# How does health connect us all?

AstraZeneca Annual Report and Form 20-F Information 2010

AstraZeneca

#### **Financial highlights**



\$13.6bn

Core operating profit unchanged at \$13,603 million (\$13,621 million in 2009)

# **\$6.71**

Core EPS for the full year increased by 5% to \$6.71 (\$6.32 in 2009)



#### 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 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 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 of 1995 and the UK Companies Act 2006, we are providing the following cautionary statement: This Annual Report 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 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 the Company undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects' 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things, those factors identified in the Principal risks and uncertainties section from page 96 of this Annual Report. Nothing in this Annual Report should be construed as a profit forecast.

#### Inclusion of reported performance, Core financial measures and constant exchange rate growth rates

For further information in relation to the inclusion of reported performance, Core financial measures and constant exchange rate (CER) growth rates as used in the Overview from page 2 and throughout the Business Review and Corporate Governance from pages 24 and 94 respectively, please refer to the Financial Review section on page 80.

Throughout this Annual Report, 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, 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 2010 obtained from IMS Health, a leading supplier of statistical data to the pharmaceutical industry. For the US, dispensed new or total prescription data and audited sales data are taken, respectively, from IMS Health National Prescription Audit and IMS National Sales Perspectives for the 12 months ended 31 December 2010; 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 are given at CER. For the purposes of this Annual Report, unless otherwise stated, references to the world pharmaceutical market or similar phrases are to the 44 countries contained in the IMS Health MIDAS Quantum database, which amounted to approximately 96% (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 Annual Report.

#### 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 Annual Report.

#### Definitions

The Glossary and the Market definitions table from page 217 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. 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 are references to days and/or months in 2010.

#### Figures

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

# Overview

# Health is something that connects us all

In our mission to make a meaningful difference to the world's health, we work closely with governments and regulators, those who pay for healthcare, our partners in industry and academia, and doctors. Through our activities we touch a great number of people's lives and we are acutely conscious of our responsibility to patients and society in general.



#### **Directors' Report**

The following sections comprise the Directors' Report which has been prepared in accordance with the requirements of the Companies Act 2006:

- > Our Strategy and Performance
- > Business Review
- > Corporate Governance
- > Development Pipeline
- > Shareholder Information
- > Corporate Information

#### Welcome to our 2010 Annual Report

You will find this Annual Report and all the case studies featured in this document on our website, **astrazeneca.com/annualreport2010** 

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135 Financial Statements

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#### AstraZeneca at a glance

#### Who we are



61,000 employees worldwide

10

10 medicines with sales of over \$1 billion in 2010

**1000** Active in over 100 countries

AstraZeneca is a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business

Our mission is to make a meaningful difference to patient health through great medicines

We are committed to acting responsibly and to the sustainable development of our business

Our mission requires us to do things in the right way – to behave in accordance with our values and to act with integrity

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

#### What we do

We discover, develop and commercialise prescription medicines for six important areas of healthcare: Cardiovascular, Gastrointestinal, Infection, Neuroscience, Oncology and Respiratory & Inflammation

We have a broad range of medicines that includes established treatments for many serious illnesses, such as our antibiotic, *Merrem/Meronem* and *Losec/Prilosec* for acid-related diseases

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

We had 10 medicines with sales of more than \$1 billion each in 2010

Cardiovascular

**Crestor** for managing cholesterol levels

**Seloken/Toprol-XL** for hypertension, heart failure and angina

**Atacand** for hypertension and heart failure

Gastrointestinal

**Nexium** for acid reflux

Infection Synagis for RSV, a respiratory infection in infants

Neuroscience

Seroquel IR for schizophrenia and bipolar disorder

Seroquel XR for schizophrenia, bipolar disorder and major depressive disorder

Oncology Arimidex for breast cancer

**Zoladex** for prostate and breast cancer

Respiratory & Inflammation Symbicort for asthma and chronic obstructive pulmonary disease

#### How we work

Our activities touch many people's lives and we are committed to working in a spirit of collaboration to achieve our goal of better health for patients

For patients and doctors, we provide medicines for some of the world's most serious illnesses

For the people who pay for healthcare, we work to make sure that our medicines offer value for money

For our employees, we provide a culture in which they can feel appreciated, energised and rewarded for their contribution

For our shareholders, we aim to deliver value through our continued focus on innovation and running our business efficiently

For the wider community, we want to be valued for the contribution our medicines make to society and trusted for the way in which we do business

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

#### 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, Mexico, Brazil and Russia

In 2010, we had sales of \$13,727 million in the US, \$9,168 million in Western Europe, \$5,176 million in Established ROW and \$5,198 million in Emerging Markets

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

Of our 61,000 employees worldwide, 45.6% are in Europe, 30.5% in the Americas and 23.9% in Asia, Africa and Australasia

Around 15,700 people work in our R&D organisation and we have 14 principal R&D centres in eight countries, including Sweden, the US and the UK

We have 9,300 employees at 23 Supply and Manufacturing sites in 16 countries

# \$4.2bn

Core investment of \$4.2 billion in our R&D organisation in 2010

80

Over 80 major externalisation transactions completed over the past three years

46%

46% of sales and marketing workforce based in Emerging Markets compared with 16% in 2002

23

23 Supply and Manufacturing sites

Overview

#### Our year in brief

# Summary financial and operational information for 2010

#### **Financial highlights**

Sales \$m (unchanged)

Sales \$m (unchanged)	
2010	33,269
Core operating profit \$m	ו (unchanged)
2010	13,603
2008	10,958
Core gross margin \$m (-	1%)
2010	27,024
Core earnings per Ordin	ary Share \$ (+5%)
2010	6.71
Net cash flow from oper	rating activities \$m
	rating activities \$m 10,680
2010	10,680
2010 2009 2008	10,680 11,739 8,742
2010 2009 2008 Reported operating prof	10,680 11,739 8,742
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2008 Reported operating prof 2010 2008 Reported gross margin S 2010 2009	10,680 11,739 8,742 fit \$m (-1%) 11,494 11,543 9,144 \$m (-1%) 26,880 27,029 25,003
2010 2009 2008 Reported operating prof 2010 2009 2008 Reported gross margin S 2010 2009 2008 Reported basic earnings	10,680 11,739 8,742 fit \$m (-1%) 11,494 11,543 9,144 \$m (-1%) 26,880 27,029 25,003 s per Ordinary Share \$ (+7%)

#### **Operational overview**

92

92 projects in clinical development, including 9 in Phase III or under regulatory review. 34 withdrawn during the year

7%

Revenue in the US fell 7%, while revenue in Rest of World rose by 7%

**\$556** Annual Crestor and Seroquel sales exceeded \$5 billion each

\$5.1bn

Revenue in Emerging Markets grew to over \$5.1 billion, a 16% increase

\$2.4bn

The first phase of the restructuring programme is now complete, resulting in annual benefits of \$2.4 billion



Net share repurchases totalled \$2.1 billion in 2010

**Financial Statements** 

- > Single R&D organisation in place, including new leadership team, global organisation structure and governance framework
- > Vimovo approved in the US and the EU; Brilique approved in the EU with Complete Response Letter received for Brilinta in the US; Kombiglyze™ XR (Onglyza™/metformin combination) approved in the US; decisions made in December to discontinue development of motavizumab and Certriad
- > Completed a deal with Rigel for the Phase III development of fostamatinib (for rheumatoid arthritis), and TC-5214, our neuroscience collaboration with Targacept, also entered Phase III development
- > Agreement with HealthCore, which maintains the largest commercially insured population data environment in the US, enables 'real world' studies of health outcomes
- > Portfolio of more than 100 generic products being licensed across 30 Emerging Markets for marketing under our brand
- > Crestor substance patent upheld in the US courts
- > Ranked in the top 8% in the sector in the Dow Jones Sustainability World and European Indexes
- > Reviewed and revised Responsible Business Plan to align it with strategic business priorities
- > Additional ways of reporting sales and marketing performance introduced to support increased transparency
- > Improvement in senior leader communications with employees but slight decline in employee engagement

All growth rates are at CER

#### Product performance summary

Arimidex (2009: \$1,921m; 2008: \$1,857m)

**\$1,512m** -22%

Atacand (2009: \$1,436m; 2008: \$1,471m)

**\$1,483m** +3%

Crestor (2009: \$4,502m; 2008: \$3,597m)

\$5,691m +24%

Nexium (2009: \$4,959m; 2008: \$5,200m)

\$4,969m 0%

Seloken/Toprol-XL (2009: \$1,443m; 2008: \$807m)

**\$1,210m** -17%

Seroquel IR (2009: \$4,171m; 2008: \$4,223m)

**\$4,148m** -1%

Seroquel XR (2009: \$695m; 2008: \$229m)

**\$1,154m** +67%

Symbicort (2009: \$2,294m; 2008: \$2,004m)

**\$2,746m** +20%

Synagis (2009: \$1,082m; 2008: \$1,230m)

**\$1,038m -4%** 

**Zoladex** (2009: \$1,086m; 2008: \$1,138m)

**\$1,115m 0%** 



## 2010 was a year in which AstraZeneca maintained its strong financial performance

Comis Sheather

Louis Schweitzer Chairman

#### **Dividend information**



Dividend per Ordinary Share 2010

Dividend for 2010	\$	Pence	SEK	Payment date
First interim dividend	0.70	44.9	5.12	13 September 2010
Second interim dividend	1.85	116.7	11.99	14 March 2011
Total	2.55	161.6	17.11	

Distributions to shareholders \$m	2010	2009	2008
Dividends	3,361	2,977	2,739
Share repurchases	<b>2,604</b> <sup>1</sup>	-	610

<sup>1</sup> Share repurchases in 2010, net of proceeds from the issue of share capital equal to \$494 million, were \$2,110 million.

**Financial Statements** 

Additional Information

In the face of sustained pressures on the business, 2010 was a year in which AstraZeneca maintained its strong financial performance. We also made good progress in implementing our strategy to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business.

Group sales in 2010 were unchanged at \$33,269 million. Reported operating profit was \$11,494 million, down 1%. Reported earnings per share for the full year were up 7% at \$5.60 (2009: \$5.19). Within the unchanged revenue total there was strong sales growth for medicines such as *Crestor, Symbicort* and *Seroquel XR*, and revenue outside the US increased by 7%, including a 16% increase in Emerging Markets. On the other hand US revenue was down by 7%. As expected, revenue in the US was affected by generic competition for *Arimidex, Pulmicort Respules* and *Toprol-XL*, as well as the absence of the H1N1 influenza (swine flu) vaccine revenue that benefited 2009 revenues.

#### **Pharmaceutical sector**

Our performance in 2010 took place against a background of continued world pharmaceutical market growth. This growth is being driven by increasing and ageing populations, as well as expanding numbers of patients in emerging markets who can benefit from our medicines, together with the increasing prevalence of chronic diseases and advances in science and technology. On the other hand, the pharmaceutical sector, including AstraZeneca, faces a number of challenges in the form of competition, particularly from generic versions of medicines, and declining R&D productivity. In addition, most of our sales take place in highly regulated markets where cost containment by governments and other payers for healthcare is a priority, especially in the wake of the economic downturn. We expect this pressure to continue, most notably in the US and European markets and the Board will keep its plans under continuous review to ensure we are able to respond to changes.

AstraZeneca fully recognises the importance of its reputation. We are committed to doing business in an ethical and proper manner and take compliance with all laws seriously. Oversight of the pharmaceutical sector by regulators and competition authorities has intensified in recent years. The Board, assisted by the Audit Committee, plays an active role in monitoring performance.

#### Our strategy

Against this outlook, the Board believes its focused strategy is the most value-creating path for AstraZeneca. Our business model is based on using the best science and technology to invent and acquire, develop, produce and distribute innovative medicines that make a meaningful difference to patient health around the world.

Underpinning this model is the creation, protection and subsequent sharing of intellectual property. It is on this basis that we continue to invest in new medicines and work to protect and optimise our investments by rigorously defending our patent rights. We were therefore pleased with the court decision upholding the validity and enforceability of the *Crestor* US substance patent.

The focus of our efforts to implement our strategy in 2010 was on making the transformational changes to the business needed to generate sustainable long-term value. At the heart of these changes was the creation of a single R&D organisation which we are reshaping and in which we are investing to improve productivity and secure targeted levels of return. Complementing this is a single Commercial organisation which not only ensures that our medicines reach the doctors and patients who need them, but also works closely with R&D to ensure that our pipeline delivers the medicines most likely to deliver technical and commercial success. That includes working with payers to ensure that they value and are willing to purchase our medicines.

Also central to our strategy is a firm belief in external collaboration. We have a desire to access the best science, whatever its origins, and to act as a valued and trusted partner.

We have undertaken significant restructuring initiatives in furtherance of our strategy. The first phase of the restructuring programme is now complete, resulting in the realisation of annual benefits of \$2.4 billion achieved to date at a cumulative cost of around \$2.5 billion.

#### Outlook and cash returns to shareholders

We continue to plan on the basis that revenue will be in the range of \$28-\$34 billion a year over the 2010-14 period, as revenue growth from key franchises that retain exclusivity and continued growth in Emerging Markets are pressured by the loss of market exclusivity on a number of products.

In recognition of the Group's strong balance sheet and sustainable significant cash flow, and the Board's confidence in the strategic direction and long-term prospects for the business, we announced, in conjunction with the full year 2009 results, the adoption of a progressive dividend policy, intending to maintain or grow the dividend each year. After providing for business investment, funding the progressive dividend policy and meeting our debt service obligations, the Board will also keep under review the opportunity to return cash in excess of these requirements to shareholders through periodic share repurchases.

The Board has recommended a second interim dividend of \$1.85, an 8% increase over the second interim dividend awarded in 2009. This brings the dividend for the full year to \$2.55 (161.6 pence, SEK 17.11), an increase of 11% from 2009. In 2010, cash distributions to shareholders through dividends totalled \$3,361 million and net share repurchases totalled \$2,110 million.

#### **Board changes**

There were a number of Board changes during the year. John Buchanan and Bo Angelin both left the Board immediately after the 2010 AGM. John had been a Director for eight years and had also chaired the Audit Committee. His contribution to the work of the Board and the Audit Committee over those years was significant and we benefited greatly from his skills, experience and thoughtful approach. Bo was appointed as a Director in 2007 and stepped down in order to concentrate on his scientific work. He provided valuable insight to the Board and the Science Committee during his time as a Director. On behalf of their fellow Directors, I would like to thank both for their excellent service to AstraZeneca.

Bruce Burlington joined the Board in August. He brings with him a wealth of pharmaceutical industry experience following a career at the FDA and subsequently at Wyeth, now part of Pfizer Inc. In January 2011, Shriti Vadera joined the Board. Her experience of emerging markets, and knowledge of global finance and public policy, will be invaluable. I would like to welcome both Bruce and Shriti to the Board.

