacturing, marketing
AstraZeneca Pharmaceuticals Co., Limited	China	100	Research and development, manufacturing, marketing
AstraZeneca KK	Japan	80	Manufacturing, marketing

All shares are held indirectly.

The companies and other entities listed above are those whose results or financial position principally affected the figures shown in the Group Financial Statements. A full list of subsidiaries, joint ventures and associates will be annexed to the Company's next annual return filed with the Registrar of Companies. The country of registration or incorporation is stated alongside each company. The accounting year ends of subsidiaries and associates are 31 December, except for Aptium Oncology, Inc. which, owing to local conditions and to avoid undue delay in the preparation of the Financial Statements, is 30 November. AstraZeneca operates through 282 subsidiaries worldwide. Products are manufactured in 18 countries worldwide and are sold in over 100 countries. The Group Financial Statements consolidate the Financial Statements of the Company and its subsidiaries at 31 December 2009.

# Independent Auditor's Report to the Members of AstraZeneca PLC

We have audited the Parent Company Financial Statements of AstraZeneca PLC for the year ended 31 December 2009 set out on pages 188 to 192. The financial reporting framework that has been applied in their preparation is applicable law and UK Accounting Standards (UK Generally Accepted Accounting Practice).

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's 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 and the Company's members, as a body, for our audit work, for this report, or for the opinions we have formed.

# Respective responsibilities of directors and auditors

As explained more fully in the Directors' Responsibilities Statement set out on page 122, the Directors are responsible for the preparation of the Parent Company Financial Statements and for being satisfied that they give a true and fair view. Our responsibility is to audit the Parent Company Financial Statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's (APB's) Ethical Standards for Auditors.

# Scope of the audit of the financial statements

A description of the scope of an audit of financial statements is provided on the APB's website, frc.org.uk/apb/scope/UKP.

#### **Opinion on financial statements**

In our opinion, the Parent Company Financial Statements:

- Sive a true and fair view of the state of the Company's affairs as at 31 December 2009.
- Have been properly prepared in accordance with UK Generally Accepted Accounting Practice.
- Have been prepared in accordance with the requirements of the Companies Act 2006.

#### Opinion on other matters prescribed by the Companies Act 2006 In our opinion:

- > The part of the Directors' Remuneration Report to be audited has been properly prepared in accordance with the
- Companies Act 2006.
   The information given in the Directors' Report for the financial year for which the financial statements are prepared is consistent with the Parent Company

Financial Statements.

# Matters on which we are required to report by exception

We have nothing to report in respect of the following matters:

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- > Adequate accounting records have not been kept by the Parent Company, or returns adequate for our audit have not been received from branches not visited by us.
- > The Parent Company Financial Statements and the part of the Directors' Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- Certain disclosures of Directors' Remuneration specified by law are not made; or
- > We have not received all the information and explanations we require for our audit.

#### **Other matters**

We have reported separately on the Group Financial Statements of AstraZeneca PLC for the year ended 31 December 2009.

#### Jimmy Daboo

Senior Statutory Auditor

For and on behalf of KPMG Audit Plc, Statutory Auditor Chartered Accountants 8 Salisbury Square, London, EC4Y 8BB

28 January 2010

# AstraZeneca PLC

### Registered Number: 2723534

## **Balance Sheet**

		2009	2008
At 31 December	Notes	\$m	\$m
Fixed assets			
Fixed asset investments	1	25,230	26,727
Current assets			
Debtors – other		1	1
Debtors – amounts owed by Group undertakings		8,966	8,217
		8,967	8,218
Total assets		34,197	34,945
Creditors: Amounts falling due within one year			
Non-trade creditors	2	(252)	(414)
Interest bearing loans and borrowings	3	(1,790)	(650)
		(2,042)	(1,064)
Net current assets		6,925	7,154
Total assets less current liabilities		32,155	33,881
Creditors: Amounts falling due after more than one year			
Amounts owed to Group undertakings	3	(283)	(283)
Interest bearing loans and borrowings	3	(8,582)	(10,255)
		(8,865)	(10,538)
Net assets		23,290	23,343
Capital and reserves			
Called-up share capital	6	363	362
Share premium account	4	2,180	2,046
Capital redemption reserve	4	94	94
Other reserves	4	2,922	2,743
Profit and loss account	4	17,731	18,098
Shareholders' funds	5	23,290	23,343

\$m means millions of US dollars.

The Financial Statements on pages 188 to 192 were approved by the Board of Directors on 28 January 2010 and were signed on its behalf by:

#### David R Brennan Simon Lowth Director Director

# **Accounting Policies**

#### **Basis of accounting**

The Company Financial Statements are prepared under the historical cost convention, modified to include revaluation to fair value of certain financial instruments as described below, in accordance with the Companies Act 2006 and UK Generally Accepted Accounting Practice (UK GAAP). The Group Financial Statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union and as issued by the IASB and are presented on pages 128 to 132.

The following paragraphs describe the main accounting policies under UK GAAP, which have been applied consistently.

#### New accounting standards

The Company has adopted the following accounting standards in the year:

The Amendments to FRS 2 'Accounting for Subsidiary Undertakings', FRS 6 'Acquisitions and Mergers', FRS 20 (IFRS 2) 'Amendment regarding Vesting Conditions and Cancellations', FRS 28 'Corresponding Amounts', FRS 29 (IFRS 7) 'Financial Instruments: Disclosures', UITF Abstract 42 (IFRIC 9) 'Reassessment of Embedded Derivatives' and FRS 26 (IAS 39) 'Financial Instruments Recognition and Measurement'. The adoptions have no impact on the net results or net assets of the Company.

The Amendments to FRS 20 (IFRS 2) 'Share-based Payment – Group Cash-settled Share-based Payment Transactions' and FRS 30 'Heritage Assets' have been issued but not yet adopted by the Company.

#### **Foreign currencies**

Profit and loss account items in foreign currencies are translated into US dollars at average rates for the relevant accounting periods. Assets and liabilities are translated at exchange rates prevailing at the date of the Company Balance Sheet. Exchange gains and losses on loans and on short-term foreign currency borrowings and deposits are included within net interest payable. Exchange differences on all other transactions, except relevant foreign currency loans, are taken to operating profit.

#### **Taxation**

The charge for taxation is based on the result for the year and takes into account taxation deferred because of timing differences between the treatment of certain items for taxation and for accounting purposes. Full provision is made for the effects of these differences. Deferred tax assets are recognised where it is more likely than not that the amount will be realised in the future. These estimates require judgements to be made including the forecast of future taxable income. Deferred tax balances are not discounted.

Accruals for tax contingencies require management to make judgements and estimates in relation to tax audit issues. Tax benefits are not recognised unless the tax positions will probably be sustained. Once considered to be probable, management reviews each material tax benefit to assess whether a provision should be taken against full recognition of that benefit on the basis of potential settlement through negotiation and/or litigation.

Any recorded exposure to interest on tax liabilities is provided for in the tax charge. All provisions are included in creditors due within one year.

#### Investments

Fixed asset investments, including investments in subsidiaries, are stated at cost and reviewed for impairment if there are indications that the carrying value may not be recoverable.

#### **Share-based payments**

The issuance by the Company to employees of its subsidiaries of a grant over the Company's options, represents additional capital contributions by the Company to its subsidiaries. An additional investment in subsidiaries results in a corresponding increase in shareholders' equity. The additional capital contribution is based on the fair value of the grant issued, allocated over the underlying grant's vesting period.

#### **Financial instruments**

Loans and other receivables are held at amortised cost. Long-term loans payable are held at amortised cost.

#### Litigation

Through the normal course of business, AstraZeneca is involved in legal disputes, the settlement of which may involve cost to the Company. Provision is made where an adverse outcome is probable and associated costs can be estimated reliably. In other cases, appropriate descriptions are included.