#### Appreciation

2010 was a successful and challenging year for AstraZeneca. We maintained our strong financial performance and took and implemented difficult decisions to ensure the future success of the Group. None of this would have been possible without the leadership of David Brennan and the other members of his executive team. My thanks, and those of the whole Board, go to them and all our employees who did so much in 2010 for the long-term success of AstraZeneca.

#### Louis Schweitzer

Chairman

It is the manner in which we do business as much as what we do that will determine our long-term success



DauckMunn

David R Brennan Chief Executive Officer

#### **Operational highlights**



Single R&D organisation in place

Achieved major market approvals for *Vimovo* and *Brilique/Brilinta*; made submissions for dapagliflozin and *Zinforo*, but disappointments on other pipeline products

8%

Ranked in the top 8% in the sector in the Dow Jones Sustainability World and European Indexes \$5bn

Annual *Crestor* and *Seroquel* sales exceeded \$5 billion each

**\$5.1bn** 

Revenue in Emerging Markets grew to over \$5.1 billion, a 16% increase

#### **Chief Executive Officer's Review**

2010 emphasised that it is the manner in which we do business as much as what we do that will determine our long-term success. It told us that, if we are to deliver our strategy and make a meaningful difference to the health of patients through great medicines, then we need to act with integrity and remain true to our values. We need to behave as an integrated organisation and work in collaboration with patients, doctors, payers and our many other stakeholders.

#### Transforming R&D

That journey starts with an R&D organisation that delivers worldclass performance and where increased externalisation means we can access diverse sources of innovation. We made significant progress in 2010 with the creation of a single R&D organisation and of a leadership team comprising the best internal and external leaders. This includes the appointment of Martin Mackay as President, Global R&D. We have also put in place a new global organisation structure and governance framework. We are consolidating our site footprint and have refocused our resources on a smaller number of high-potential activities.

The need for change is undiminished. Our R&D record over the past few years is disappointing and our results in 2010 were mixed. On the positive side, *Vimovo*, our medicine for arthritic pain, which we developed with Pozen Inc. was approved and launched in the EU and the US. *Brilique/Brilinta*, our treatment for acute coronary syndromes, has also been approved in the EU. Kombiglyze™ XR, a fixed dose combination of Onglyza™ and metformin, a further product in our BMS diabetes collaboration, was approved in the US.

In 2010, we made major regulatory submissions for vandetanib (for thyroid cancer), *Zinforo* (an anti-bacterial medicine), dapagliflozin (for diabetes) and *Axanum* (a cardiovascular medicine). We completed a deal with Rigel for the Phase III development of fostamatinib (for rheumatoid arthritis), and TC-5214, our neuroscience collaboration with Targacept, also entered Phase III development.

However, both *Brilinta* and *Axanum* received Complete Response Letters from the FDA during the year. We responded to the *Brilinta* letter in January 2011 and remain confident in our submission. Complete Response Letters were also received for motavizumab (for treating serious respiratory syncytial virus (RSV) disease) and *Certriad* (for the treatment of lipid abnormalities). Following these letters, we have withdrawn the biological license application relating to motavizumab and recorded an impairment charge of \$445 million. In addition, we have ended our licence agreement with Abbott for the development of *Certriad*.

#### Leveraging our commercial assets

Hand in hand with transforming R&D is the need to leverage our commercial assets. Our key medicines, such as *Crestor, Symbicort* and *Seroquel XR*, achieved double digit growth in 2010. Both *Crestor* and *Seroquel XR* were helped by US and EU approvals for additional indications. *Nexium* is already approved in 120 countries and in 2010 we signed an agreement with Daiichi Sankyo for its co-promotion and supply in Japan after it is approved for use.

We are also focusing our efforts on ensuring that we have the right capabilities to successfully launch and commercialise the next wave of medicines from our pipeline, as well as to deliver our expansion plans in Emerging Markets, both through organic growth of products from our current portfolio and pipeline and also through selective additions of AstraZeneca branded generics. In 2010, we identified a portfolio of more than 100 generic products which we are currently licensing across 30 Emerging Markets. To help us license these dossiers and source the molecules, we are working with a number of companies in India, and have signed an agreement with Torrent to supply us with a portfolio of branded generic medicines.

We are creating a much stronger focus on those who pay for our medicines to help us ensure that our medicines get to the right patients, at the right time and at a price they can afford, while reflecting our investment. As part of this, we have signed a collaboration agreement with HealthCore, which maintains the largest commercially insured population data environment in the US. This will enable us to carry out 'real world' studies of health outcomes, which is of increasing importance to payers around the world.

In April 2010, we signed an agreement with the US Department of Justice to settle an investigation relating to the sales and marketing of *Seroquel*. The requirements of the associated Corporate Integrity Agreement include a number of active monitoring and self-reporting obligations which we have put in place.

#### Efficiency across the value chain

To be successful we need to be a lean and agile organisation. We continue to drive our operations strategy, simplifying and streamlining our infrastructure and reducing costs. Making changes to reshape the business and make it fit for purpose going forward affects a large number of people. In many parts of the business that 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 dealing responsibly and sympathetically with affected individuals and the communities in which they live.

#### People acting with integrity

A good reputation is critical to our business success. We need to earn and maintain the trust of our customers, collaborators and all those with whom we do business. That means each of us needs to act with integrity and in accordance with our values. It explains why we set such great store by compliance with our Code of Conduct. During 2010, we reviewed our existing sales and marketing policies and standards and created a single new Global Policy on External Interactions which we aim to launch in the first quarter of 2011.

A good reputation also requires a commitment to acting responsibly and to the sustainable development of our business. To that end, our responsible business objectives are closely aligned to our business strategy and, in 2010, we reviewed and reshaped our corporate responsibility priority action plan.

Finally, I am grateful for the dedication and hard work of all our employees. The pace of change will not let up in 2011 but I remain confident that together we have the talent, motivation and commitment needed to improve patient health through great medicines.

#### David R Brennan

Chief Executive Officer

#### **Our Strategy and Performance**

#### Our marketplace

The world pharmaceutical market grew by 5.2% in 2010 and more people than ever around the world had access to modern medicines, including more patients in emerging markets. Indeed, as the World pharmaceutical markets figure below shows, average revenue growth in Emerging Markets was, at nearly 14%, more than three times the rate in Established Markets.

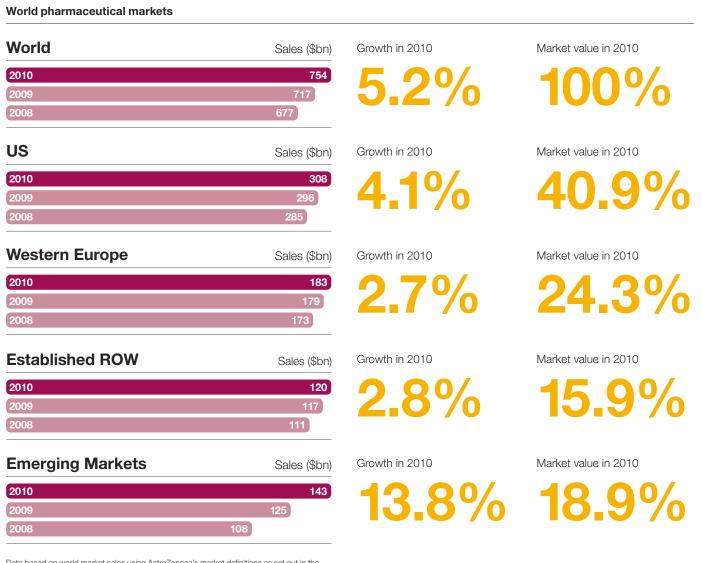
While demand for medicines and world pharmaceutical markets, especially Emerging Markets, continued to grow in 2010, researchbased pharmaceutical companies faced a challenging marketplace. Pricing pressures intensified in most Established Markets with increased competition from generic medicines and greater constraints being placed on our business by payers. In addition, industry-wide R&D productivity continued to decline. In 2010, the top five pharmaceutical markets in the world remained the US, Japan, Germany, France and China, with the US representing 40.9% of global prescription pharmaceutical sales (2009: 41.2%).

#### 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 modern standards of healthcare continues to increase, particularly among the elderly, who represent a rising proportion of populations in developed nations.

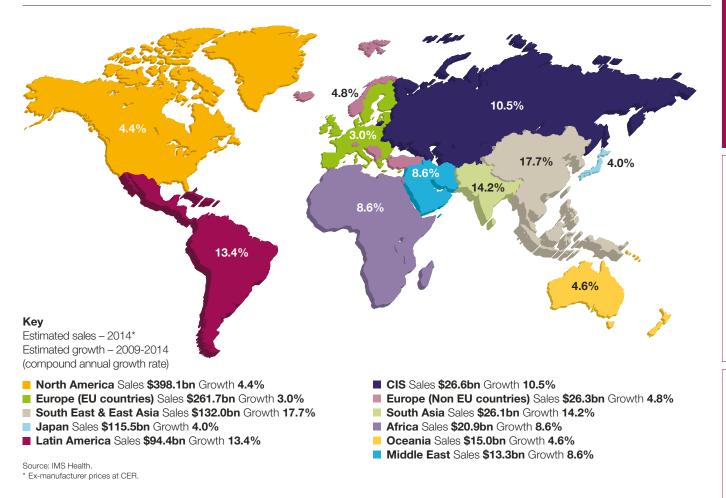
Furthermore, faster-developing economies, such as China, India and Brazil, offer new opportunities for the industry to help an expanding number of patients who can benefit from medicines. Emerging Markets now represent approximately 85% of the world population. In addition, their pharmaceutical revenues grew significantly faster than those in Established Markets in 2010 and, as the Estimated pharmaceutical market growth 2009-2014 figure opposite shows, it is estimated that this trend will continue.



Data based on world market sales using AstraZeneca's market definitions as set out in the Market definitions table on page 217. Source: IMS Health.

# **Business Review**

#### Estimated pharmaceutical market growth 2009-2014



#### Unmet medical need

In most established markets, ageing populations and certain lifestyle choices such as smoking, a poor diet and lack of exercise 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 increasing in middle-income countries and is now beginning to have an impact in the least developed countries. For example, WHO research shows that about 90% of the premature deaths from non-communicable diseases are in developing countries, amounting to more than eight million deaths annually. WHO estimates that, if nothing is done, deaths from these diseases will increase by a further 17% before 2015, with Africa seeing the greatest increase of 27%, compared with 6% in Europe.

#### Advances in science and technology

Innovation leading to new drugs is critical to meeting unmet medical need. Existing drugs will continue to be important in meeting the growing demand for healthcare, particularly as the increasing use of generic medication improves access and frees up total healthcare funds. At the same time, advances in disease understanding and the application of new technologies will be required to ensure the delivery of new medicines. Such approaches include personalised healthcare and predictive science as well as other new therapeutic modalities.

The use of large molecules, or biologics, is becoming an increasingly important source of innovation. Forecasts for 2016 predict that of the world's top 100 pharmaceutical products, 48% of sales will come from biologics. This compares with only 31% in 2009 and 15% 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. Most pharmaceutical companies now pursue both small molecules and biologics R&D.

#### The challenges

#### **Pricing pressure**

Most of our sales continue to be generated in highly regulated markets where governments exert various levels of control on pricing and reimbursement. Cost containment in healthcare, including containment of pharmaceutical spending, continues to be a focus. The global economic downturn has enhanced this focus and the pricing and reimbursement environments in many markets continue to be highly dynamic.

In March 2010, President Barack Obama signed into law the Affordable Care Act. It is intended to expand healthcare coverage and improve healthcare delivery while reducing the federal budget deficit and sets in motion significant changes to the US healthcare system, the world's largest. Healthcare reform implementation impacts the pharmaceutical industry significantly, with some provisions directly targeting the sector. Expansion of healthcare coverage to an estimated 32 million uninsured people and the enhanced focus on ensuring quality healthcare will potentially increase patient access to appropriate treatments, including prescription medicines. Efforts to expand access to government healthcare programmes require additional sources of funding. The pharmaceutical industry, including AstraZeneca, has shown its commitment to these efforts through its agreement, among other things, to help close the coverage gap in the Medicare Part D prescription drug programme and by paying an annual industry fee.

#### **Our Strategy and Performance**

While many of the coverage expansion provisions do not take effect until 2014, the legislation will have an immediate and direct impact on healthcare activities across stakeholders in the US healthcare system. More generally, it will have broad implications for how healthcare is delivered, covered and reimbursed. The pharmaceutical industry is working with policymakers and regulators during the implementation phases of healthcare reform with a view to ensuring that they strike a balance between containing costs, while also promoting an environment that fosters medical innovation.

In Germany, Europe's largest pharmaceutical market, healthcare reforms brought into force this year are set to have a significant long-term impact on the demands being placed on pharmaceutical manufacturers to produce information and evidence from clinical trials. In addition, these reforms include a number of short-term measures to lower Germany's healthcare spending, including provisions that allow for an increase in mandatory rebates and a freeze on drug prices. Similar short-term measures have been implemented as a direct response to economic challenges in several other European markets in 2010, including Spain, Portugal and Greece. Each of these markets has either imposed price cuts, or increased mandatory rebates on pharmaceutical products. These actions present a considerable challenge for the research-based pharmaceutical industry.

Nevertheless, pricing remains one of the principal levers that countries can use to stimulate pharmaceutical innovation and investment. Recognition of this has led to a number of positive developments, such as exemptions in Japan, the world's second largest pharmaceutical market for certain innovative medicines from the country's biennial price cuts.

More information regarding the impact of price controls and reductions, as well as the impact of healthcare reform in the US, can be found in the Principal risks and uncertainties section from page 96. The principal aspects of price regulation in our major markets are described further in the Geographical Review from page 70.

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

Over the last 30 years, investment in R&D in the US has increased from \$2 billion to \$45 billion a year, whereas approvals by the FDA have generally remained at 25-30 a year. Against this background, the research-based pharmaceutical industry is pursuing increased productivity to ensure a strong pipeline of commercially viable medicines for launch. The challenge now is greater than ever with the pursuit of newer, more challenging biological targets. In an attempt to increase the quality of candidates progressed through development, novel paradigms are being employed for less well-validated targets, while clinical 'proof of concept' is now the defining measure of success.

Organisationally, companies are addressing this challenge in a variety of ways. Some companies are employing Lean business improvement tools and/or shared risk operating models to bring potential drug candidates to the proof of concept milestone. Others have sought to increase output with limited incremental cost or restructured R&D functions to promote innovation and entrepreneurship. Some companies have acquired others with synergistic development pipelines.