# Notes to the Company Financial Statements

### **1 Fixed asset investments**

		Investments in s		
	Shares \$m	Loans \$m	Total \$m	
Cost and net book value at 1 January 2009	16,188	10,539	26,727	
Transfer to current assets	-	(1,757)	(1,757)	
Capital contribution – UITF 44	179	-	179	
Exchange	-	76	76	
Amortisation	-	5	5	
Cost and net book value at 31 December 2009	16,367	8,863	25,230	

### 2 Non-trade creditors

	2009	2008
	\$m	\$m
Amounts due within one year		
Short term borrowings (unsecured)	12	173
Other creditors	226	228
Amounts owed to Group undertakings	14	13
	252	414

## 3 Loans

3 Loans			
	Repayment dates	2009 \$m	2008 \$m
Amounts due within one year			
Interest bearing loans and borrowings (unsecured)			
US dollars			
Floating Rate Note	2009	-	650
Euros			
4.625% Non-callable bond	2010	1,073	-
5.625% Non-callable bond	2010	717	-
		1,790	650
Amounts due after more than one year			
Amounts owed to subsidiaries (unsecured)			
US dollars			
7.2% Loan	2023	283	283
Interest bearing loans and borrowings (unsecured)			
US dollars			
5.4% Callable bond	2012	1,744	1,742
5.4% Callable bond	2014	748	748
5.9% Callable bond	2017	1,743	1,742
6.45% Callable bond	2037	2,717	2,716
Euros			
4.625% Non-callable bond	2010	-	1,053
5.625% Non-callable bond	2010	-	702
5.125% Non-callable bond	2015	1,072	1,051
Pounds sterling			
5.75% Non-callable bond	2031	558	501
		8,582	10,255
		2009	2008
		\$m	\$m
Loans or instalments thereof are repayable:			
After five years from balance sheet date		6,373	7,041
From two to five years		2,492	1,742
From one to two years		-	1,755
Within one year		1,790	650
Total unsecured		10,655	11,188

All loans are at fixed interest rates. Accordingly the fair values of the loans will change as market rates change. However, since the loans are held at amortised cost, changes in interest rates and the credit rating of the Company do not have any effect on the Company's net assets.

### **4 Reserves**

	Share	Capital	Other	Profit and	2009	2008
	premium account	redemption reserve	reserves	loss account	Total	Total
	\$m	\$m	\$m	\$m	\$m	\$m
At beginning of year	2,046	94	2,743	18,098	22,981	22,582
Profit for the year	-	-	-	2,658	2,658	3,436
Dividends	-	-	-	(3,026)	(3,026)	(2,767)
Gain on cash flow hedge in anticipation of debt issue	-	-	-	1	1	1
Share-based payment	-	-	179	-	179	178
Share re-purchases	-	-	-	-	-	(607)
Share premium	134	-	-	-	134	158
At end of year	2,180	94	2,922	17,731	22,927	22,981
Distributable reserves at end of year	-	-	1,841	17,731	19,572	18,787

As permitted by section 408 (4) of the Companies Act 2006, the Company has not presented its own profit and loss account.

At 31 December 2009, \$17,731m (31 December 2008: \$16,946m) of the profit and loss account reserve was available for distribution. Included in other reserves is a special reserve of \$157m, arising on the redenomination of share capital in 1999.

During 2008, the Company adopted the requirements of UITF Abstract 44 'Group and Treasury Share Transactions'. Included within other reserves at 31 December 2009 is \$1,081m (31 December 2008: \$902m) in respect of cumulative share-based payment awards. These amounts are not available for distribution.

### 5 Reconciliation of movement in shareholders' funds

	2009	2008
	\$m	\$m
At beginning of year	23,343	22,946
Net profit for the financial year	2,658	3,436
Dividends	(3,026)	(2,767)
Gain on cash flow hedge in anticipation of debt issue	1	1
Share-based payment	179	178
Issue of AstraZeneca PLC Ordinary Shares	135	159
Re-purchase of AstraZeneca PLC Ordinary Shares	_	(610)
Net (decrease)/increase in shareholders' funds	(53)	397
Shareholders' funds at end of year	23,290	23,343

Details of dividends paid and payable to shareholders are given in Note 21 to the Group Financial Statements on page 154.

#### **6 Share capital**

	Authorised	Allotted, called-up and fully paid	
	2009 \$m	2009 \$m	2008 \$m
Issued Ordinary Shares (\$0.25 each)	363	363	362
Unissued Ordinary Shares (\$0.25 each)	237	-	-
Redeemable Preference Shares (£1 each – £50,000)	-	-	-
	600	363	362

The total authorised number of Ordinary Shares at 31 December 2009 was 2,400,000,000, of which 1,450,958,562 Ordinary Shares were in issue.

The Redeemable Preference Shares carry limited class voting rights and no dividend rights. This class of shares is capable of redemption at par at the option of the Company on the giving of seven days' written notice to the registered holder of the shares.

#### **6 Share capital continued**

The movements in share capital during the year can be summarised as follows:

At 31 December 2009	1,451	363
Issues of shares	4	1
At 1 January 2009	1,447	362
	No. of shares (million)	\$m

#### Share schemes

A total of 3,477,014 Ordinary Shares were issued during the year in respect of share schemes. Details of movements in the number of Ordinary Shares under option are shown in Note 24 to the Group Financial Statements; details of options granted to Directors are shown in the Directors' Remuneration Report.

#### Shares held by subsidiaries

No shares in the Company are held by subsidiaries.

#### 7 Litigation and environmental liabilities

In addition to those matters disclosed below, there are other cases where the Company is named as a party to legal proceedings. These are described in Note 25 to the Group Financial Statements.

#### Exanta (ximelagatran)

The consolidated amended complaint that had alleged claims on behalf of purchasers of the Company's 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 was dismissed in its entirety. Plaintiffs appealed this decision and the Second Circuit Court of Appeals summarily affirmed the trial court's dismissal of the action. Plaintiffs have not appealed the Second Circuit Court of Appeals' decision. This litigation is therefore concluded.

#### **Informal SEC inquiry**

In October 2006, AstraZeneca received from the SEC a letter requesting documents related to its business activities in Italy, Croatia, Russia and Slovakia for the period 1 October 2003 to the present. The SEC's request generally seeks documents concerning any payments to doctors or government officials and related internal accounting controls. The request also seeks policies, correspondence, audits and other documents concerning compliance with the Foreign Corrupt Practices Act, as well as any allegations or communications with prosecutors' offices relating to corruption or bribery of doctors or government officials. AstraZeneca has produced documents in response to this request. It is not currently possible to predict the outcome of this inquiry.

#### **EU Commission Sector Inquiry**

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. In the final report, published in July 2009, the Commission 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 co-operate fully with the request.

#### Other

The Company has guaranteed the external borrowing of a subsidiary, in the amount of \$288m.

#### 8 Statutory and other information

There are no employees of the Company (2008: nil). The Directors of the Company were paid by another Group company in 2009 and 2008.

# **Group Financial Record**

For the year ended 31 December	2005	2006	2007	2008	2009
	\$m	\$m	\$m	\$m	\$m
Revenue and profits Revenue	23,950	26,475	29,559	31,601	32,804
Cost of sales	(5,356)	(5,559)	(6,419)	(6,598)	(5,775)
Distribution costs	(2,330)	(226)	(0,419)	(0,398)	(298)
	(3,379)	(3,902)	(5,162)	. ,	
Research and development	(8,695)	(9,096)	(10,364)	(5,179) (10,913)	(4,409)
Selling, general and administrative costs	193	524	728	524	(11,332) 553
Other operating income and expense Operating profit	6,502	8,216	8,094	9,144	11,543
Finance income	665	888	959	854	462
	(500)	(561)	(1,070)	(1,317)	(1,198)
Finance expense Profit before tax	6,667	8,543	7,983	8,681	10,807
Taxation	· · · · · · · · · · · · · · · · · · ·	,	,	,	
	(1,943)	(2,480)	(2,356)	(2,551)	(3,263)
Profit for the period	· · · · · · · · · · · · · · · · · · ·	6,063	5,627	6,130	7,544
Other comprehensive income for the period, net of tax	(1,122)	931	342	(1,906)	(54)
Total comprehensive income for the period	3,602	6,994	5,969	4,224	7,490
Profit attributable to:	4 700	0.040		0.101	7.501
Equity holders of the Company	4,706	6,043	5,595	6,101	7,521
Minority interests	18	20	32	29	23
Earnings per share	<b></b>	<b></b>	<b>0</b> 071	<b>#</b> 4.00	
Earnings per \$0.25 Ordinary Share (basic)	\$2.91	\$3.86	\$3.74	\$4.20	\$5.19
Earnings per \$0.25 Ordinary Share (diluted)	\$2.91	\$3.85	\$3.73	\$4.20	\$5.19
Dividends	\$1.025	\$1.410	\$1.750	\$1.900	\$2.09
Return on revenues					
Operating profit as a percentage of revenues	27.2%	31.0%	27.4%	28.9%	35.2%
Ratio of earnings to fixed charges	85.6	92.7	15.6	13.5	19.9
	2005	2006	2007	2008	2009
At 31 December	\$m	\$m	\$m	\$m	\$m
Statement of Financial Position					
Property, plant and equipment, goodwill and intangible assets	9,697	11,657	29,649	29,240	29,422
Other investments	306	146	299	605	446
Deferred tax assets	1,117	1,220	1,044	1,236	1,292
Current assets	13,720	16,909	16,996	15,869	23,760
Total assets	24,840	29,932	47,988	46,950	54,920
Current liabilities	(6,839)	(9,447)	(15,218)	(13,415)	(17,640)
Non-current liabilities	(4,310)	(5,069)	(17,855)	(17,475)	(16,459)
Net assets	13,691	15,416	14,915	16,060	20,821
Share capital	395	383	364	362	363
Reserves attributable to equity holders	13,202	14,921	14,414	15,550	20,297
Minority equity interests	94	112	137	148	161
Total equity and reserves	13,691	15,416	14,915	16,060	20,821
For the year ended 31 December	2005	2006	2007	2008	2009
Cash flows	\$m	\$m	\$m	\$m	\$m
Net cash inflow/(outflow) from:	6 740	7600	7 510	0 740	11 700
Operating activities	6,743	7,693	7,510	8,742	11,739
Investing activities	(1,182)	(272)	(14,887)	(3,896)	(2,476)
Financing activities	(4,572)	(5,366)	6,051	(6,362)	(3,629)
	989	2,055	(1,326)	(1,516)	5,634

#### Ratio of earnings to fixed charges

For the purpose of computing these ratios, earnings consist of the income from continuing ordinary activities before taxation of Group companies and income received from companies owned 50% or less, plus fixed charges. Fixed charges consist of interest on all indebtedness, amortisation of debt discount and expense and that portion of rental expense representative of the interest factor.

# **Additional Information**

Development Pipeline	
Shareholder Information	
Corporate Information	
Cross-reference to Form 20-F	
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# **Development Pipeline**

## at 28 January 2010

				Estimated	
Therapy area	Compound	Mechanism	Areas under investigation	MAA	NDA
Phase I proje	cts				
Cardiovascular	AZD6482	PI3K-beta inhibitor	thrombosis		
	AZD4017	11BHSD inhibitor	diabetes/obesity		
	AZD6714	GK activator	diabetes		
	AZD8329	11BHSD inhibitor	diabetes/obesity		
	AZD7687	diacylglycerol acyl transferase -1 inhibitor	diabetes/obesity		
Gastrointestinal	AZD2066	metabotropic glutamate receptor 5 antagonist	GERD		
	AZD2516	metabotropic glutamate receptor 5 antagonist	GERD		
Infection	MEDI-534	RSV/PIV-3 vaccine	RSV/PIV prophylaxis		
	MEDI-560	PIV-3 vaccine	intranasal immunisation		
	MEDI-550	pandemic influenza virus vaccine	pandemic influenza vaccine		
	MEDI-557	YTE – extended half-life RSV MAb	RSV prophylaxis		
	MEDI-559	RSV vaccine	RSV prophylaxis		
	AZD5847	Oxazolidinone anti-bacterial inhibitor	tuberculosis		-
	AZD9742	BTGT4 IV	MRSA		
	CEF1041#	beta lactamase inhibitor/cephalosporin	MRSA		
Neuroscience	AZD3241	myeloperoxidase (MPO) inhibitor	Parkinson's disease		
	AZD6280	GABA receptor subtype partial agonist	anxiety		
	AZD2516	metabotropic glutamate receptor 5 antagonist	chronic neuropathic pain		
	AZD3043#	GABA-A receptor modulator	short acting sedative and anaesthetic		
	AZD8418	glutamatergic modulator	schizophrenia		
	AZD2423	chemokine antagonist	chronic neuropathic pain		
Oncology	AZD4769	EGFR tyrosine kinase inhibitor	solid tumours		
	AZD8931	erbB kinase inhibitor	solid tumours		
	AZD7762	CHK1 kinase inhibitor	solid tumours		
	AZD8330# (ARRY-424704)	MEK inhibitor	solid tumours		
	CAT-8015	recombinant immunotoxin	haematological malignancies		
	AZD8055	TOR kinase inhibitor	range of tumours		
	MEDI-573	IGF	solid tumours		
	MEDI-575	PDGFR-alpha	solid tumours		
	AZD1480	JAK2 inhibitor	myeloproliferative diseases /solid tumours		
Incology	AZD4547	FGFR tyrosine kinase inhibitor	solid tumours		
	MEDI-547#	EphA2 conjugate	solid tumours		
	AZD2014	MTOR inhibitor	solid tumours		
	AZD6244 (ARRY-142886)/MK2206#	MEK/AKT inhibitor	solid tumours		
Respiratory &	CAM-3001#	anti-GM-CSFR	rheumatoid arthritis		
Inflammation	AZD8566	CCR5	COPD		
	AZD8075	CRTh2 antagonist	asthma/COPD		
	AZD5985	CRTh2 antagonist	asthma/COPD		
	AZD2551	protease inhibitor	COPD		
	AZD5423	isegra	COPD		
	AZD5122	CXCR2	- COPD		
	AZD8683	Muscarinic antagonist	- COPD		
	AZD5069	CXCR2	- COPD		
	MEDI-546#	anti-IFNaR MAb	scleroderma		

<sup>1</sup> Subject to expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act. #Partnered product.