#### **Regulatory requirements**

Pharmaceuticals is one of the most regulated industries. This reflects the public interest in safeguarding patients. While efforts to harmonise these regulations globally are increasing, their number and impact continue to grow, thereby raising the cost of doing business. Given the nature and geographic scope of our business, we maintain important interactions with many health authority regulatory bodies in numerous countries. In our largest markets, these bodies include the FDA in the US, and the European Commission and the EMA in the EU. Regulators are also continuing to apply a more systematic approach to safety assessment and to the management of known and emerging risks, both before and after a medicine is approved. At the same time, there is growing public demand for access to and transparency of data, especially clinical data, to understand the overall risk and benefit and the rationale for a health authority's decisions. While transparency and co-operation between health authorities today is becoming routine, this co-operation does not always lead to identical regulatory outcomes.

Clinical trials are being conducted across a number of countries and regions. This requires a comprehensive understanding of the differing regional determinants of safety, efficacy and clinical practice, as well as knowledge of local ethics, human subject protection and good clinical practice requirements. In order to support the registration of our products in a given regulatory jurisdiction, programmes providing foreign clinical trial data must meet the requirements of local health authorities to ensure relevance to their specific population.

Health authorities are also increasingly interested in the efficacy of pharmaceuticals after they have been approved, which can also result in additional regulations. This trend reflects the increasing pressures from both health technology assessors and payers to assess not only the safety of our products but also their relative effectiveness in the healthcare system.

#### Competition

Our main competitors are other research-based pharmaceutical companies that develop and sell innovative, patent-protected prescription medicines and vaccines, as well as smaller biotechnology and vaccine companies.

Generic versions of drugs are very competitive because 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 has traditionally occurred when patents expire, but can also occur where the validity of patents is being disputed or has been successfully challenged before expiry. Such early challenges by generics to patents on innovative products have increased and generic companies are increasingly willing to launch generic products 'at risk', in other words, prior to resolution of the relevant patent litigation. This can result in significant market presence for the generic equivalent of an innovative product during the period in which such patent litigation remains unresolved, even though the courts may subsequently rule that such product is properly protected by a valid patent. The unpredictable nature of such patent litigation has led innovators to seek to settle such challenges on terms acceptable to both innovator and generic manufacturer. However, some competition authorities have sought to challenge the scope or even availability of settlement agreements of this type.

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 than it is a small molecule medicine. However, some biologics are, or will become, subject to competition from 'biosimilars' as regulatory authorities in Europe and the US continue implementing abbreviated approvals processes for biosimilars. Acute coronary syndromes – or ACS – is a term used to describe sudden chest pain and other symptoms caused by an insufficient blood supply to the heart. They are the most common manifestation of coronary heart disease (CHD) with over 2.5 million occurrences in the developed world each year. Despite the availability of current treatment options, data suggests that up to 15% of patients die within one year of their cardiovascular event.

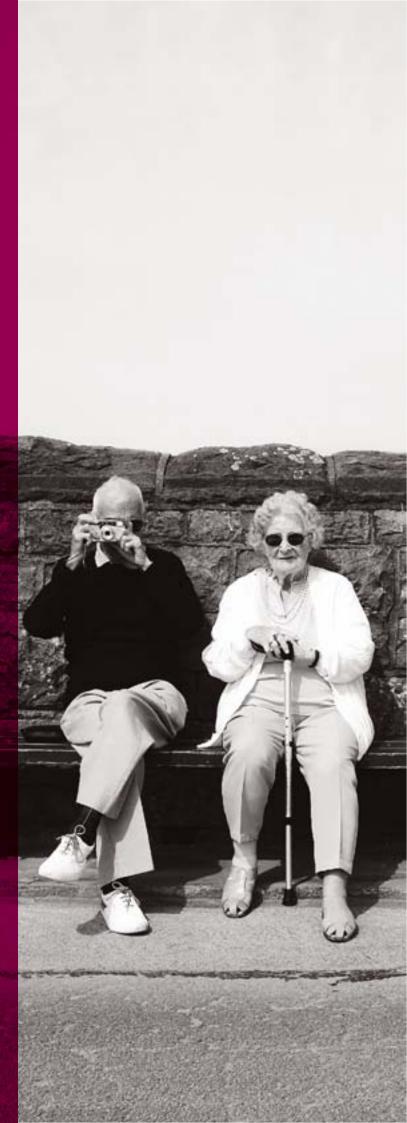
Brilinta/Brilique (ticagrelor tablets) is an oral antiplatelet treatment we have developed for ACS. The clinical development for Brilinta/Brilique included the PLATO study, one of the largest clinical trials we have ever undertaken, involving 18,624 patients in 43 countries. PLATO was designed to reflect current clinical management of ACS patients and to establish whether Brilinta/Brilique could improve cardiovascular outcomes beyond those afforded by clopidogrel (Plavix<sup>™</sup>/Iscover<sup>™</sup>). The overall PLATO results demonstrated the superiority of ticagrelor in reducing heart attacks and cardiovascular death in patients with ACS. The data has provided the basis for regulatory filings worldwide.

For more than half a century, AstraZeneca has been at the forefront of R&D in cardiovascular diseases. *Brilinta/Brilique* was discovered at our laboratories in the UK and represents another example of our commitment to developing and delivering innovative medicines that make a meaningful difference to patient health.

# Who can help me survive a heart attack?



Because health connects us all For more information go to the Therapy Area Review from page 50.



#### **Our Strategy and Performance**

#### **Our strategy**

Each year, at the beginning of our business planning cycle, we assess the challenges and opportunities presented by our marketplace, test our short- and long-term planning assumptions, and critically assess our capabilities as an organisation. We do so to assure ourselves that, whatever our past successes, the strategic path we are following is the right one. This section summarises our strategic plans for the future as well as our performance against our targets in 2010.

#### **Our vision**

The executive team, with the endorsement of the Board, believes that the most value-creating strategy for AstraZeneca is to be a focused, integrated, innovation-driven, 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 will continue to enable us to make acceptable levels of return 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, while remaining open to working with partners and outsourcing to capture operational efficiencies
- > innovation-driven in that we believe our technology base will continue to deliver innovative products that will benefit patients and for which payers will pay
- > global in that we believe we have the ability to meet healthcare needs in both established and emerging markets efficiently and effectively.

We believe that there are ongoing opportunities to create value for those who invest in pharmaceutical innovation, and that AstraZeneca has the skills and capabilities to take advantage of these opportunities and turn them into long-term value through the research, development and marketing of medicines that make a difference in healthcare. For us, this is the core of our responsibility to our stakeholders and society. Successful pharmaceutical innovation, delivered responsibly, brings benefits for patients, creates value for shareholders and contributes to the economic and social welfare of the communities we serve.

#### **Our business model**

Our business model is based on using the best innovative science and technology to invent or acquire, produce and distribute medicines that make a meaningful difference to people's health around the world. We span a broad range of therapeutic modalities, as well as primary and specialty care in a number of therapy areas, and are active in over 100 countries around the world. Our commitment to scientific innovation is coupled with our belief that success will require more external collaboration, including more collaboration with industry and academic partners.

The Life-cycle of a medicine overview on page 20 illustrates the value chain of discovery, development and commercialisation. It starts with the identification of unmet medical need and market opportunity, the search for a potential medicine, through clinical trials, regulatory submission, a medicine's launch and management of its life-cycle.

An inherent element of our business model is the creation, protection and subsequent sharing of intellectual property assets as shown below:

Creation and acquisition of intellectual property through innovative R&D

Application for patents to protect the intellectual property assets developed in a potential medicine

Clinical development programmes generating further innovations in the use of the potential medicine and intellectual property rights in the data required for regulatory submissions

Period of intellectual property protection for an innovative medicine which allows a return to be made on the investment undertaken

Expiry of intellectual property rights and commoditisation of knowledge which typically sees generic versions of a medicine entering a market A key goal for our planning process is to ensure that we can continue to sustain the cycle of successful innovation and, as a result, continue to refresh our portfolio of patented products – and so generate value for shareholders.

#### Our strategic priorities to 2014

We have identified the following medium-term strategic priorities as necessary to support the delivery of our strategic ambitions. They have confirmed our view that the pace of change across the business needs to accelerate if we are to be successful in meeting our goal of creating enduring value for shareholders by being one of the best-performing biopharmaceutical companies.

#### Pipeline

While we are confident that long-term growth in demand for innovative biopharmaceuticals will remain strong, it is clear that substantial improvement in R&D productivity is needed if we are to be certain of securing the targeted levels of return on the investment required to create shareholder value on a sustainable basis. To achieve that improvement, we intend to follow a more focused approach to R&D investment with the intention of improving the quality of R&D output and thereby increasing its returns. This focus involves a reduction in the number of disease area targets, consolidation onto a smaller number of sites and a reduction in headcount. It also involves investment in building industry-leading capabilities and accessing the best opportunities from outside our laboratories.

#### **Deliver the business**

Our enhanced programme of external collaboration in our R&D activities includes working with payers to build an industry-leading capability in payer partnering. In this way, when we develop our new medicines we will also develop the required health economics, cost/benefit information and 'value-in-use' data required by payers. This will help us gain global reimbursement, broad market access and optimal pricing for our medicines.

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 made in Emerging Markets. In addition to commercialising the current and new product offerings being developed internally, we will 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 continue to use business improvement programmes, such as Lean, 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 continue to make greater use of outsourcing and strategic collaborations with other organisations.

#### People and values

We recognise that talented, motivated and capable people are critical to the successful achievement of our strategic ambitions. As a result, we are focusing on building new critical capabilities, such as:

- > 'payer partnering' and personalised healthcare
- > further improving leadership and management capability
- > acquiring and retaining talent, for example in support of our growth plans in Emerging Markets
- > increasing the diversity of our talent pool, so that it better reflects our future business shape.

These priorities are underpinned by determined efforts to improve employee engagement and to build a high performance culture whose hallmarks are creativity, courage and collaboration.

A good reputation is critical to our business success. We therefore need to earn and maintain the trust of customers, partners and stakeholders if we are to deliver our strategy. This requires us to do things in the right way – to behave in accordance with our values and to act with integrity. We also need to connect with our stakeholders, including patients, doctors, regulators, governments and payers, if we are to understand their needs better and deliver on our commitment to improving patient health.

Our commitment to acting responsibly and to the sustainable development of our business underpins our work to implement our strategic priorities. To that end, our responsible business objectives are closely aligned to, and support delivery of, our business strategy. In the light of dialogue with stakeholders, we have reviewed and reshaped our corporate responsibility priority action plan during the year. We have put at the top of the agenda those areas most impacted by our business changes and which are therefore instrumental enablers of our business strategy. We will focus on sales and marketing practices, access to healthcare, research ethics (including animal welfare), human rights and supplier management. We will be maintaining focus on all other aspects of our corporate responsibility, such as patient safety and the environment.

#### Medium-term planning assumptions

When we announced our full year results for 2009, we set out a series of medium-term planning assumptions which we updated in January 2011. We continue to plan on the basis that revenue for the five years to 2014 will be in the range of \$28-\$34 billion a year, as revenue growth from key franchises that retain exclusivity and Emerging Markets is pressured by the loss of market exclusivity on a number of products. Our latest risk-adjusted view is that revenue contribution from recently launched products and the pipeline is in the range of \$3-\$5 billion.

Based on continued productivity improvements (including successful completion of restructuring initiatives), our planning assumption remains that Core operating margin, before investment in research and development (Core pre-R&D operating margin) will be in the range of 48% to 54% of revenue. These levels of revenue and margins would generate the requisite operating cash flow over the planning period to support the reinvestment needs of the business, debt service obligations and shareholder distributions. Over the planning period, we expect that between 40% and 50% of our pre-R&D post-tax cash flows will be reinvested in internal and external R&D and capital investments to drive future value and growth.

#### **Our Strategy and Performance**

#### Business objectives and key performance indicators

Within AstraZeneca, 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 objectives. Regular reviews are undertaken in order to monitor and assess progress against business and budget targets, and to assess key risks and mitigating actions. Quarterly reports provide the Board and the 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 setting our objectives we sought to ensure that they were aligned with our medium-term planning assumptions for the five years to 2014. For each of our objectives we have developed KPIs by which

# What drives the growth of our business?

See Our marketplace section from page 10.

### Expanding patient populations

**2** Unmet medical need

3

Advances in science and technology

### What challenges do we face?

See Our marketplace section from page 10.

#### **Pricing pressure**

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

### Tougher regulatory environment

Generic competition and patent expiry

### What do we want to achieve?

See Our strategic priorities to 2014 section on page 15.

#### **Financial**

Sustain annual revenues of \$28-\$34 billion

Sustain Core pre-R&D operating margins of 48%-54%

Reinvest 40%-50% of pre-R&D post-tax cash flows in R&D and capital investments

Achieve target return on invested capital

#### **Pipeline**

Average of two or more commercially valuable first approvals in major markets per year

40% of our pipeline sourced from outside our laboratories

#### **Deliver the business**

Grow market share of key brands that retain exclusivity

Successfully commercialise recent launches and the next wave

Sustain double digit sales growth in Emerging Markets

#### **Business shape**

Maintain gross margin in excess of 80%

Improve Sales and Marketing effectiveness and efficiency

Procurement savings across all functions Focus on working capital management

#### **People and values**

Achieve global high performing norm rating for employee engagement

Achieve a step change in our leadership and management capability

Ensure a culture of ethics and integrity is embedded in all business practices

we have measured our success in delivering our strategy. During the year we also sought to ensure that we managed the business appropriately both to optimise our opportunities and mitigate the risks we faced. The chart below illustrates this relationship and summarises our objectives for 2010. The Performance in 2010 section that follows sets out our performance against our KPIs during the year.

#### **Our KPIs**

See Performance in 2010 section on page 18.

> Revenue

- > Core pre-R&D operating profit/margin
- > Core EPS
- > Reinvestment rate
- > Cash flow

#### > Product approvals

- > Regulatory submissions
- > Phase III investment decisions
- > Licensing deals/acquisitions
- > Market share of key brands
- > Revenue from new product launches
- > Emerging Market sales growth
- > Gross margin
- > SG&A costs
- > R&D cost efficiency
- > Procurement savings
- > Employee engagement
- > Leadership communications
- > DJSI ranking
- > Sales and marketing breaches

### What might stop us from achieving our objectives?

See Risk section from page 94.

We face a diverse range of risks and uncertainties that may adversely affect any one or more parts of our business. Our approach to risk management is designed to encourage clear decision making as to which risks we take as a business and how we manage those risks, in each case informed by an understanding of the commercial, financial, compliance, legal and reputational implications of these risks.