				Estimated	filing date
Therapy area	Compound	Mechanism	Areas under investigation	MAA	NDA
Phase II proje	cts				
Cardiovascular	AZD0837	direct thrombin inhibitor	thrombosis		-
	AZD6370	GK activator	diabetes		-
	AZD1656	GK activator	diabetes	2015	201
Gastrointestinal	Lesogaberan (AZD3355)	GABA <sub>B</sub> agonist	GERD	2013	201
	AZD1386	vanilloid receptor antagonist	GERD		
Infection	CytoFab <sup>™#</sup>	anti-TNF-alpha polyclonal antibody	severe sepsis	2014	2014
	AZD7295	NS 5A inhibitor	hepatitis C	2015	201
	MEDI-3250	flu vaccine (quadravalent)	seasonal influenza		
	CAZ1041#	beta lactamase inhibitor/cephalosporin	serious infections	2012	n/a
Neuroscience	AZD3480#	Alpha4/beta2 neuronal nicotinic receptor agonist	ADHD		
	AZD6765	NMDA receptor antagonist	MDD	2013	2013
	AZD2327	enkephalinergic receptor modulator	anxiety and depression		
	AZD2066	metabotropic glutamate receptor 5 antagonist	chronic neuropathic pain		
	AZD8529	glutamatergic modulator	schizophrenia		
		oral peripherally-acting opioid antagonist	opioid-induced constipation		2013
		nicotinic ion channel blocker	MDD	2014	2012
	TC-5619#	Alpha7 neuronal nicotinic receptor agonist	cognitive disorders in schizophrenia		
	AZD7268	enkephalinergic receptor modulator	depression/anxiety		
	AZD1446#	Alpha4/beta2 neuronal nicotinic receptor agonist	Alzheimer's disease/ADHD		
Oncology	Recentin	VEGFR tyrosine kinase inhibitor	NSCLC	2013	201
	AZD6244# (ARRY-142886)	MEK inhibitor	solid tumours	2014	2014
	Olaparib	PARP inhibitor	gBRCA breast cancer	2012	2012
	Olaparib	PARP inhibitor	serious ovarian cancer	2012	2014
	AZD1152	aurora kinase inhibitor	haematological malignancies	2012	2012
Respiratory &	AZD1981	CRTh2 receptor antagonist	asthma/COPD		
Inflammation	MEDI-528#	anti-IL-9 antibody	asthma		
	CAT-354	anti-IL-13 antibody	asthma		
	AZD9668	neutrophil elastase inhibitor	COPD	2014	2014
	AZD1236	matrix metallo-proteinase inhibitor	COPD		201
	AZD3199	iLABA	asthma/COPD		
	MEDI-563#	anti-IL-5R antibody	asthma		
	MEDI-545#	anti-IFN-alpha antibody	SLE, myositis		
	AZD9164	LAMA	COPD		
	AZD8848	Toll-like receptor-7 agonist	asthma		
	AZD0040				
				Estimated	filing date
Therapy area	Compound	Mechanism	Areas under investigation	MAA	NDA
Phase II line e	xtensions				
Infection	Motavizumab#	humanised MAb binding to RSV F protein	early and late treatment of RSV in paediatrics >1 yr		201
				Estimated	filing date
Therapy area	Compound	Mechanism	Areas under investigation	MAA	NDA

Cardiovascular	Onglyza™#	DPP-4 inhibitor	diabetes	Launched	Launched
	Brilinta/Brilique	ADP receptor antagonist	arterial thrombosis	Filed	Filed
	Certriad <sup>#</sup>	statin + fibrate fixed combination	dyslipidaemia		Filed
	Dapagliflozin#	SGLT2 inhibitor	diabetes	Q4 2010	Q4 2010 <sup>2</sup>
Infection	Motavizumab#	humanised MAb binding to RSV F protein	RSV prevention	Q4 2010	Filed
	Ceftaroline#	affinity to penicillin-binding proteins	pneumonia/skin infections	Q3 2010	n/a
Neuroscience	Vimovo#	naproxen + esomeprazole	signs and symptoms of OA, RA and ankylosing spondylitis	Filed	Filed
Oncology	Zactima	VEGFR/EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer – orphan	Q3 2010	Q3 2010
	Recentin	VEGFR tyrosine kinase inhibitor	CRC	Q4 2010	Q4 2010
	Recentin	VEGFR tyrosine kinase inhibitor	recurrent glioblastoma – orphan	Q4 2010	Q4 2010
	Zibotentan (ZD4054)	endothelin A receptor antagonist	castrate resistant prostate cancer	H1 2011	H1 2011

<sup>1</sup> Subject to expiry or termination of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act. <sup>2</sup> Timing subject to CV event rate. # Partnered product.

				Estimat	ed filing date
Therapy area	Compound	Mechanism	Areas under investigation	MAA	NDA
Phase III line	extensions				
Cardiovascular	Crestor	statin	outcomes in subjects with elevated CRP	Filed	Filed
	Onglyza <sup>™/</sup> metformin FDC <sup>#</sup>	DPP-IV inhibitor + biguanide FDC	diabetes	Q3 2010	Filed
	Dapagliflozin/ metformin FDC <sup>#</sup>	SGLT2 inhibitor + biguanide FDC	diabetes	H2 2011	H2 2011
Gastrointestinal	Nexium	proton pump inhibitor	peptic ulcer bleeding	Launched	Filed
	Axanum	proton pump inhibitor + low dose aspirin FDC	low dose aspirin associated peptic ulcer	Q3 2010 <sup>3</sup>	Filed
Infection	FluMist	live, attenuated, intranasal influenza virus vaccine	influenza	Filed	Launched
	MEDI-3414	H1N1 influenza	pandemic flu prevention		Launched
Neuroscience	Seroquel	$D_2/5HT_2$ antagonist	bipolar maintenance	Launched	Launched
	Seroquel XR	D <sub>2</sub> /5HT <sub>2</sub> antagonist	MDD	Filed	Approved
	Seroquel XR	$D_2/5HT_2$ antagonist	GAD	Filed	Filed
Oncology	Iressa	EGFR tyrosine kinase inhibitor	NSCLC	Launched	TBD
	Faslodex	oestrogen receptor antagonist	1st line advanced breast cancer		
	Faslodex	oestrogen receptor antagonist	high dose (500mg) 2nd line advanced breast cancer	Filed	Filed

 $^{\rm 3}$  Previously, submission was indication only. Now covers fixed-dose combination. "Partnered product.

Therapy area	Compound	Areas under investigation
Discontinued	projects	
Cardiovascular	AZD1305	arrhythmias
Infection	AZD9639	RSV treatment
	CMV Vaccine	cytomegalovirus
Neuroscience	AZD5904	multiple sclerosis
	AZD6088	chronic neuropathic pain
	AZD1386	chronic neuropathic pain
	AZD7325	anxiety
	AZD4694	Alzheimer's disease PET diagnostic
	AZD1940	nociceptive and neuropathic pain
	AZD2624	schizophrenia
Oncology	Saracatinib	solid tumours
	Zactima	NSCLC
	AZD6918	solid tumours
	MEDI-538	leukaemia/lymphoma
	AZD4877	haematological malignancies
Respiratory &	AZD9056	RA
Inflammation	AZD5672	RA

During 2009, AstraZeneca reclassified into pre-clinical development, the EBV vaccine which appeared in Phase II of the Development Pipeline table in the 2008 Annual Report and Form 20-F Information. AstraZeneca has out-licensed the development of the pneumococcal vaccine which appeared in Phase I of the Development Pipeline table in the 2008 Annual Report and Form 20-F Information.

Therapy area	Compound	Areas under investigation	
Discontinued	l line extensions		
Oncology	Faslodex	adjuvant	
Respiratory &	Symbicort pMDI EU	asthma	
Inflammation	Symbicort pMDI EU	COPD	
	Unit Dose Budesonide	asthma	

As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

Compounds in development are displayed by phase.

# **Shareholder Information**

2005	2006	2007	2008	2009
1,581	1,532	1,457	1,447	1,451
1,617	1,564	1,495	1,453	1,448
2837	3529	2984	2888	2947
1861	2574	2093	1748	2147
2829	2744	2164	2807	2910.5
-	1,581 1,617 2837 1861	1,581         1,532           1,617         1,564           2837         3529           1861         2574	1,5811,5321,4571,6171,5641,495283735292984186125742093	1,5811,5321,4571,4471,6171,5641,4951,45328373529298428881861257420931748

### Percentage analysis at 31 December 2009 of issued share capital

By size of account	2009
No. of shares	%
1 – 250	0.5
251 – 500	0.7
501 – 1,000	0.8
1,001 – 5,000	1.1
5,001 – 10,000	0.2
10,001 – 50,000	1.1
50,001 – 1,000,000	13.0
Over 1,000,0001	82.6
Issued share capital	100.0

<sup>1</sup> Includes VPC and ADR holdings.

At 31 December 2009, the Company had 125,363 registered holders of 1,450,958,562 Ordinary Shares. At 31 December 2009, there were approximately 141,000 holders of ADRs representing 5.39% of the issued share capital and 158,000 holders of shares held under the VPC Services Agreement representing 18.52% of the issued share capital. The ADRs, each of which is equivalent to one Ordinary Share, are issued by JPMorgan Chase Bank (JPMorgan).

#### AstraZeneca PLC

Since April 1999, following the merger of Astra and Zeneca, the principal markets for trading in the shares of the Company are the London Stock Exchange (LSE), the Stockholm Stock Exchange (SSE) and the New York Stock Exchange (NYSE). The table below sets out, for the four quarters of 2008 and for the first two quarters and last six months of 2009 the reported high and low share prices of the Company, on the following bases:

> For shares listed on the LSE the reported high and low middle market closing quotations are derived from the Daily Official List.

> For shares listed on the SSE the high and low closing sales prices are as stated in the Official List.

> For ADSs listed on the NYSE the reported high and low sales prices are as reported by Dow Jones (ADR quotations).

			Ordinary LSE		ADS		Ordinary SSE <sup>1</sup>
		High (pence)	Low (pence)	High (US\$)	Low (US\$)	High (SEK)	Low (SEK)
2008	– Quarter 1	2345.0	1748.0	45.70	35.50	296.5	211.5
	– Quarter 2	2289.0	1981.0	44.57	39.36	268.0	235.5
	– Quarter 3	2766.0	2130.0	49.85	43.42	321.5	255.5
	– Quarter 4	2888.0	2075.0	44.76	34.10	340.5	253.5
2009	– Quarter 1	2947.0	2147.0	41.60	30.24	331.0	261.5
	– Quarter 2	2728.0	2276.0	45.01	33.40	351.0	279.5
	– July	2878.0	2644.0	47.54	43.01	356.0	336.0
	– August	2869.0	2722.5	47.31	45.24	338.0	326.0
	– September	2856.0	2691.0	46.02	43.91	333.0	305.0
	– October	2830.0	2742.0	46.19	43.64	323.1	308.0
	– November	2778.0	2690.5	46.38	44.34	319.0	310.1
	– December	2930.0	2753.0	47.00	45.35	339.5	315.0

<sup>1</sup> Principally held in bearer form.

During 2009, there were no shares re-purchased under the Company's share re-purchase programme. The total number of shares re-purchased to date since the beginning of the re-purchase programme in 1999 is 376.3 million Ordinary Shares (at an average price of 2661 pence per Ordinary Share) for a consideration, including expenses, of \$18,099 million. The excess of the consideration over the nominal value was charged against the profit and loss account reserve. Ordinary Shares issued in respect of share schemes totalled 3.5 million.

In 1999, in connection with the merger between Astra and Zeneca through which the Company was formed, the Company's share capital was redenominated in US dollars. On 6 April 1999, Zeneca shares were cancelled and US dollar shares issued, credited as fully paid on the basis of one dollar share for each Zeneca share then held. This was achieved by a reduction of capital under section 135 of the Companies Act 1985. Upon the reduction of capital becoming effective, all issued and unissued Zeneca shares were cancelled and the sum arising as a result of the share cancellation credited to a special reserve, which was converted into US dollars at the rate of exchange prevailing on the record date. This US dollar reserve was then applied in paying up, at par, newly created US dollar shares.

At the same time as the US dollar shares were issued, the Company issued 50,000 Redeemable Preference Shares for cash, at par. The Redeemable Preference Shares carry limited class voting rights, no dividend rights and are capable of redemption, at par, at the option of the Company on the giving of seven days' written notice to the registered holder of the Redeemable Preference Shares.

A total of 826 million Ordinary Shares were issued to Astra shareholders who accepted the merger offer before the final closing date, 21 May 1999. The Company received acceptances from Astra shareholders representing 99.6% of Astra's shares and the remaining 0.4% was acquired in 2000, for cash.

#### **Major shareholdings**

At 28 January 2010, the following had disclosed an interest in the issued Ordinary Share capital of the Company in accordance with the requirements of rule 5.1.2 of the UK Listing Authority's Disclosure and Transparency Rules:

	Date of	Percentage
	disclosure	of issued
lumber of shares	to Company <sup>1</sup>	share capital
100,885,181	8 Dec 2009	6.94%
72,776,277	6 Oct 2009	5.01%
56,991,117	3 Feb 2009	3.92%
51,587,810	3 Feb 2009	3.55%
67,398,874	3 Feb 2009	4.64%
_	56,991,117 51,587,810	56,991,117         3 Feb 2009           51,587,810         3 Feb 2009

<sup>1</sup> Since the date of disclosure to the Company, the interest of any person listed above in Ordinary Shares may have increased or decreased. No requirement to notify the Company of any increase or decrease would have arisen unless the holding moved up or down through a whole number percentage level. The percentage level may increase (on the cancellation of shares following a re-purchase of shares under the Company's share re-purchase programme) or decrease (on the issue of new shares under any of the Company's share plans).

No other person held a notifiable interest in shares, comprising 3% or more of the issued Ordinary Share capital of the Company.

Changes in the percentage ownership held by major shareholders during the past three years are set out below. Major shareholders do not have different voting rights.

			Percentage of iss	sued share capital
Shareholder	28 Jan 2010	29 Jan 2009	31 Jan 2008	31 Jan 2007
BlackRock, Inc.	6.94%	_	-	_
Invesco Limited	5.01%	-	-	_
Axa SA	3.92%	4.90%	4.87%	_
Investor AB	3.55%	4.38%	4.36%	4.14%
Legal & General Investment Management Limited	4.64%	4.09%	4.06%	3.43%
Capital Research and Management Company	-	4.92%	4.89%	11.70%
Wellington Management Co., LLP	-	4.18%	4.16%	3.95%
Barclays PLC	-	4.26%	4.24%	4.03%

ADSs evidenced by ADRs issued by JPMorgan, as depositary, are listed on the NYSE. At 28 January 2010, the proportion of Ordinary Shares represented by ADSs was 5.47% of the Ordinary Shares outstanding.

Number of registered holders of Ordinary Shares at 28 January 2010:

> In the US 781 > Total 124,757

Number of record holders of ADRs at 28 January 2010:

> In the US 2,298 > Total 2,319

So far as the Company is aware, it is neither directly nor indirectly owned nor controlled by one or more corporations or by any government.

At 28 January 2010, the total amount of the Company's voting securities owned by Directors and officers of the Company was:

Title of class	Amount owned	Percentage of class
Ordinary Shares	300,474	0.02%

The Company does not know of any arrangements, the operation of which might result in a change in the control of the Company.

#### **Related party transactions**

During the period 1 January 2010 to 28 January 2010, there were no transactions, loans, or proposed transactions between the Company and any related parties which were material to either the Company or the related party, or which were unusual in their nature or conditions (see also Note 27 to the Financial Statements on page 185).

#### Options to purchase securities from registrant or subsidiaries

(a) At 28 January 2010, options outstanding to subscribe for Ordinary Shares were:

	Subscription price	
Number of shares	pence	Normal expiry date
63,251,333	1882 – 3487	2010 – 2019

The weighted average subscription price of options outstanding at 28 January 2010 was 2474 pence. All options were granted under Company employee share schemes.

(b) Included in paragraph (a) are options granted to Directors and officers of the Company as follows:

	Subscription price	
Number of shares	pence	Normal expiry date
2,324,523	1882 - 3487	2010 - 2019

(c) Included in paragraph (b) are options granted to individually named Directors. Details of these option holdings at 31 December 2009 are shown in the Share options table on page 118.

During the period 1 January 2010 to 28 January 2010, no Director exercised any options.

#### **Dividend payments**

For Ordinary Shares listed on the LSE and the SSE and ADRs listed on the NYSE, the record date for the second interim dividend for 2009, payable on 15 March 2010, is 5 February 2010 and the ex-dividend date is 3 February 2010.

The record date for the first interim dividend for 2010, payable on 13 September 2010, is 6 August 2010.

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.

#### Shareview

The Company's shareholders with internet access may visit the website, shareview.co.uk, and register their details to create a portfolio. Shareview is a free and secure on-line service from the Company's registrars, Equiniti Limited, which gives access to shareholdings, including balance movements, indicative share prices and information about recent dividends.