**Corporate Governance** 

**Business Review** 

#### Performance in 2010

#### Financial

#### Overall strong financial performance. Exceeded targets for revenue, Core EPS and cash flow

- > Global revenue was unchanged at CER at \$33.3 billion. This was ahead of target primarily as a result of strong operational performance, delayed generic entry and less generic erosion across the US and Europe than assumed in our targets.
- > Core pre-R&D operating margin was 53.5%, near the top end of the medium-term planning assumption range of 48% to 54%.
- > Core EPS increased by 5% at CER to \$6.71. This was ahead of target as a result of the above revenue performance and strong operational execution.
- > Reinvestment rate was just below the medium-term planning assumption range of 40% to 50% due to the better than expected pre-R&D post-tax cash flows. AstraZeneca continues to expect this range to hold over the planning period although anticipates variances within any particular year.
- > Net cash inflow before financing activities of \$8,340 million reflects the strong business performance.

See Financial Review from page 78 for more information.

#### **Pipeline**

#### Achieved major market approvals for *Vimovo* and *Brilique*; made submissions for dapagliflozin and *Zinforo*, but disappointments on other pipeline products

- > Vimovo approved in the US and the EU; Brilique approved in the EU with Complete Response Letter received for Brilinta in the US; Kombiglyze™ XR (Onglyza™/metformin combination) approved in the US; additional indications approved for Crestor in the US and the EU and for Seroquel XR in the EU; decisions made in December to discontinue development of motavizumab and Certriad.
- > Dapagliflozin and vandetanib NDAs submitted in the US and the EU; Zinforo and Axanum MAAs submitted in the EU; Recentin trials data did not support regulatory submissions; no submissions planned for zibotentan.
- > Completed deal with Rigel for the development of fostamatinib.
- > Phase III trials started for fostamatinib and TC-5214.

See Therapy Area Review from page 50 for more information.

#### **Deliver the business**

#### Global revenue was unchanged at \$33.3 billion

- > Strong double-digit sales growth for Crestor, Symbicort and Seroquel XR. Annual Crestor and Seroquel sales exceeded \$5 billion each.
- > Launches under way and planned for *Brilinta/Brilique*, *Vimovo* and Kombiglyze™ XR.
- > Achieved target of double-digit growth in Emerging Markets with revenues over \$5.1 billion, a 16% increase over 2009.

See Financial Review from page 78 and Therapy Area Review from page 50 for more information.

#### **Business shape**

#### Achieved or exceeded targets

- > Core gross margin of 81.2% slightly ahead of 80% target.
- > Achieved planned improvement in Core SG&A costs with 2% reduction.
- > Achieved Core R&D efficiency savings with spend of \$4.2 billion.
- > Achieved \$541 million of procurement savings against a target of \$500 million.
- See Financial Review from page 78 for more information.

#### **People and values**

Improvement in senior leader communications, but slight decline in employee engagement. Continued focus on application of Code of Conduct

- > Employee engagement score as measured by our global employee survey (FOCUS) reduced from 84% in 2009 to 83% in 2010.
- > Improvement of 4% in senior leader communications measure in 2010 over 2009 as measured by FOCUS.
- > Maintained position in the DJSI World Index (the top 10% of the largest 2,500 companies) as sustainability leader, as well as listing on the DJSI STOXX European Index.
- > 11 confirmed breaches of external sales and marketing regulations or codes globally (2009: 24).

See People section from page 36 and Responsible Business section from page 40 for more information.

Research tells us that many patients prescribed drugs do not take their medicine as they should – whether the right amount, at the right time or in the right way. The position is worst for inhaled medicines, which include some of our asthma medicines. Research also tells us that we can use packaging – which is usually our only way of communicating directly with patients – to improve adherence to a medicine's instructions.

The opportunity for AstraZeneca to use packaging design to influence behaviour is being pursued through a range of initiatives. These include customising packaging to address patient needs better and making the pack part of the treatment. At the same time we are simplifying processes where possible and aim to improve the efficiency with which we use packaging materials by 20% by 2015.

One example of our work is the packaging for our children's asthma inhalers in Spain, which now features an image of a kite – associated with fresh air and physical activity – to help children feel more positive about taking their medicine.

Better packaging can help make our medicines more effective. That helps us and our patients, and improves treatment outcomes.

# What will help me take my medicine?





Because health connects us all For more information go to the Supply and <u>Manufacturing</u> section from page 34.

#### **Our Strategy and Performance**

#### Life-cycle of a medicine

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

### 3

#### **Phase I studies**

Studies typically in small groups of healthy human volunteers or, in certain cases, patients, to understand how the potential medicine is absorbed in the body, distributed around it and excreted; also determine an appropriate dosage and identify side effects

Begin to develop manufacturing route to ensure the manufacturing process is robust and costs are minimised

May involve external clinicians and organisations in the design and running of these studies

### 5

#### Phase III studies

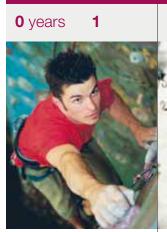
Studies in a larger group of patients to gather information about effectiveness and safety of the medicine and evaluate the overall risk/benefit profile

Create appropriate branding for the new medicine in preparation for its launch

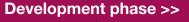
At any stage of the development process the medicine may have been acquired from a collaborating company. The collaborator may remain involved in the future development and commercialisation of the medicine

9

#### Discovery phase >>







4



#### **1** Find potential medicine

Identify the unmet medical need and market opportunity, and undertake laboratory research to find a potential medicine that should be potent, selective and absorbed into and well tolerated by the body

Begin the process of seeking patent protection for the potential medicine

Collaborate with academia and external clinicians to access the best external science and medical opinion

#### 2 Safety and initial efficacy studies

Undertake studies in the laboratory and in animals to understand if the potential medicine should be safe to introduce into humans and in what quantities

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

Regulatory authorities are informed of proposed trials which are then conducted within the framework of the regulations

#### 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 submission**

Seek approval from regulatory authorities to manufacture, market and sell the medicine

Submit package of clinical data which demonstrates the safety profile and efficacy of the medicine to the regulatory authorities

Regulatory authorities decide whether to grant marketing authorisation based on the medicine's safety profile, effectiveness and quality

Large numbers of national, regional and local payers grant approval for the pricing and/or reimbursement of the medicine

#### Launch new medicine

Raise awareness of patient benefit and appropriate use

Market and sell medicine; continuously monitor, record and analyse reported side effects; review need to update the side effect warnings to ensure that patients' wellbeing is maintained

Clinicians begin to prescribe medicine and patients begin to benefit

12

### 9

#### Life-cycle management

Broaden understanding of the full potential of the medicine

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

Submit data packages with requests for line extensions

Regulatory authorities review the data to assess the risk/benefit of using the medicine in the new disease or population and issue a decision

#### Post launch: delivering to patients >>





### 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

Sponsors and regulatory authorities monitor the safety of medicines postapproval and update the prescribing information as necessary

### **10** Patent expiry

Typically, when patents protecting the medicine expire, generic versions of the medicine may enter the market





# How can I help manage my asthma?

Approximately 300 million people worldwide suffer from asthma. It is one of the most common chronic diseases and its prevalence is increasing every year, especially among children. It is estimated that by 2025 there will be an additional 100 million sufferers.

Although asthma cannot be cured, it can be treated effectively. Research shows that with the right treatment nearly all asthma patients can achieve and maintain good asthma control, enabling them to live full and active lives.

Our *Symbicort* medicine provides important improvement in the health of many patients with asthma. *Symbicort* pMDI (pressurised metered-dose inhaler) is approved in the US for the treatment of asthma in patients 12 years of age and older.

Outside the US, our *Symbicort Turbuhaler* maintenance and reliever therapy (SMART) combines both regular maintenance and as-needed reliever therapies. It is the only asthma treatment regime to do so and allows patients to control daily symptoms and reduce the severity and number of asthma attacks using a single inhaler. It gives asthma patients what they want in daily symptom control and also gives them what they need in the longer term – improved asthma management.



Because health connects us all For more information go to the Therapy Area Review from page 50.

# How will we deliver our strategy? We need the following resources, skills and capabilities in place to achieve our long-term goals:

## An R&D function with world-class productivity

focused on delivering a range of innovative, differentiated and commercially attractive medicines through collaboration, and underpinned by patent and intellectual property rights. See page 26

# **2** A sales and marketing activity undertaken in the right way

and focused on our customers and their patients' needs. See page 32

# **3** A reliable supply and manufacturing operation

that ensures our customers and patients receive their medicines when they want and need them. See page 34

## **A diverse and talented** workforce

with the right skills, in the right place at the right time. See page 36

# **5** A commitment to responsible development of our business

which delivers value for our shareholders and for our other stakeholders. See page 40

#### Business review

This section includes information that fulfills the requirements of a business review under the Companies Act 2006. The Our Strategy and Performance, Corporate Governance, Development Pipeline, Shareholder Information and Corporate Information sections from pages 10, 94, 206, 211 and 216, respectively, are incorporated into this section.

Details of the more significant risks to AstraZeneca are set out in the Principal risks and uncertainties section from page 96.

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 178.

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 217 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 section.

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 2010.

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

## **Research and Development** Focused on delivering innovative and valued medicines

6

Focus on six areas of healthcare

92

92 projects in clinical development, including 9 in Phase III or under regulatory review. 34 withdrawn during the year



Core investment of \$4.2 billion in our R&D organisation



"...we are creating an environment that allows our scientists to drive innovation and collaborate successfully with internal and external partners to bring forward valued new medicines"

Martin Mackay President, Global R&D We are committed to using the best science and technology to invent and acquire, produce and distribute innovative medicines that make a meaningful difference to people's health around the world. This commitment is matched by our recognition that a substantial improvement in R&D productivity is needed if we are to be certain of securing targeted levels of return on our investment.

We are transforming our single R&D organisation to meet this challenge. By appointing new world-class leaders and confirming the best internal people in leadership positions, we are creating an environment that allows our scientists to drive innovation and collaborate successfully with internal and external partners to bring forward valued new medicines. Our strategy for change comprises the following elements:

- > prioritising our resources in those areas where we believe we
- can be most successful through a focused disease area strategy > ensuring shareholders' funds are invested wisely, using an
- effective and flexible R&D operating model
- > building the capabilities we need to ensure delivery of our strategy
- > ensuring we access the best new opportunities, regardless of their origin.

#### **Disease area focus**

We are prioritising our resources and focusing our internal discovery activities on those diseases within our existing therapy areas where we believe there is the greatest potential. This process of prioritisation is designed to ensure that, as we look ahead, the projects we have in our pipeline constitute the programmes which we believe are most likely to deliver technical and commercial success. The Disease areas table opposite indicates where we will be focusing our activities within our therapy areas. It also indicates those areas that we consider to be less attractive and where we will be decreasing our discovery investment or exiting an area altogether.

While we will be exiting in-house discovery research in some disease areas, we will continue to look at new therapeutic areas via externalisation, ensuring that we optimise our own assets and look at in-licensing or acquiring opportunities where we believe there is further value.

#### **Disease areas**

	High attractiveness	Medium attractiveness	Low attractiveness	Overview
Cardiovascular/ Gastrointestinal	> Diabetes 'glucose plus' metabolism	<ul> <li>&gt; Obesity</li> <li>&gt; Atherosclerotic cardiovascular disease</li> <li>&gt; Haemophilia/bleeding disorders</li> <li>&gt; Diabetes complications (including nephropathy)</li> <li>&gt; Atrial fibrillation conversion/maintenance</li> </ul>	> Reflux > Thrombosis	2
Oncology	> Breast cancer > Lung cancer	<ul> <li>&gt; Hepatocellular cancer</li> <li>&gt; Gastric cancer</li> <li>&gt; Prostate cancer</li> <li>&gt; Haematological cancers</li> <li>&gt; Colorectal cancer</li> </ul>	> Ovarian cancer > Bladder cancer	Busi
Respiratory &         Inflammation         > Systemic Lupus         Erythematosus (SLE)         (biologics)    Neuroscience > Alzheimer's disease modification > Neuropathic pain		<ul> <li>&gt; Rheumatoid arthritis (biologics)</li> <li>&gt; Severe asthma</li> <li>&gt; Chronic obstructive pulmonary disease (COPD)</li> </ul>	> Systemic scleroderma	Business Review
		> Nociceptive pain > Cognition	> Schizophrenia/bipolar > Depression > Anxiety	
Infection	> Resistant bacterial infections	> Respiratory syncytial virus (RSV) treatment/vaccine > Influenza	> Other vaccines > Hepatitis C	Corporate Governance
narrower portfolio. Our air	e projects we are working on m has been to ensure we put believe are most likely to be s	our effort which focus on particular disease are		àovernance

We have also reviewed the projects we are working on within this narrower portfolio. Our aim has been to ensure we put our effort behind those projects we believe are most likely to be successful. Our measure is not the number of candidate medicines, it is the number of de-risked, value adding, proof of concept medicines, that is where there is evidence that gives us a high degree of confidence of success. Our focus is on identifying and resourcing key projects that have the potential to deliver a differentiated, commercially attractive medicine to patients in the first wave for any given mechanism.

Our pipeline includes 92<sup>1</sup> projects in the clinical phase of development. As shown in the Development projects chart overleaf, we now have a total of 34 projects in Phase I, 32 projects in Phase II, 9 projects in late stage development, either in Phase III or under regulatory review, and we are running 17 significant life-cycle management projects. During 2010, across the clinical portfolio, 24 projects have successfully progressed to their next phase (including 14 projects entering first human testing); 34 projects have been withdrawn. Further details are set out in the Therapy Area Review from page 50 and in the Development Pipeline table from page 206.

#### **Operating model**

As demonstrated by the Life-cycle of a medicine overview on page 20, our R&D activities span the entire life-cycle of a medicine. To help our focus on quality and reimbursable medicines, we have created a new organisational structure which brings together drug discoverers and developers to focus and collaborate in specific disease areas. The operating model we have adopted is shown on page 29 and comprises the following key elements:

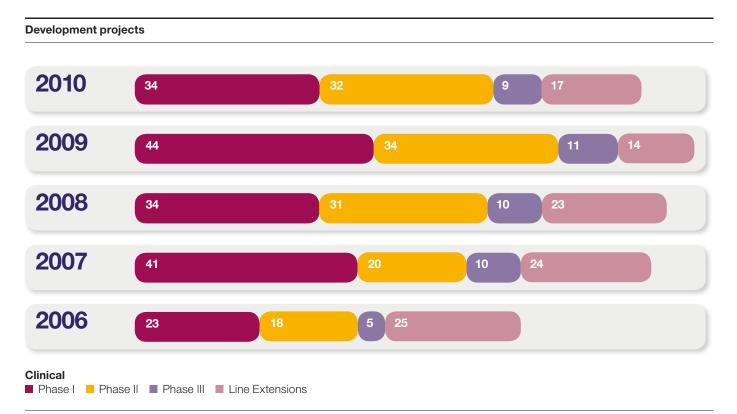
<sup>1</sup> Includes seven life-cycle management projects re-introduced from BRIC-MT and Japan.