#### ShareGift

The Company welcomes and values all of its shareholders, no matter how many or how few shares they own. However, shareholders who have only a small number of shares whose value makes it uneconomic to sell them, either now or at some stage in the future, may wish to consider donating them to charity through ShareGift, an independent charity share donation scheme. One feature of the scheme is that there is no gain or loss for UK capital gains tax purposes on gifts of shares through ShareGift, and it may now also be possible to obtain UK income tax relief on the donation. Further information about ShareGift can be found on its website, sharegift.org, or by contacting ShareGift on 020 7930 3737 or at 17 Carlton House Terrace, London SW1Y 5AH. ShareGift is administered by The Orr Mackintosh Foundation, registered charity number 1052686. More information about the UK tax position on gifts of shares to ShareGift can be obtained from HM Revenue & Customs, whose website address is hmrc.gov.uk.

#### **The Unclaimed Assets Register**

The Company supplies unclaimed dividend data to the Unclaimed Assets Register (UAR), which provides investors who have lost track of shareholdings with an opportunity to search the UAR's database of unclaimed financial assets on payment of a small, fixed fee. The UAR donates part of the search fee to charity. The UAR can be contacted on 0870 241 1713 or at PO Box 9501, Nottingham NG80 1WD.

### **Results**

Unaudited trading results of AstraZeneca in respect of the first three months of 2010 will be published on 29 April 2010 and results in respect of the first six months of 2010 will be published on 29 July 2010.

#### **Documents on display**

The Memorandum of Association of the Company and Articles and other documents concerning the Company which are referred to in this Annual Report may be inspected at the Company's registered office at 15 Stanhope Gate, London W1K 1LN.

#### **Taxation for US residents**

The following summary of the material UK and US federal income tax consequences of ownership of Ordinary Shares or ADRs held as capital assets by US resident shareholders is based on current UK and US federal income tax law, including the US/UK double taxation convention relating to income and capital gains, which entered into force on 31 March 2003 (the Convention). This summary does not describe all of the tax consequences that may be relevant in light of the US resident shareholder's particular circumstances. US resident shareholders are urged to consult their tax advisers regarding US federal income tax consequences of the ownership and disposition of Ordinary Shares and ADRs in their particular circumstances. This discussion is also based in part on representations of JPMorgan as depositary for ADRs and assumes that each obligation in the deposit agreement among the Company, JPMorgan and the holders from time to time of ADRs and any related agreements will be performed in accordance with its terms. The US Treasury has expressed concerns that parties to whom ADRs are released before shares are delivered to the depositary (pre-release), or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADRs, may be taking actions that are inconsistent with the claiming, by US holders of ADRs, of foreign tax credits for US federal income tax purposes. Such actions would also be inconsistent with the claiming of the reduced tax rate, described below, applicable to dividends received by certain non-corporate US resident shareholders. Accordingly. the availability of the reduced tax rate for dividends received by certain non-corporate US resident shareholders could be affected by actions that may be taken by parties to whom ADRs are pre-released.

This discussion assumes that we are not, and will not become, a passive foreign investment company, as discussed below.

# UK and US income taxation of dividends

The UK does not currently impose a withholding tax on dividends paid by a UK company, such as the Company.

For US federal income tax purposes, distributions paid by the Company to a US resident shareholder are included in gross income as foreign source ordinary dividend income to the extent of the Company's current or accumulated earnings and profits, calculated in accordance with US federal income tax principles. Because the Company does not maintain calculations of its earning and profits under US federal income tax principles, it is expected that distributions generally will be reported to US resident shareholders as dividends. The amount of the dividend will be the US dollar amount received by the depositary for US resident holders of ADRs (or in the case of Ordinary Shares, the US dollar value of the pounds sterling payments made, determined at the spot pound sterling/US dollar rate on the date the dividend is received by the US resident shareholders, regardless of whether the dividend is converted into US dollars), and it will not be eligible for the dividends received deduction generally available to US corporations. If the dividend is converted into US dollars on the date of receipt, US resident holders of Ordinary Shares or ADRs generally should not be required to recognise foreign currency gains or losses in respect of the dividend income. They may have foreign currency gain or loss if the amount of such dividend is not converted into US dollars on the date of its receipt.

Subject to applicable limitations and the discussion above regarding concerns expressed by the US Treasury, dividends received by certain non-corporate US resident holders of Ordinary Shares or ADRs in taxable years beginning before 1 January 2011 may be subject to US federal income tax at a maximum rate of 15%. US resident shareholders should consult their own tax advisers to determine whether they are subject to any special rules which may limit their ability to be taxed at this favourable rate.

#### **Taxation on capital gains**

Under the Convention, each contracting state may, in general, tax capital gains in accordance with the provisions of its domestic law. Under present UK law, individuals who are neither resident nor ordinarily resident in the UK, and companies which are not resident in the UK, will not be liable for UK tax on capital gains made on the disposal of their Ordinary Shares or ADRs, unless such Ordinary Shares or ADRs are held in connection with a trade, profession or vocation carried on in the UK through a branch or agency.

A US resident shareholder will generally recognise US source capital gains or losses for US federal income tax purposes on the sale or exchange of Ordinary Shares or ADRs in an amount equal to the difference between the US dollar amount realised and such holder's US dollar adjusted tax basis in the Ordinary Shares or ADRs. US resident shareholders should consult their own tax advisers about the treatment of capital gains, which may be taxed at lower rates than ordinary income for non-corporate US resident shareholders and capital losses, the deductibility of which may be limited.

# Passive Foreign Investment Company (PFIC) rules

We believe that we were not a PFIC for US federal income tax purposes for the year ended 31 December 2009, and do not expect to be a PFIC in the foreseeable future. However, since PFIC status depends on the composition of our income and assets and the market value of our assets (including, among others, less than 25% owned equity investments) from time to time, there can be no assurance that we will not be considered a PFIC for any taxable year. If we were treated as a PFIC for any taxable year during which Ordinary Shares or ADRs were held, certain adverse tax consequences could apply to US resident shareholders.

#### **UK** inheritance tax

Under the current Double Taxation (Estates) Convention (the Estate Tax Convention) between the US and the UK, Ordinary Shares or ADRs held by an individual shareholder who is domiciled for the purposes of the Estate Tax Convention in the US, and is not for the purposes of the Estate Tax Convention a national of the UK, will generally not be subject to UK inheritance tax on the individual's death or on a chargeable gift of the Ordinary Shares or ADRs during the individual's lifetime, provided that any applicable US federal gift or estate tax liability is paid, unless the Ordinary Shares or ADRs are part of the business property of a permanent establishment of the individual in the UK or, in the case of a shareholder who performs independent personal services, pertain to a fixed base situated in the UK. Where the Ordinary Shares or ADRs have been placed in trust by a settlor who, at the time of settlement, was a US resident shareholder, the Ordinary Shares or ADRs will generally not be subject to UK inheritance tax unless the settlor, at the time of settlement, was not domiciled in the US and was a UK national.

In the exceptional case where the Ordinary Shares or ADRs are subject to both UK inheritance tax and US federal gift or estate tax, the Estate Tax Convention generally provides for double taxation to be relieved by means of credit relief.

#### UK stamp duty reserve tax and stamp duty

A 1.5% stamp duty reserve tax is payable upon the deposit of Ordinary Shares in connection with the creation of, but not subsequent dealing in, ADRs. A 0.5% stamp duty is payable on all purchases of Ordinary Shares.

#### Exchange controls and other limitations affecting security holders

There are no governmental laws, decrees or regulations in the UK restricting the import or export of capital or affecting the remittance of dividends, interest or other payments to non-resident holders of Ordinary Shares or ADRs.