> Small molecule iMeds

- > Oncology
- > Infection
- > Respiratory & Inflammation
- > Aligned small molecule and biologics iMeds
  - > Cardiovascular and Gastrointestinal
  - > Neuroscience
- > Biologics iMeds
  - > Oncology
  - > Infection
  - > Respiratory & Inflammation
- > A ninth, New Opportunities iMed, will focus on identifying opportunities in disease areas outside, or complementary to, our current research areas. This will be done by seeking to acquire commercially viable late stage assets as well as by generating additional value from existing internal assets through alternative uses of such assets in disease areas of high unmet medical need.

All iMeds are responsible for sourcing innovation from both inside and outside AstraZeneca and are accountable for delivering de-risked, differentiated proof of concept potential medicines to Global Medicines Development that target the right area and show a medical benefit for patients.

#### **Delivering our strategy**



#### Global Medicines Development (GMD): Later stage

development is undertaken by GMD. It provides a single, global platform dedicated to conducting trials for small molecules and biologics of the highest quality. It is accountable for delivering the regulatory packages in support of new medicine launches that are commercially attractive and reimbursable.

**Operation and governance**: A key strength of our new R&D organisation is that it facilitates a more entrepreneurial climate, increases the transparency of risk and drives stronger links between early discovery activities and Phase II studies. This is complemented by rigorous oversight of Phase IIa/IIb studies to the launch of a new medicine and beyond. The Portfolio Investment Board (PIB) evaluates projects to help ensure AstraZeneca is developing the kind of medicines that will make a difference for patients and return shareholder value. The PIB provides the necessary focus for our R&D investment and provides appropriate oversight of investment opportunities across disease areas and modalities. It is also charged with delivering a pipeline of products capable of generating attractive returns on invested capital. Further information about the PIB can be found in the Corporate Governance Report section from page 109.

#### Investing in capabilities

The success of our R&D transformation rests in part on building industry leading capabilities to bring more valued and reimbursable medicines to market. In 2010, we announced an investment of more than \$200 million over five years to develop the tools and people to help us reshape R&D performance. This investment supports scientific collaborations, development of existing staff, recruitment of new talent and provision of new infrastructure, including informatics platforms. We are making steady progress across all these areas.

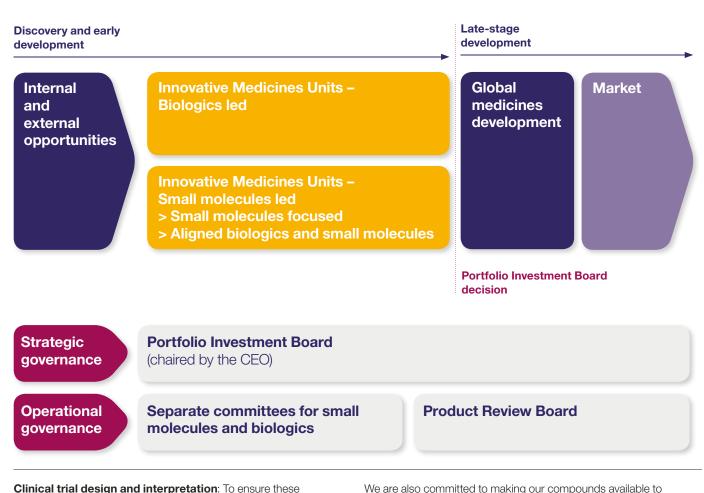
**Payer considerations**: Our R&D and Commercial organisations are working together to deliver the best global reimbursement dossier for our medicines. Within GMD, we are building a Payer Evidence Group that supports both Commercial and R&D. In 2010, as part of our strategy to be an industry leader in demonstrating the value of medicines to payers, AstraZeneca signed a collaboration agreement with HealthCore, which maintains the largest commercially insured population data environment in the US. The collaboration enables us to significantly upscale our 'real world' studies of the key health outcomes that are increasingly important to payers. Additionally, through our membership in the European Healthcare Leadership Network, we are working with payers and other external stakeholders to define early on the basis for demonstrating value. An AstraZeneca diabetes drug in Phase I is the focus of one of the first pilots.

**Personalised healthcare**: Identifying patients most likely to benefit from our medicines is the goal of the newly formed Personalised Healthcare and Biomarker function. This group supports internal biomarker development and has established vital strategic alliances with external diagnostic companies to support our drug projects. We now have 25% of our clinical development portfolio progressing personalised healthcare strategies.

**Predictive science**: We are integrating modelling and simulation into many different aspects of R&D. Examples include safety screening models that enable rapid assessment of common toxicities and *in silico* modelling of human exposure which has guided the design of antibodies with differentiated properties and subsequently informed their clinical development.

**New therapeutic modalities:** In 2010, we continued to make significant investments in new biologics technologies to generate novel and highly differentiated biologic therapeutics. For example, in neurology, we have engineered a human protease to effectively degrade beta amyloid, which holds great potential for treating Alzheimer's disease. We have also entered into external collaborations to develop new approaches in the areas of small interfering ribonucleic acids (siRNAs) and regenerative medicine.

# Overview



**Clinical trial design and interpretation**: To ensure these capabilities are firmly integrated into our drug development programmes and that we realise the benefits of clear clinical decisions, we have also invested to improve the quality of our design capability for clinical trials.

**Culture**: We are progressing an integrated programme to drive cultural change throughout the R&D organisation. A significant first step was the appointment of new leadership teams, together with an evolution of our business systems to facilitate a move towards a more innovative, collaborative and creative culture.

#### **External focus**

**R&D** operating model

We intend to increase our externalisation efforts to access the best, most cutting-edge science, whatever its origin, with a target of 40% of our pipeline sourced from outside our laboratories by 2014. By bringing together the best minds to address medical problems, we aim to facilitate ground-breaking discoveries, either within our organisation or through a public or private partnership focused on the problem. As part of this approach, we are involved in the Innovative Medicines Initiative (IMI) which brings together the European pharmaceutical industry and the European Commission with the aim of improving the tools, technologies, methodologies and knowledge management to bring new medicines to market. Over the next 10 years, IMI participants have pledged a total of \$2.7 billion, half from the private sector and half from the public sector. We are also committed to making our compounds available to organisations pursuing new therapies. In a collaboration with the UK's Medical Research Council, we are sharing access to our compound libraries to aid the search for potential new treatments for serious diseases.

In all our collaborations, we recognise that 'one size does not fit all'. We seek to partner and collaborate in novel ways that maximise not only the collective scientific knowledge of all participants, but also the unique knowledge that each partner brings to the process, including in Emerging Markets. It is this approach that underpins our exclusive worldwide licence agreement with Rigel for the global development and commercialisation of fostamatinib (formerly known as R788), Rigel's late-stage investigational product for rheumatoid arthritis, and our collaboration with Dainippon Sumitomo for a potential asthma treatment.

#### **Our resources**

At the end of 2010, we had a global R&D organisation with approximately 15,700 people (12,400 full time equivalent employees) at 14 principal centres in eight countries.

As communicated last year, our plans for transforming R&D include a number of site changes which will result in a simplified site footprint with a clear role for each facility. These changes will affect approximately 3,500 employees, with a net reduction of 1,800 positions. In the UK, we have exited R&D activities in Avlon, KuDOS and Arrow Therapeutics, and we will exit all R&D activities in our Charnwood site during 2011. In North America, we have exited all

#### **Delivering our strategy**

pharmaceutical development activities from Newark, Delaware, and all drug discovery activities at Wilmington, Delaware. In January 2011, we signed an agreement to sell our site in Lund, Sweden, and we are on track to exit this site during 2011.

A number of our remaining sites will grow to accommodate activities from the sites we are closing. These sites include our main small molecule facilities in the UK (Alderley Park and Macclesfield); Sweden (Mölndal) and the US (Waltham, Massachusetts). Other sites that have a focus on research are in Sweden (Södertälje), Canada (Montreal, Quebec) and France (Reims). 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 own research capabilities in Asia Pacific which include our 'Innovation Centre China' research facility in Shanghai and our research facility in Bangalore, India.

In 2010, there was Core investment of \$4.2 billion in our R&D organisation (2009: \$4.3 billion; 2008: \$5 billion). In addition, \$1,017 million was spent on acquiring product rights (such as in-licensing) (2009: \$764 million; 2008: \$2,743 million) and we invested around \$284 million on the implementation of the R&D strategy and enhancing capabilities in the US. A further \$283 million was approved during the year to further the support for the R&D strategy by facilitating the consolidation of resources at key locations and developing IT platforms.

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

We recognise our responsibility to ensure that we underpin our continued drive for R&D excellence with sound ethical practice worldwide. We want to be recognised for our high quality science and for the impact we can make on serious diseases. We also want to continue to be trusted. This means setting and living up to high standards of ethical practice across all aspects of our research activity worldwide.

You can read more about our standards of ethical practice and 2010 performance in the Responsible Business section from page 40.

## Intellectual Property

### Protecting ownership of our inventions



"The principal economic safeguard in our industry is a well-functioning patent system that recognises our effort and rewards our innovation with appropriate protection"

#### Jeff Pott

General Counsel

The discovery and development of a new medicine requires a significant investment of resources by research-based 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 being copied with a reasonable amount of certainty for a reasonable period of time.

The principal economic safeguard in our industry is a wellfunctioning patent system that recognises our effort and rewards our innovation with appropriate protection, allowing time to generate the revenue we need to reinvest in new pharmaceutical innovation. We have confidence in our inventions and commit significant resources both to establishing and defending the patent and related intellectual property protections for these inventions.

#### Patent process

Applications for patent protection are filed on our inventions to safeguard the large subsequent investment required to get potential new drugs approved for marketing. Further innovation means that we may seek additional patent protection as we develop a product and its uses. We apply for patents via 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 application 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 178.

#### Patent expiries for our key marketed products

				US	revenue (\$m)	
Key marketed products*#		US Patent expiry		2010	2009	2008
Nexium		20151		2,695	2,835	3,101
Crestor		2016		2,640	2,100	1,678
Toprol-XL/Seloken		Expired		689	964	295
Atacand		2012		216	263	262
Symbicort		2014 (combination), 2023 (i	formulation), 2026 (pMDI device)	721	488	255
Pulmicort/Pulmicort Respu	lles	2019 <sup>2</sup> (Respules), 2018 (Tu 2019 (Turbuhaler device)	rbuhaler formulation),	305	804	982
Arimidex		Expired		494	878	754
Zoladex		Expired		46	54	72
Seroquel IR		2012		3,107	3,074	2,895
Seroquel XR		2017 (formulation)		640	342	120
Synagis		2015 (composition), 2023 (i	formulation)	646	782	923
Prilosec/Losec		Expired		47	64	171
Merrem/Meronem		Expired		127	177	207
Casodex		Expired		16	148	292
					evenue (\$m) <sup>3</sup>	
Key marketed products*#	EU Patent expiry	Canadian Patent expiry	Japanese Patent expiry	2010	2009	2008
Nexium	2014	2014	2014	1,422	1,395	1,387
Crestor	2017	2012	2017	2,201	1,782	1,410
Toprol-XL/Seloken	Expired	Expired	Expired	169	181	220
Atacand	2010 to 2014 depending on country	2011	2014	837	808	836
Symbicort	2018 (formulation) 2019 (Turbuhaler device)	2012 (combination) 2018 (formulation) 2019 (Turbuhaler device)	2017 (combination) 2018 (formulation) 2019 (Turbuhaler device)	1,621	1,459	1,420
Pulmicort/ Pulmicort Respules	2018 (Respules) 2018 (Turbuhaler formulation) 2022 (pMDI device)	2018 (Respules) 2018 (Turbuhaler formulation)	2018 (Respules) 2018 (Turbuhaler formulation) 2022 (pMDI device)	353	347	364
Arimidex	2011	2012	2012	843	875	930
Zoladex	Expired	Expired	Expired	718	744	775
Seroquel IR	2012	Expired	2012	705	792	1,009
Seroquel XR	2017 (formulation)	2017 (formulation)	N/A	401	301	90
Synagis	2015 (composition)	2015 (composition)	2015 (composition)	392	300	307
Prilosec/Losec	Expired	Expired	Expired	660	641	619
Merrem/Meronem	Expired	Expired	Expired	377	409	387
Casodex	Expired	Expired	Expired	457	588	838

\* Patents are or may be challenged by third parties and generics may be launched 'at risk'. See the Principal risks and uncertainties section from page 96. Many of our products are subject to

challenges by third parties. Details of material challenges by third parties can be found in Note 25 to the Financial Statements from page 178. Additional patents relating to the stated products may have terms extending beyond the quoted dates.

Licence agreements with Teva and Ranbaxy Pharmaceuticals Inc. 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.
<sup>3</sup> Aggregate revenue for the EU, Canada and Japan.

The generic industry is increasingly challenging innovators' patents at earlier stages 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 risks relating to patent litigation and early loss and expiry of patents is contained in the Principal risks and uncertainties section from page 96.

#### **Data exclusivity**

Regulatory Data Protection (RDP or 'data exclusivity') is an important intellectual property right which arises in respect of data which is required to be submitted to regulatory authorities in order to obtain marketing approvals for our medicines. Significant investment is required to generate such data (for example, through conducting global clinical trials); and the use of this proprietary data is protected from use by third parties (such as generic manufacturers) for a number of years in a limited number of countries. The period of such protection and the extent to which the right is respected differs significantly between these countries. We believe in enforcing our rights to

RDP and consider it an important protection for our inventions, particularly as patent rights are increasingly being 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 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 tables above set out certain patent expiry dates and sales for our key marketed products. The 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.

## Sales and Marketing Reinforcing our leading positions and investing in new regions

100
Active in over 100 countries
1000
Portfolio of more than 100 generic products being licensed across 30 Emerging Markets for marketing under the AstraZeneca brand

\$5bn

Annual Crestor and Seroquel sales exceeded \$5 billion each



"All our work is underpinned by a strong set of global standards which build on our Code of Conduct and our planned new Global Policy on External Interactions"

#### Tony Zook

Executive Vice-President, Global Commercial Operations

Our global marketing and sales operations organisation is active in over 100 countries. As well as building on our leading positions in the US and Other Established Markets, such as Canada, 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 217 for more information on AstraZeneca's market definitions.

We work to ensure success in individual markets by having highly accountable local leaders who understand their markets and have a strong focus on profitable business growth. They are supported by a single global Commercial organisation that develops global product strategies, leverages best practice and drives synergies. It also ensures a strong customer focus and commercial direction in the management of our pipeline and marketed products. All our work is underpinned by a strong set of global standards which build on our Code of Conduct and our planned new Global Policy on External Interactions. For more information on this Policy, see the Sales and marketing ethics section on page 43.

#### **Driving commercial success**

Delivering commercial success requires us to be able to maximise the value of our portfolio across the whole life-cycle of a medicine, from early in a product's R&D phase to maximising the earnings from our more mature medicines.

At an early stage in the medicine discovery process we define what we believe the profile of a medicine needs to be, in order to work most effectively in combating a particular disease. These disease target product profiles 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. They help shape our therapy area and marketing strategies. More information on payer considerations can be found in the Investing in capabilities section from page 28. Activities in 2010 focused on ensuring continued commercial excellence through growing the market share of our key products that retain market exclusivity, such as *Crestor, Seroquel XR* and *Symbicort.* In addition, we must ensure that we successfully commercialise recently launched medicines, such as Onglyza<sup>™</sup> and *Vimovo*, or prepare for the launch of the next wave of medicines, such as *Brilique/Brilinta*. At the same time we do not lose sight of the need to optimise the value of our mature medicines and drive their growth in new markets. For example, in 2010 we signed an agreement with Daiichi Sankyo for the co-promotion and supply in Japan of *Nexium*, which is already approved in more than 120 countries. Under this agreement, we will develop and manufacture the product, Daiichi Sankyo will be responsible for its distribution and both parties will promote it after it is approved for use.

#### Global strategies tailored to meet local needs

All our markets have an important role to play in delivering our commercial strategy. They are the base from which we drive growth and achieve business performance, while both ensuring that costs remain under control and our capabilities are strengthened. Nevertheless, we need to prioritise our investment in markets to ensure we allocate resources in the most cost-effective way. We did so in 2010 according to criteria such as market size and growth, risk profile, our current position in a market and its commercial relevance. This allows us to identify those markets of major significance to us, those that will become important drivers of our business in the future and those Established Markets where we need to change our approach to deliver sustained success. We are supporting our work in these markets with investment in the capabilities necessary to deliver our business objectives.

#### **Emerging markets**

It has been estimated that emerging markets will contribute around 70% of pharmaceutical industry growth in the next five years, and branded generics represent approximately 50% by value in them. We are continuing our programme of investment in large emerging markets such as China, Mexico, Brazil and Russia as well as high growth, medium-sized and smaller markets.

To maximise our opportunities, we are launching a range of branded genericised medicines. This range will comprise a complementary portfolio of differentiated products that will be promoted alongside our patented original medicines in markets where we already have a developed commercial infrastructure, existing relationships with healthcare professionals and a strong reputation. In 2010, we continued the programme of launches we began in India in 2009 and launched a generic anti-infective medicine in a number of markets. In addition, we have identified a portfolio of more than 100 generic products which we are currently licensing across 30 Emerging Markets for marketing under the AstraZeneca brand. To help us license these dossiers and source the molecules, we are working with a number of companies in India who work to our rigorous quality and process standards. This includes an agreement with Torrent to supply us with a portfolio of generic medicines for which Torrent already has licences in a range of countries. Internally, we have created a dedicated cross-functional team to support our branded generics business.

#### **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 is appropriate, given that the external environment is placing significant downward pressure on drug 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, to those who pay for healthcare and to 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.

Meeting the needs of payers is an increasingly important requirement for us. In order to develop products that meet those needs, we are focusing even more on understanding the priorities and requirements of both payers and healthcare providers. Building on this information we can then demonstrate to our customers how our products offer value and support cost-effective healthcare delivery. 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 lower healthcare costs by reducing the need for more expensive care, such as hospital stays or surgery, or through preventing patients from developing more serious or debilitating diseases that are costly to treat. They also contribute to increased productivity by reducing or preventing the incidence of diseases that keep people away from work.

We continually review our range of medicines (both those on the market and in the pipeline) to identify areas where they may meet a particularly critical healthcare need but where for a number of reasons patient access may be challenging. Such critical healthcare needs may be either where our medicines treat diseases that are (or are becoming) prevalent in developing countries, or where they are potentially a leading or unique therapy addressing an unmet medical need and offering significant patient benefit in treating a serious or life-threatening condition. In such cases, where appropriate, we aim to provide patient access to these medicines through expanded patient access programmes. Examples of such programmes exist worldwide. 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.

#### An effective sales force

We sell our medicines in more than 100 countries around the world. Most of our sales are made through wholly-owned local marketing companies. Elsewhere, we sell through distributors or local representative offices. Our products are marketed primarily to doctors (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 the traditional marketing method and our efforts are focused on making this channel as effective and efficient as possible with the use of telephone sales teams and dedicated customer service staff. Increasingly, our sales force is 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.

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.

#### Sales and marketing ethics

The pharmaceutical sector is subject to increased oversight by regulators, competition and other authorities. As we drive the growth of our business and reshape our geographic footprint, we remain committed to the responsible delivery of commercial success. You can read more about our standards of ethical practice and 2010 performance in the Responsible Business section from page 40.

## Supply and Manufacturing Maximising efficiency for the reliable provision of high quality medicines

23

23 manufacturing sites in 16 countries

23

23 inspections from 13 different regulatory authorities



Capital expenditure on supply and manufacturing facilities totalled approximately \$333 million



"Key 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 cost-effective way"

#### **David Smith**

Executive Vice-President, Global Operations and Information Services

Our strategy is to balance in-house manufacturing in efficient plants with external manufacturing capabilities, particularly in relation to the early stages of our production process. As discussed in the Sales and Marketing section above, we also see opportunities to use outsourced production in our branded generics business. This balance is designed to give us product integrity and quality assurance while affording us cost efficiency and volume flexibility.

#### **Continuous improvement**

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 what eliminates waste. This programme has delivered significant benefits in recent years, including reduced manufacturing lead times and lower stock levels, both of which 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 are now applying them to the whole of our supply chain. In 2010, we reinforced our commitment to creating a Lean supply and manufacturing organisation with a global campaign to recruit more Lean experts into our manufacturing sites and supply chain functions. This has included the creation of a new global centre of excellence comprising Lean experts from a broad range of industrial backgrounds to provide support and co-ordination to the accelerated development of our Lean supply system. This enables us to learn from other industries how to operate our supply chains at a much higher performance level than is generally found in the pharmaceutical sector.

The inauguration of a new regional packing centre in Wuxi, China in 2010 was a key milestone. We operate this centre to our global standards and apply a broad range of Lean techniques and principles. We believe it will improve our competitiveness in Asian markets.

#### **Product quality**

We are committed to delivering product quality that underpins both the safety and efficacy of our medicines. We have a comprehensive quality management system in place designed to assure the quality of our products and regulatory compliance.







## What is being done to make sure my medicines are genuine?

 Because health connects us all
 For more information on our work to prevent and detect counterfeiting, go to our website, astrazeneca.com/responsibility.

Manufacturing facilities and processes for medicines must observe rigorous standards of quality and are subject to inspections by regulatory authorities to ensure compliance with prescribed standards. Authorities have the power to require changes and improvements to facilities and processes, to halt production and impose conditions that must be satisfied before production can resume. Regulatory standards are not harmonised globally and do change over time.

We hosted 23 inspections from 13 different regulatory authorities in 2010. All observations from such inspections 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 providing input into 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**

Capital expenditure on Supply and Manufacturing facilities totalled approximately \$333 million in 2010 (2009: \$360 million; 2008: \$369 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.

At the end of 2010, approximately 9,300 people at 23 sites in 16 countries were working on the manufacturing and supply of our products. Approximately 8,350 people work in formulation and packaging and 350 people work in active pharmaceutical ingredient (API) supply. 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); Australia (North Ryde); China (Wuxi); Puerto Rico (Canovanas); Germany (Wedel); Mexico (Lomas Verdes); Brazil (Cotia); and Argentina (Buenos Aires). The WHO estimates that between 1% and 30% (rising to 50% on the internet) of medicines sold worldwide are counterfeit. Every year, thousands of patients are seriously harmed or killed as a result of taking these products rather than the real thing. Counterfeiting is particularly prevalent in the developing world and with medicines bought online.

To combat the problem we have a comprehensive product security strategy which includes:

- > partnering with others to strengthen enforcement and raise awareness
- > securing products through pack features and enhanced integrity of the supply chain
- > combating illegal operations through proactive investigation of suspicious activity and reported incidents.

In 2010, a life-threatening counterfeiting operation was thwarted following an investigation in Colombia. Twenty four members of a criminal gang were arrested in May on charges relating to making and selling a counterfeit of our antibiotic, *Meronem.* Suspicions first came to light in 2007 when we received reports from employees about suspect *Meronem* bearing the same batch number. A painstaking investigation was carried out, including the use of undercover techniques to gather evidence. By early 2010, we were able to hand over enough evidence for the Colombian police to conduct a series of raids.

During 2010, we also opened a small packaging plant in Indonesia. We operate sites for the manufacture of APIs in the UK and Sweden, complemented by the efficient use of external 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.

Some 600 permanent and an additional 250 seasonal 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 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

Given our announced intention to outsource all API manufacturing, we place particular importance on our global procurement policies and integrated risk management processes which aim to ensure the uninterrupted supply of sufficiently high quality raw materials. These and other key supplies 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 maintaining 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 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. For more information, see the Responsible Business section from page 40.

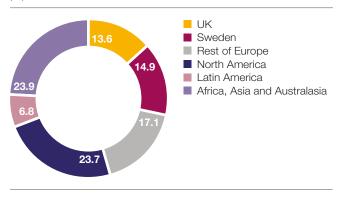
### **Delivering our strategy**

## People Nurturing a diverse and talented workforce

# 61,000

61,000 employees worldwide

## Employees by geographical area (%)





"Our people strategy is built around the key priorities we believe to be critical to delivering our business objectives. These include developing a high performance culture, strengthening our talent pipeline and building capabilities"

#### Lynn Tetrault

Executive Vice-President, Human Resources and Corporate Affairs

With approximately 61,000 people in over 100 countries worldwide, we value the talents, skills and capabilities that a global workforce brings to our business. Our people strategy defines our approach to managing our workforce and supports the delivery of our business strategy. Our people strategy is built around four key priorities which we believe are critical to delivering our business objectives: developing our performance culture; developing our talent pipeline; increasing our leadership and management capability; and simplifying our organisational design. We use a range of metrics to track progress against these priorities, which are reported quarterly to our human resources (HR) leadership team.

#### Developing our performance culture

A key priority of our people strategy is the continued development of a performance culture across the organisation. By strengthening our focus on setting high quality objectives aligned to our business strategy, we will ensure that performance at all levels of the organisation delivers value. The Board is responsible for setting our high-level strategic objectives and monitoring performance against them (see the Operation of the Board section from page 109). Managers across AstraZeneca are accountable for working with their teams to develop individual and team performance targets, and for ensuring that our people understand how they contribute to overall business objectives.

We will continue to empower our leaders to drive performance, to hold our managers accountable for understanding and delivering against the standards required, and provide the tools necessary to reward outstanding contributions.

Our focus on optimising performance is reinforced by performancerelated 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 119 and also in Note 24 to the Financial Statements from page 173.

#### **Developing our people**

We encourage and support our people in achieving their full potential by providing a range of learning and development (L&D) programmes which are designed to build the capabilities and encourage the behaviours needed to deliver our business strategy.

We are implementing a global approach, supported by the creation of our global talent and development organisation, to ensure that high standards of L&D practice are applied across the organisation. We continue to develop and deploy instructor-led and online development resources, which we aim to make available to all employees to increase access to learning and to support self-development.

We recognise the importance of good leadership and its critical role in stimulating high levels of performance and engagement. Our leadership development frameworks are focused on the core capabilities which we believe are essential for strong and effective leadership. These capabilities are defined for each level in the organisation and apply to all employees. The development of a pipeline of future global leaders is a high priority and we work to identify individuals with the potential for more senior and complex roles. These talent pools provide succession candidates for a range of critical leadership roles across AstraZeneca. We regard these individuals as key assets to the organisation and we proactively support them to reach their potential through, for example, global talent development programmes and targeted development opportunities.

We complement our leadership capabilities with a set of manager accountabilities which define what we expect from our managers. Building line manager capability is supported by a suite of global learning programmes which address people management, change management and other critical capabilities.

The significant shift in the footprint of our global workforce has placed a high priority on acquiring and retaining key talent. Our strategic workforce planning (SWP) framework enables the business to develop the workforce required to deliver our strategy by ensuring that the right skills are in the right place at the right time to successfully deliver our business objectives. SWP generally takes a longer-term view of five to seven years and helps us identify and develop the necessary HR solutions to attract, retain, develop and deploy our workforce.

We remain committed to making full use of the talents and resource of all our people. We have policies in place to avoid discrimination, including on the grounds of disability. Our policies cover recruitment and selection, performance management, career development and promotion, transfer and training (including re-training, if needed, for people who have become disabled) and reward.

#### **Diversity and inclusion**

Our global workforce provides a diversity of skills, capabilities and creativity and we value the benefits that such diversity can bring to our business. We aim to foster a culture of respect and fairness where individual success depends solely on ability, behaviour, work performance and demonstrated potential. As we reshape our organisation and geographic footprint, our continuing challenge is to ensure that diversity in its broadest sense is reflected in our workforce and leadership, and integrated into our business and people strategies. Fifty one percent of our global workforce are women and twenty five percent of senior managers reporting to the SET are women. As part of developing a global diversity and inclusion strategy, we have identified the need to look more closely at the advancement of women within AstraZeneca. Working with an external expert, we completed an extensive research project involving employees across a wide range of countries to understand what is preventing a greater number of women from reaching more senior levels in the business. Findings were shared with the Board and the SET, which resulted in the formation of a global steering group chaired by our CEO and made up of senior leaders from across the business.

The steering group is focused on driving change in three key areas that emerged as themes from the research: 'Leadership & Management Capability', 'Transparency in Talent Management & Career Progression' and 'Work Life Challenges'. This work will continue to inform the development of our diversity and inclusion strategy.

#### **Engagement and dialogue**

We use a variety of global leadership communications channels to engage our people in our business strategy. In addition, local leaders and managers hold regular meetings with their teams. We also use the intranet, video conferencing and Yammer (a social media tool) to encourage dialogue. We added a feedback mechanism to our annual global employee survey (FOCUS) in 2010 and received over 22,000 comments on a variety of topics, which are now informing our 2011 engagement plans.

We measure levels of engagement, the effectiveness of our communications and other areas critical to the performance of our business through our annual FOCUS survey. The results are communicated to all employees. Eighty eight percent of our people participated in our 2010 survey, reflecting their continued confidence in this feedback mechanism. Although our employee engagement score declined by one percentage point from 2009, leadership category scores improved by five percentage points and the leadership communication score improved by four percentage points. The survey also identified the key areas for attention in 2011, including work/life balance, change management and further improvement in leadership communications.