There are no limitations under English law, the Articles or the Company's Memorandum of Association on the right of non-resident or foreign owners to be the registered holders of, or to exercise voting rights in relation to, Ordinary Shares or ADRs or to be registered holders of notes or debentures of Zeneca Wilmington Inc. or the Company.

#### **Exchange rates**

For the periods up to April 1999, Astra accounted for and reported its results in Swedish kronor, whereas Zeneca accounted for and reported its results in pounds sterling. Consistent with AstraZeneca's decision to publish its Financial Statements in US dollars, the financial information in this document has been translated from Swedish kronor and pounds sterling into US dollars at the following applicable exchange rates:

	SEK/US\$	US\$/GBP
Average rates (profit and loss account, cash flow)		
1995	7.1100	1.5796
1996	6.7000	1.5525
1997	7.6225	1.6386
1998	7.9384	1.6603
1999	8.2189	1.6247
End of year spot rates (balance sheet)		
1995	6.6500	1.5500
1996	6.8400	1.6900
1997	7.8500	1.6600
1998	8.0400	1.6600
1999	8.5130	1.6185

The following information relating to average and spot exchange rates used by AstraZeneca is provided for convenience:

	SEK/US\$	US\$/GBP
Average rates (income statement, cash flow)		
2007	6.7692	2.0003
2008	6.5130	1.8728
2009	7.6552	1.5496
End of year spot rates (balance sheet)		
2007	6.4051	1.9932
2008	7.7740	1.4437
2009	7.1636	1.6072

# Corporate Information

# History and development of the Company

AstraZeneca PLC was incorporated in England and Wales on 17 June 1992 under the Companies Act 1985. It is a public limited company domiciled in the UK. The Company's registered number is 2723534 and its registered office is at 15 Stanhope Gate, London W1K 1LN (telephone +44 (0)20 7304 5000). From February 1993 until April 1999, the Company was called Zeneca Group PLC. On 6 April 1999, the Company changed its name to AstraZeneca PLC.

The Company was formed when the pharmaceutical, agrochemical and specialty chemical businesses of Imperial Chemical Industries PLC were demerged in 1993. In 1999, the Company sold the specialty chemical business. Also in 1999, the Company merged with Astra of Sweden. In 2000, it demerged the agrochemical business and merged it with the similar agribusiness of Novartis AG to form a new company called Syngenta AG.

In 2007, the Group acquired Medlmmune, a biologics and vaccines business based in the US.

The Group owns and operates numerous R&D, production and marketing facilities worldwide. Its corporate headquarters are at 15 Stanhope Gate, London W1K 1LN.

### Articles Objects

The Company's objects were originally set out in its Memorandum of Association. However, by operation of law, these objects are now deemed to be provisions of the Articles. As is typical of companies registered in England and Wales, the Company's objects are broad and wide-ranging and include manufacturing, distributing and trading pharmaceutical products.

Any amendment to the Articles requires the approval of shareholders by a special resolution at a general meeting of the Company.

## Directors

The Board has the authority to manage the business of the Company, for example, through powers to allot and re-purchase its shares, subject where required to shareholder resolutions. Subject to certain exceptions, Directors do not have power to vote at Board meetings on matters in which they have a material interest.

The quorum for meetings of the Board is a majority of the full Board, of whom at least four must be Non-Executive Directors. In the absence of a quorum, the Directors do not have power to determine compensation arrangements for themselves or any member of the Board.

The Board may exercise all the powers of the Company to borrow money. Variation of these borrowing powers would require the passing of a special resolution of the Company's shareholders.

All Directors must retire from office at the Company's AGM each year and may present themselves for re-election. Directors are not prohibited, upon reaching a particular age, from submitting themselves for election or re-election.

Within two months of the date of their appointment, Directors are required to beneficially own Ordinary Shares of an aggregate nominal amount of \$125, which currently represents at least 500 shares.

# Rights, preferences and restrictions attaching to shares

The share capital of the Company is divided into 2,400,000,000 Ordinary Shares and 50,000 Redeemable Preference Shares. The Ordinary Shares represent 99.9% and the Redeemable Preference Shares represent 0.01% of the Company's total share capital (these percentages have been calculated by reference to the closing mid-point US\$/GBP exchange rate on 31 December as published in the London edition of the Financial Times newspaper). The rights and restrictions attaching to the Redeemable Preference Shares differ from those attaching to Ordinary Shares as follows:

- > The Redeemable Preference Shares carry no rights to receive dividends.
- > The holders of Redeemable Preference Shares have no rights to receive notices of, attend or vote at general meetings except in certain limited circumstances. They have one vote for every 50,000 Redeemable Preference Shares held.

- > On a distribution of assets of the Company, on a winding-up or other return of capital (subject to certain exceptions), the holders of Redeemable Preference Shares have priority over the holders of Ordinary Shares to receive the capital paid up on those shares.
- Subject to the provisions of the Companies Act 2006, the Company has the right to redeem the Redeemable Preference Shares at any time on giving not less than seven days' written notice.

# Action necessary to change the rights of shareholders

In order to vary the rights attached to any class of shares, the consent in writing of the holders of three quarters in nominal value of the issued shares of that class or the sanction of an extraordinary resolution passed at a general meeting of such holders is required.

### **General meetings**

AGMs and other general meetings, as from time to time may be required, where a special resolution is to be passed or a Director is to be appointed require 21 clear days' notice to shareholders. Subject to the Companies Act 2006, other general meetings require 14 clear days' notice.

For all general meetings, a quorum of two shareholders present in person or by proxy, and entitled to vote on the business transacted, is required.

Shareholders and their duly appointed proxies and corporate representatives are entitled to be admitted to general meetings.

### Limitations on the rights to own shares

There are no limitations on the rights to own shares.

### Property

Substantially all of our properties are held freehold, free of material encumbrances and we believe that such properties are fit for their purpose.

# **Cross-reference to Form 20-F**

The information in this document that is referenced on this page is included in AstraZeneca's Form 20-F for 2009 (2009 Form 20-F) and is filed with the SEC. The 2009 Form 20-F is the only document intended to be incorporated by reference into any filings by AstraZeneca under the Securities Act of 1933, as amended. References to major headings include all information under such major headings, including subheadings. References to subheadings include only the information contained under such subheadings. Graphs are not included unless specifically identified. The 2009 Form 20-F has not been approved or disapproved by the SEC, nor has the SEC passed comment upon the accuracy or adequacy of the 2009 Form 20-F. The 2009 Form 20-F filed with the SEC may contain modified information and may be updated from time to time.

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# Glossary

### **Market definitions**

	Other Established	Markets		Emerging Markets			
	Western Europe	Japan	Australasia	Emerging Europe	China	Emerging Asia Pacific	Other Emerging
JS	Austria	Japan	Australia	Albania*	China	Bangladesh*	Egypt
Canada	Belgium		New Zealand	Belarus*		Cambodia*	Gulf States
	Denmark			Bosnia-Herzegovina*		Hong Kong	Latin America
	Finland			Bulgaria*		India	Lebanon
	France			Croatia*		Indonesia*	Maghreb
	Germany			Czech Republic		Laos*	Saudi Arabia
	Greece			Estonia*		Malaysia	South Africa
	Holland			Georgia*		Philippines	
	Iceland*			Hungary*		Singapore	
	Ireland			Kazakhstan*		South Korea	
	Italy			Latvia*		Sri Lanka*	
	Luxembourg*			Lithuania*		Taiwan	
	Norway			Macedonia*		Thailand	
	Portugal			Poland		Vietnam*	
	Spain			Romania*			
	Sweden			Russia*			
	Switzerland			Serbia/Montenegro*			
	UK			Slovakia			
				Slovenia*			
				Turkey			
				Ukraine*			

Established Markets means North America and Other Established Markets.