#### **FOCUS** engagement scores

83%
84%
82%
80%

There is no FOCUS engagement score for 2007 as the survey was biennial until 2008.

Overview

### **Delivering our strategy**

#### Simplifying our organisational design

We constantly look for ways to increase the efficiency and effectiveness of our organisation. As outlined in the Research and Development and Sales and Marketing sections from pages 26 and 32 respectively, in 2010 we have improved accountability and decision making through the creation of single global Commercial and R&D functions, each led by a single accountable leader.

In addition to these structural changes, the composition of our global workforce has changed significantly in recent years. Our strategic focus on business growth in Emerging Markets and an increased biologics capability has meant the workforce in these areas has grown substantially (as shown in the Sales and Marketing workforce composition figure below). This increase has been accompanied by headcount reductions through restructuring in R&D, operations, support functions and our sales and marketing workforce in Established Markets. The net effect of these changes since 2007 has been to reduce our total headcount from 67,400 to 61,000.

Our business change activity in 2010 and over the next three to four years will predominantly be associated with the implementation of our R&D and Commercial strategies. The changes are designed to make sure that we are building critical capabilities, driving efficiencies and aligning resources to business opportunities. As announced in the first half of 2010, these programmes are planned to impact 10,400 positions by 2014, with a reduction of 2,600 positions in 2010.

We work to ensure a level of global consistency in managing employee relations, while allowing enough flexibility to support the local markets in building good relations with their workforces, taking into account local laws and circumstances. To that end, relations with trade unions are nationally determined and managed locally in line with the applicable legal framework and standards of good practice. However, each change programme has its unique challenges and a standard solution may not always be appropriate. Where this is the case, the appropriate solution is developed through consultation with employee representatives or, where applicable, trade unions, with the aim of retaining key skills and mitigating job losses.

Following a period of consultation, we made a number of changes to the UK defined benefit pension scheme in 2010. These changes resulted in some localised industrial action.

## Sales and Marketing workforce composition Emerging Markets Established Markets

2010	46%	54%
2002 16%		84%



## Who is protecting me from new infections?

Seventy years ago, the discovery of antibiotics revolutionised the treatment of bacterial infections and saved millions of lives. But the growing problem of bacterial resistance threatens to put global health at serious risk. Finding new antibiotics that will be effective against bacterial resistance is not impossible, but it is challenging. It is also an area that has not been a primary focus for the pharmaceutical industry in recent years. AstraZeneca is one of a few key players that has continued to invest in antibiotic research and in 2010 we made a regulatory submission in the EU for a new antibiotic, Zinforo, that will provide new treatment options for Gram-positive infections such as those due to MRSA.

Another clear example of the challenge is provided by tuberculosis. TB claims 5,000 lives every day and multi-drug resistant TB affects half a million people annually. To accelerate development of new treatments, a collaboration led by the Bill and Melinda Gates Foundation, the TB Alliance, and the Critical Path Institute has brought AstraZeneca, including our dedicated TB facility in Bangalore, India, together with other pharmaceutical companies, government agencies, donors, advocates, academics and NGOs.

No single organisation can win the bacterial battle. We need a vibrant pipeline of new classes of antibiotics. Working together creatively in partnership with others we believe we can make a greater contribution to that goal.



Because health connects us all For more information go to the Therapy Area Review from page 50.

## **Responsible Business** Committed to delivering value responsibly

# 11

11 confirmed breaches of external sales and marketing regulations or codes globally

# 8%

Ranked in the top 8% in the sector in the Dow Jones Sustainability World and European Indexes

# 1,950

Completed over 1,950 Responsible Procurement assessments, accounting for around 75% of our third party spend



Michele Hooper Senior independent Non-Executive Director and Chairman of the Audit Committee



Dame Nancy Rothwell Non-Executive Director with responsibility for overseeing Responsible Business

"We believe that to be successful in delivering our strategic priorities, a strong focus on responsible business is essential. It's fundamental to our reputation. Stakeholders need to be confident that we apply sustainability considerations and high ethical standards across all our activities, whether in-house or outsourced, in both Established and Emerging Markets. Being welcomed as a trusted partner as we reshape our geographic footprint and increase our externalisation is critical to our success." In this section we describe how we are working to deliver business success responsibly, including summary information about our commitment and performance in some key areas. Further information about these areas and others is available on our website, astrazeneca.com/responsibility.

#### Introduction

At AstraZeneca, we are dedicated to the research, development, manufacture and marketing of medicines that make a difference in healthcare. For us, this is at the core of our responsibility to our stakeholders and to society. Successful pharmaceutical innovation, delivered responsibly, brings benefits for patients, creates value for shareholders and contributes to the economic development of the communities we serve.

As described in the Our marketplace section from page 10, AstraZeneca operates in a dynamic environment that presents both opportunities and challenges. To make sure we are well positioned to manage these, our business strategy is driving significant changes across our organisation. Previous sections have outlined how we are transforming R&D, expanding our footprint in Emerging Markets, boosting our efforts to source innovation from outside AstraZeneca and increasingly working in partnerships that broaden the base for success in improving healthcare. At the same time, we continue to drive efficiency and effectiveness across the organisation, including increased outsourcing to a diverse range of strategic suppliers.

Our work to implement these changes is underpinned by our continued commitment to the sustainable development of our business which delivers value for our stakeholders and for us. To that end, our responsible business objectives must be closely aligned to, and support delivery of, our business strategy. In the light of our accelerated strategy, the insights gained from dialogue with our stakeholders and our internal risk assessment, we reviewed and reshaped our Corporate Responsibility (CR) Plan during 2010. Our new Responsible Business Plan combines our CR and compliance agenda and puts at the top those areas most impacted by the changes to our business and which are therefore key enablers of our strategy.

This means a specific focus on:

- > R&D ethics underpinning our drive for innovation with sound ethical practice worldwide
- > Sales and marketing practices driving consistently high ethical standards to promote our medicines responsibly worldwide
- > Human rights making sure that we continue to develop and drive a consistent approach across all our activities
- > Access to healthcare exploring ways of increasing access to healthcare for underserved patient populations
- > Suppliers working only with organisations who embrace ethical standards that are consistent with our own.

As well as managing specific responsible business challenges associated with the changes to our strategy, we will be maintaining focus on other aspects of our responsibility:

- > Patient safety
- > Environment
- > Employee safety, health and wellbeing
- > Community investment.

Our new Responsible Business Plan, which will include associated objectives, targets and KPIs, maps our agenda and sets our direction for the next five years. We aim to launch it in the first quarter of 2011 and publish it on our website, astrazeneca.com at the time. Because this is a dynamic and evolving area, we will continue to engage with our stakeholders and work within the business to understand how we can further improve our performance.

#### Accountabilities and responsibilities

The Board is responsible for our Responsible Business framework and Non-Executive Director, Dame Nancy Rothwell, oversees implementation and reporting to the Board. Michele Hooper chairs the Audit Committee which oversees the work of the Global Compliance function.

The SET and senior managers throughout the Group are accountable for responsible business management within their areas, based on the global framework but taking into account national, functional and site issues and priorities. Line managers are accountable for ensuring that their teams understand the requirements and that people are clear about what is expected of them as they work to achieve AstraZeneca's business goals. Individually, everyone in AstraZeneca has a responsibility to integrate responsible business considerations into their day-to-day decision making, actions and behaviours.

Our dedicated Global Corporate Responsibility Team works together with the SET areas and the Global Compliance function across the business to ensure that responsible business risks and opportunities are identified and managed appropriately, in line with our strategic business objectives.

#### **External engagement and benchmarking**

Stakeholder engagement is critical to keeping in touch with the demands of sustainable development. It was particularly important in 2010 as we worked to develop our new Responsible Business Plan and, alongside our ongoing stakeholder dialogues, we held a number of multi-stakeholder events. For example, we hosted two roundtable discussions in London and Stockholm to gain a better understanding of what our stakeholders believe to be important responsibility considerations as our business moves into emerging markets. Participants included socially responsible investors (SRIs), medical researchers, academics, politicians and regulators. We also arranged an event specifically for key SRI contacts. The agenda reflected areas of interest expressed by the SRI community and so focused on R&D strategy, emerging market strategy and responsible procurement. The insights we gained from these

events, and other single-issue engagement during the year, significantly influenced the shape of our new Plan. We will continue to engage with our stakeholders on the further development of the Plan to ensure that we are staying in close touch with the changing expectations of a responsible business.

We also use the insights we gain from external surveys to develop our approach in line with best practice on a global basis. A member of the Dow Jones Sustainability Index since 2001, we continue to be ranked among the sustainability leaders in the pharmaceutical sector. In the 2010 Index, we increased individual scores for nine out of 23 criteria (compared to 14 out of 24 criteria in 2009) including improved marks for innovation management and stakeholder engagement. We lost ground in some areas including corporate governance, marketing practices and environmental policy. To better understand these lower scores, we have commissioned an in-depth external benchmark survey and the analysis will be used to inform our improvement planning. The survey is expected to report in the first quarter of 2011.

#### External assurance

Bureau Veritas has provided external assurance on responsible business 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 our 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 had an annual turnover in 2009 of €2.6 billion.

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

We are determined to make sure that the strategic changes we are making within R&D are underpinned by our ongoing commitment to delivering innovation responsibly. 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.

#### **Clinical trials**

Clinical trials are the means by which we study the effects of a potential new medicine in humans. We conduct clinical trials at multiple sites in several different countries. A broad geographic span helps us to ensure that those taking part in our studies 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.

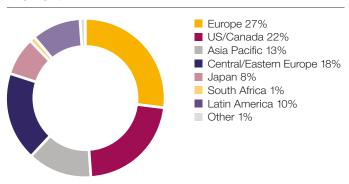
Our global governance process for determining where we place clinical trials provides the framework for ensuring a consistent approach worldwide. We take several factors into account, including the availability of experienced and independent ethics committees and a robust regulatory regime, as well as sufficient numbers of trained healthcare professionals and patients willing to participate in a trial.

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.

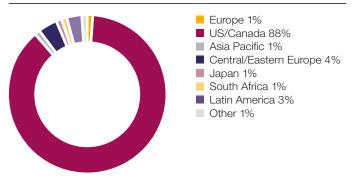
One of our core responsibilities to those taking part in our trials is to make sure that we protect them from any unnecessary risks.

### **Delivering our strategy**

#### Patients in global AstraZeneca small molecule studies by geographical area in 2010



## Patients in global AstraZeneca biologics studies by geographical area in 2010



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. As well as compliance with all relevant laws, we have strict internal procedures for managing safety issues during clinical trials and ensuring we act in the best interests of participants.

All our clinical studies are conceptually designed and finally interpreted in-house but some of them are run for us by external contract research organisations (CROs). In 2010, around 47% of patients in our small molecule studies and around 87% of patients in our biologics studies were monitored by CROs on our behalf. We contractually require CROs to work to our global standards.

We publish information about the registration and results of all our clinical trials, whether favourable or unfavourable to AstraZeneca, on a range of public websites including our own dedicated site, astrazenecaclinicaltrials.com. By the end of 2010, we had registered over 1,250 trials and published the results of more than 800.

#### **Animal research**

Animal studies continue to play a vital role in the search for new medicines. They provide essential information, not available through other methods, about the effects of a potential new therapy on disease and the body. Regulatory authorities around the world also require safety data from pre-clinical testing in animals before a new medicine can be tested in humans.

As we work to improve our R&D productivity, we remain committed to minimising our use of animals without compromising the quality of the research data. All research using animals is carefully considered and justified, not only to confirm the scientific need for a study, but also to make sure that it has been designed so that the minimum number of animals is used and that they are exposed to as little pain and distress as possible. Wherever possible, we use non-animal methods, such as computer modelling, that eliminate the need to use animals early in drug development or reduce the number required. We also work to refine our existing methods. This replacement, reduction and refinement of animal studies is known as 'the 3Rs' and to support our drive for continuous improvement, we work both within AstraZeneca and the wider scientific community to share 3Rs knowledge and learning.

The number of animals we use will continue to vary because it depends on a number of factors, including the amount of preclinical research we are doing, the complexity of the diseases under investigation and the regulatory requirements. We believe that, without our active commitment to the 3Rs, our animal use would be much greater. In 2010, we used approximately 408,000 animals in-house (2009: 393,000). In addition, approximately 21,000 animals were used by external CROs on our behalf (2009: 17,000).

The welfare of the animals we use continues to be a top priority and our standards apply worldwide. In addition to mandatory inspections by government authorities, we have a formal programme of regular audits of our internal animal research facilities conducted by our own qualified staff. To make sure that they continue to support our drive for consistently high standards of animal care worldwide, we updated our standards during 2010 to increase clarity about their scope and associated accountabilities and responsibilities.

External CROs that conduct animal studies on our behalf are required to comply with our global standards and we undertake a regular risk-based programme of audits to ensure our expectations are being met.

We support the introduction of new legislation across EU member states, which has created consistent standards regarding the use of laboratory animals. We actively contributed to discussions to ensure that the new EU Directive 2010/63/EU on animals used for scientific purposes, which became law in November, strikes a balance between improving animal welfare and maintaining the ability to conduct R&D in Europe that brings benefit for patients.

#### Stem cell research

We believe that stem cell research may offer new opportunities to develop innovative and safer medicines. Our commitment to high ethical standards in this area of research is reflected in our Bioethics Policy which demands compliance with all external regulations and with our own codes of practice.

Some research in this field uses stem cells from human embryos (human embryonic stem cells (hESC)) created during in vitro fertilisation procedures but which become surplus to requirements. We are particularly interested in the potential of stem cells to differentiate into normal human cells, such as cardiac myocytes (heart muscle cells) or hepatocytes (liver cells). If achieved, these could be used to improve prediction of the safety, metabolism and efficacy of emerging candidate drugs at an earlier stage in the process and would help us to overcome the current limitations that a restricted supply of human tissue presents. Significant scientific progress has been made in the development of such stem cell based research models, with some promising results. However, more work is needed to understand the full potential of this type of research. We do not have all the necessary skills and technologies in-house, and so are working with external partners who have expertise and an ethical commitment consistent with our own. These include Stem Cells for Safer Medicines, a UK public-private partnership, and Cellartis AB, a biotech company.

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**Financial Statements** 

Induced pluripotent stem cells (iPSC), which can be obtained safely from adult volunteers and do not involve embryos at all, may provide a scientifically viable alternative to hESC. We are in the process of establishing a dedicated iPSC department to facilitate the application of iPSC as a tool to derive more native-like human cells *in vitro*. We also plan further collaborations in this field.