Latin America includes Argentina, Brazil, Chile, Colombia, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru and Venezuela. Gulf States includes Bahrain<sup>\*</sup>, Dubai<sup>\*</sup>, Kuwai<sup>\*</sup>, Oman<sup>\*</sup>, Qatar<sup>\*</sup> and UAE. Maghreb means Algeria, Morocco and Tunisia<sup>\*</sup>. \*IMS Health data is not available or AstraZeneca does not subscribe for IMS Health data for these countries.

The above table is not an exhaustive list of all the countries in which AstraZeneca operates.

## **US** equivalents

#### Terms used in this Annual Report

and Form 20-F Information	US equivalent or brief description		
Accruals	Accrued expenses		
Allotted	Issued		
Bank borrowings	Payable to banks		
Called-up share capital	Issued share capital		
Creditors	Liabilities/payables		
Current instalments of loans	Long-term debt due within one year		
Debtors	Receivables and prepaid expenses		
Earnings	Net income		
Finance lease	Capital lease		
Fixed asset investments	Non-current investments		
Freehold	Ownership with absolute rights in perpetuity		
Interest payable	Interest expense		
Interest receivable	Interest income		
Loans	Long-term debt		
Prepayments	Prepaid expenses		
Profit	Income		
Profit and loss account	Income statement/consolidated statement of income		
Reserves	Retained earnings		
Share premium account	Premiums paid in excess of par value of Ordinary Shares		
Short term investments	Redeemable securities and short-term deposits		
Statement of recognised income and expense	Statement of comprehensive income		

The following abbreviations and expressions have the following meanings when used in this Annual Report:

Abbott means Abbott Pharmaceuticals PR Ltd. with respect to Trilipix<sup>™</sup> and/or *Certriad* and Abbott Laboratories, Inc. with respect to *Crestor*.

**ADR** means an American Depositary Receipt evidencing title to an ADS.

**ADS** means an American Depositary Share representing one underlying Ordinary Share.

**AGM** means an Annual General Meeting of the Company.

Alcon means Alcon Research, Ltd.

**ANDA** means an abbreviated new drug application, which is a marketing approval application for a generic drug submitted to the FDA.

**Annual Report** means this Annual Report and Form 20-F Information 2009.

Array means Array BioPharma Inc.

**Articles** means the Articles of Association of the Company.

Astellas means Astellas Pharma, Inc.

Astra means Astra AB, being the company with whom the Company merged in 1999.

AstraZeneca means the Company and its subsidiaries.

BMS means Bristol-Myers Squibb Company.

Board means the Board of Directors of the Company.

**CEO** means the Chief Executive Officer of the Company.

CER means constant exchange rates.

CFO means the Chief Financial Officer of the Company.

**CHMP** means the Committee for Medicinal Products for Human Use, being a committee of the EMEA.

Code of Conduct means the Group's Code of Conduct.

**Combined Code** means the UK Combined Code on Corporate Governance that sets out standards of good practice in corporate governance for the UK.

**Company** means AstraZeneca PLC (formerly Zeneca Group PLC (**Zeneca**)).

Complete Response Letter means a letter issued by the FDA communicating their decision to a drug company that its NDA or biological licensing application is not approvable as submitted. The submitting drug company is required to respond to the Complete Response Letter if it wishes to pursue an approval for its submission.

**cost growth rates** means percentage growth of a particular cost category over the comparable cost category for the previous year.

Dako means Dako Denmark A/S.

Director means a director of the Company.

earnings per share (EPS) means profit for the year after tax and minority interests, divided by the weighted average number of Ordinary Shares in issue during the year.

EMEA means the European Medicines Agency.

EU means the European Union.

FDA means the US Food and Drug Administration, which is part of the US Department of Health and Human Services Agency, which is the regulatory authority for all pharmaceuticals (including biologics and vaccines) and medical devices in the US.

Forest means Forest Laboratories Holdings Limited.

GAAP means Generally Accepted Accounting Principles.

GDP means gross domestic product.

**GIA** means AstraZeneca's group internal audit.

gross margin means the margin, as a percentage, by which sales exceed the cost of sales, calculated by dividing the difference between the two by the sales figure.

Group means AstraZeneca PLC and its subsidiaries.

IAS means the International Accounting Standards.

**IASB** means the International Accounting Standards Board.

**IFRS** means the International Financial Reporting Standards or an International Financial Reporting Standard, as the context requires.

Jubilant means Jubilant Biosys Ltd.

KPI means key performance indicator.

KPMG means KPMG Audit Plc.

Listing Standards means the corporate governance and listing standards of the NYSE.

MAA means a marketing authorisation application, which is an application for authorisation to place medical products on the market. This is a specific term used in the EU and European Economic Area markets.

MAb means monoclonal antibody, a biologic that is specific; that is, it binds to and attacks one particular antigen.

MedImmune means MedImmune, LLC (formerly MedImmune, Inc.).

Merck means Merck Sharp & Dohne Corp (formerly Merck & Co., Inc.).

moving annual total (MAT) means a figure that represents the financial value of a variable for 12 months.

**NDA** means a new drug application to the FDA for approval to market a new medicine in the US.

Nektar means Nektar Therapeutics.

NGOs means non-governmental organisations.

Novexel means Novexel S.A.

NSAID means a non-steroidal anti-inflammatory drug.

NYSE means the New York Stock Exchange.

operating profit means sales, less cost of sales, less operating costs, plus operating income.

**Ordinary Share** means an ordinary share of \$0.25 each in the share capital of the Company.

Orphan Drug means a drug which has been approved for use in a relatively low-incidence indication (an orphan indication) and has been rewarded with a period of market exclusivity; the period of exclusivity and the available orphan indications vary between markets.

OTC means over-the-counter.

Paediatric Exclusivity means, in the US, a six-month period of exclusivity to market a drug which is awarded by the FDA in return for certain paediatric clinical studies using that drug. This six-month period runs from the date of relevant patent expiry. Analogous provisions are available in certain other territories.

Patent Term Extension means an extension of up to five years in the term of a US patent relating to a drug which compensates for delays in marketing resulting from the need to obtain FDA approval.

Phase I means the phase of clinical research where a new drug or treatment is tested in small groups of people (20 to 80) to check that the drug can achieve appropriate concentrations in the body, determine a safe dosage range and identify side effects. This phase includes healthy volunteer studies.

Phase II means the phase of clinical research which includes the controlled clinical activities conducted to evaluate the effectiveness of the drug in patients with the disease under study and to determine the common short-term side effects and risks associated with the drug. Phase II studies are typically conducted in a relatively small number of patients (usually no more than several hundred).

Phase III means the phase of clinical research which is performed to gather additional information about effectiveness and safety of the drug, often in a comparative setting, to evaluate the overall benefit/ risk profile of the drug. Phase III studies usually include between several hundred and several thousand patients.

pounds sterling, £, GBP, pence or p means references to the currency of the UK.

R&D means research and development.

Redeemable Preference Share means a redeemable preference share of  $\pounds 1$  each in the share capital of the Company.

Regulatory Exclusivity means any of the intellectual property rights arising from generation of clinical data and includes Regulatory Data Protection (as explained in the Intellectual property section on page 31), Paediatric Exclusivity and Orphan Drug status.

Salix means Salix Pharmaceuticals, Inc.

Sarbanes-Oxley Act means the US Sarbanes-Oxley Act of 2002.

SEC means the US Securities and Exchange Commission, the governmental agency that regulates the US securities industry/stock market.

SET means the Senior Executive Team.

SG&A costs means selling, general and administrative costs.

**sNDA** means a supplemental new drug application, which is an application made to the FDA to seek approval to market an additional indication for a drug already on the market.

Targacept means Targacept Inc.

Teva means Teva Pharmaceuticals USA, Inc.

TSR means total shareholder return, being the total return on a share over a period of time, including dividends re-invested.

UCB means UCB Pharma S.A.

**UK** means the United Kingdom of Great Britain and Northern Ireland.

US means the United States of America.

US dollar, US\$, USD or \$ means references to the currency of the US.

WHO means the World Health Organization, the United Nations' specialised agency for health.

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### Our website

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