Separately, we are exploring the potential to treat disease by modulation of stem cells within target organs which is an exciting new area often referred to as regenerative medicine. We are embarking on several external partnerships to combine the best ideas and latest innovation in academic research with our ability to search for new drugs. We are looking for the potential of small molecules or biologics to modulate stem cells in patients' tissues to repair or improve the function of diseased tissue. Our collaborations with the Institute of Ophthalmology at University College London, announced in September and Evotec AG/Develogen AG announced in December, represent important investments in regenerative medicine, which focus on exploring regenerative therapies for diabetic retinopathy and diabetes respectively.

#### Sales and marketing ethics

Driving consistently high standards of sales and marketing practice worldwide remains a top priority. This is particularly important (and at times challenging, given the diversity of business cultures around the world) as we continue our strategic drive to grow our business by expanding our presence in Emerging Markets. Alongside our work to ensure high standards are applied across our new geographies, we remain committed to continuous improvement in our Established Markets.

Compliance with all relevant external sales and marketing codes and regulations, and with our own policies, is mandatory and monitored by line managers locally, who are supported by dedicated compliance professionals. We also have a nominated signatory network that works to ensure that our promotional materials meet all applicable requirements.

Information concerning instances of potential non-compliance is collected through our compliance incident management processes 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 about our compliance and risk assurance processes is contained in the Managing risk section from page 95. We take all breaches very seriously and act to prevent repeat occurrences.

During 2010, we reviewed our existing sales and marketing policies and standards, further strengthened the requirements and consolidated the range to form a single new Global Policy on External Interactions. We aim to launch the new Policy in the first quarter of 2011, followed by training of all relevant staff to reinforce our commitment to consistent ethical interactions with stakeholders worldwide.

In 2010, we identified a total of 11 confirmed breaches of external sales and marketing regulations or codes globally (2009: 24; 2008: 15).

It should be noted that cases where regulatory authorities approach AstraZeneca with concerns or queries about sales and marketing materials or activities (for example, in the course of their routine review responsibilities) are not included in our KPI number. However, we follow up these incidents with appropriate actions so that all relevant learning is taken into account in our future activities. Global KPI: Breaches of external sales and marketing codes and regulations ruled by external bodies

3 year performance

2010 <sup>1</sup>	11	
2009 <sup>1</sup>		24
2008	15	

<sup>1</sup> Includes self-reporting activity globally which resulted in a breach being ruled.

#### Disciplinary actions: Breaches of Code of Conduct by Commercial employees 2010

	Number of	Number of employees		
Action taken	2010 <sup>1</sup>	2009 <sup>2</sup>		
Removed from role	117	99		
Formal warning	740	687		
Guidance and coaching	768	416		
Total	1,625	1,202		

<sup>1</sup> 2010 data reflects improved data capture mechanisms that will be used going forward to report

breaches by Commercial employees year-on-year. <sup>2</sup> 2009 data shows breaches of Code of Conduct by all employees and is included for comparative purposes only.

While our KPI provides a benchmark against which to measure our performance year-on-year (see above), the varying national and regulatory definitions of what constitutes an external breach will continue to create a challenge for us in interpreting the data at a global level. In addition, a single confirmed breach can involve more than one employee failing to meet the standards required and as described earlier there may be failures to meet standards which are not 'confirmed' and so will not affect the KPI.

During 2010, we looked at additional ways of reporting our performance which would support increased transparency about our practices. We are now reporting the global number of Commercial employees involved in disciplinary actions during the year, including the number of associated dismissals (see above). This information provides the broader context of our internal governance and the number of actions taken in relation to breaches of external or internal sales and marketing codes. It also reinforces for our employees and other stakeholders how seriously we take breaches of our policies.

#### **US Corporate Integrity Agreement reporting**

In April 2010, AstraZeneca signed an agreement with the US Department of Justice to settle an investigation relating to the sales and marketing of *Seroquel IR*. The requirements of the associated Corporate Integrity Agreement between AstraZeneca and the Office of the Inspector General of the US Department of Health and Human Services (OIG) include a number of active monitoring and self-reporting obligations that differ from self-reporting required by authorities in the rest of the world. To meet these obligations, AstraZeneca provides notices to the OIG describing the outcomes of particular investigations potentially relating to violations of certain laws, as well as a separate annual report to the OIG summarising monitoring and investigation outcomes relevant to Corporate Integrity Agreement requirements.

#### Human rights

Human rights remain at the core of our commitment to responsible business. As we reshape our organisation, grow our business and increase our outsourcing, we are working to make sure that we continue to drive and share best practice across all our activities.

### **Delivering our strategy**

In January 2010, AstraZeneca signed up to the United Nations Global Compact (UNGC), a strategic public-private initiative for organisations committed to social and environmental sustainability. This means that we have committed to uphold 10 internationally recognised principles in the areas of human rights, labour standards, environmental sustainability and anti-corruption. These are not new principles for AstraZeneca (as described in our Code of Conduct and global policies) but joining the UNGC reinforces how seriously we take our commitment to them. It also gives us the framework for further developing our commitment in the areas of human rights and labour standards.

In recent years, we have been participating in a project led by the Danish Institute for Human Rights (DIHR), working with the pharmaceutical industry to develop a human rights assessment tool for pharmaceutical companies, based on the DIHR's existing Human Rights Compliance Assessment Tool. The first pharmaceutical industry version of the tool was launched in November.

Our participation in the project helped to improve our understanding of the specific human rights implications for our industry and during 2010 we focused on further understanding how the human rights and labour-related UNGC principles apply to our activities.

As part of this, we conducted a human rights self-assessment pilot study in our marketing company in South Africa. The study focused on employment practices, R&D, products and marketing, and the community. The outcomes were positive overall due principally, we believe, to the extensive external regulation governing these issues in South Africa. However, the assessment usefully highlighted areas of AstraZeneca's global governance which required improvement, including increased alignment with the International Labour Organization (ILO) core conventions, which has also been raised during our stakeholder engagement. We subsequently conducted a human rights based review of our Code of Conduct and our global policies, focusing in particular on labour standards and diversity. We will be using the outcomes and recommendations on how to further strengthen our governance in these areas to inform the further development of our Code of Conduct and global policies.

We also used the DIHR assessment tool to conduct a labour review in 11 of our marketing companies, including some countries where national labour standards are not consistent with global best practice. The review focused on ILO core areas (freedom of association and collective bargaining, forced and bonded labour, child labour, discrimination, and working time and wages). The results showed that our practices are in the main consistent around the world, based on our requirement that our global standards are applied when external national standards do not meet AstraZeneca's minimum standards. However, we identified the need for more consistency in some areas, for example, working time and some aspects of diversity.

We have developed a global approach and framework for progressing our human rights agenda, including defined accountabilities and responsibilities and an action plan to ensure that human rights continue to be appropriately integrated into our strategies, policies and processes. We plan to begin a phased roll-out across AstraZeneca in the first half of 2011.

#### Access to healthcare

We continue to review our approach to improving access to healthcare in underserved communities in a sustainable way. The review includes engaging with external stakeholders and working within the business to understand the challenges and the opportunities. The assessments associated with the 2010 Access to Medicines Index are also informing our thinking. We anticipate publication of the outcome of this review in the first half of 2011 on our website, astrazeneca.com/responsibility. For further information about pricing our medicines and our intellectual property protection, see the Pricing our medicines section on page 33 and the Intellectual Property section from page 30.

#### Working with suppliers

We continue to work to make sure that our purchasing is directed only to those organisations which embrace ethical standards consistent with our own. This is particularly important given the strategic changes to our geographic footprint and our increased outsourcing activity to support improved efficiency and effectiveness across the organisation.

Our Global Responsible Procurement Standard defines the process for integrating our ethical standards into our procurement activity and decision making worldwide. The process is based on an escalating set of risk-based due diligence activities, applied in a pragmatic way. 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. The Standard includes detailed expectations of suppliers which suppliers sign up to as part of the contracting process. We will work with suppliers to help them improve their standards, rather than automatically excluding them from our supply chain but we will not use suppliers who are unable or unwilling to meet our expectations in a timely way.

Implementing our approach across the many thousands of suppliers we work with around the world will take time. We started with our largest suppliers, whose contracts with AstraZeneca are managed centrally by our Procurement team. In 2009, we completed Responsible Procurement assessments of over 800 suppliers accounting for around 65% of our third party spend. In 2010, we extended the programme to other companies in our supply chain, including smaller suppliers and those whose contracts are managed locally. Since the programme began, we have completed over 1,950 assessments which account for around 75% of our third party spend. The ongoing programme will continue throughout 2011 and beyond.

In late 2010, we introduced a requirement that our key suppliers provide independent audit verification that their ethical standards are being applied in practice. Together with our suppliers, we are partnering with experienced third party providers in this work and using an assessment programme that reflects best practice from other industry sectors, as well as the principles of the Pharmaceutical Supply Chain Initiative (a group of major pharmaceutical companies working to support suppliers in operating in line with industry expectations). We are in the early stages of engaging with suppliers on the introduction of this requirement and it will take time to embed the practice. However, we believe that this move significantly strengthens the framework for working together with our suppliers to drive continuous improvement.

We continued our Integrated Supplier Evaluation Protocol audit programme during the year and have now supplemented this with the introduction of focused Responsible Procurement assessments. In 2010, the programme covered 48 audits at 42 different suppliers (2009: 51 audits at 45 suppliers).

#### **Patient safety**

The safety of the patients who take our medicines will always be 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, beginning 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.

We have an experienced, in-house team of clinical patient safety professionals working around the world who are dedicated to the task of ensuring that we meet our commitment to patient safety. 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 (one for our small molecule products and one for biologics) have overall accountability for the benefit/risk profiles of the products we have in development and those on the market. 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.

We use an external provider, Tata Consultancy Services (TCS), to manage the data entry process for individual case safety reports relating to AstraZeneca products. As experts in their field, TCS is driving improvements in the efficiency and consistency of data entry across AstraZeneca and using TCS for this work means our patient safety teams can focus primarily on case prioritisation, the medical aspects of patient safety and continuing to improve our safety science. TCS is contractually required to comply with our patient safety standards and is closely monitored through audits against detailed quality and compliance performance indicators.

#### Environment

Managing our environmental impact continues to be a core commitment for AstraZeneca. We have made good progress in recent years and have met the majority of the 2010 objectives and targets that we set ourselves in 2005. We met our targets for waste and overall greenhouse gas footprint. However, against a targeted 12% reduction in emissions, excluding those from our respiratory therapies, we achieved a 9% reduction. We know that there will always be more to do to make sure that we effectively balance the changing priorities of our business with the needs of the external environment.

During 2010, we launched a new Safety, Health and Environment (SHE) strategy and associated objectives that set the direction for this key aspect of our responsibility over the next 10 years. New targets have been adopted to focus our efforts to 2015 and set us on track to meet our 2020 strategic ambitions.

#### Product stewardship

We aim to integrate environmental considerations into a medicine's complete life-cycle – from discovery and development, through manufacturing, marketing, use and, ultimately, disposal.

We conduct environmental risk assessments for all our new and many of our established medicines 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 voluntary testing to refine the assessments. 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 LIF, the research-based pharmaceutical industry association in Sweden. Our Environmental Risk Management Plans, introduced in 2008, now accompany new medicines along the path to launch. 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 are also starting to develop plans for 'ecopharmacovigilance' that will help us to identify and manage any potential environmental risks associated with our medicines after they have been launched.

In the design of manufacturing processes, we are applying green chemistry principles that enable potential environmental issues to be identified and designed out at an early stage. Packaging is another area where we continue to make improvements that reduce the potential impact on the environment, without compromising patient safety. We are also working with national and local authorities to encourage appropriate disposal of unused medicines.

Underpinning all of this activity is our ongoing research into the effects of pharmaceuticals in the environment (PIE). While improving all the time, understanding of the potential for long-term effects in the environment, for example to aquatic life, requires further research. This is a 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.

#### **Environmental sustainability**

We aim to minimise our environmental impact by reducing the carbon footprint and natural resource demands of our business activities.

#### Greenhouse gas emissions<sup>1</sup>

CO<sub>2</sub>-equivalents (million tonnes)

2010	1.08
2009	1.12
2008	1.22

Index (tonnes/\$m sales)

2010	34
2009	36
2008	40

Figures are calculated in line with the Greenhouse Gas (GhG) protocol guidance (ghgprotocol.org). <sup>1</sup> Data excludes MedImmune.

#### Waste production<sup>1</sup>

Total waste (thousand tonnes)

2010	44.0
2009	50.0
2008	54.1

Index (tonnes/\$m sales)

2010	1.37
2009	1.60
2008	1.79
<sup>1</sup> Data excludes MedImmune.	

### **Delivering our strategy**

We continue to drive reduction of our CO<sub>2</sub> emissions by, among other things, improving our energy efficiency and pursuing lower-carbon alternatives to fossil fuels. For example, recognising the significant global warming emissions from road travel by our sales fleets, we worked with our fleet management and leasing suppliers to introduce fleet reporting to track the CO<sub>2</sub> emissions of new and existing vehicles. We are also introducing CO<sub>2</sub> caps on new car purchases in our major markets.

Our carbon footprint is also affected by some of our respiratory therapies, specifically our pressurised metered-dose inhalers that rely on propellants such as hydrofluoroalkanes (HFAs) to deliver the medicine to a patient's airways. While HFAs have no ozone depletion potential and a third or less of the global warming potential than the chlorofluorocarbons (CFCs) they replace, they are still greenhouse gases, but we believe that the potential benefits that these therapies offer patients outweigh the potential impact on the environment.

The management of waste is another key aspect of our commitment. Our main aim is waste prevention, but where this is not practical, we focus on waste minimisation and appropriate treatment or disposal to maximise the reuse and recycling of materials.

Alongside these efforts, we are increasingly working with our suppliers to measure and manage the environmental impact of their manufacturing activity on our behalf. This is particularly important as we continue to increase our outsourcing in line with our strategic business objectives.

#### Employee safety, health and wellbeing

Providing a safe workplace and promoting the health and wellbeing of all our people remains a core consideration. We believe that a safe, healthy and energising working environment brings benefit for our employees and for our business, through people's sustained engagement and contribution to AstraZeneca's success.

We met our 2006-2010 safety and health target to reduce the combined serious injury/occupational illness rate by 50% from the 2001/2002 reference point, achieving an actual reduction of 59%.

During 2010, we launched a new SHE strategy and, in January 2011, a complementary Health and Wellbeing strategy, together with associated objectives and targets for 2011-2015. The new targets reflect our determination to stay focused on continuous improvement as we grow and reshape our business.

Driver safety remains our highest priority for improvement as we work to implement our new SHE strategy. We regret that during 2010, five of our employees died in traffic accidents while driving on AstraZeneca business. We identified the root causes of these accidents and the learning informed the further strengthening of our global standards on driver safety management and accident investigation. We also ran a global employee awareness campaign to reinforce the importance of safe driving practice. This included our new global requirement that hand-held mobile phones and other devices should never be used while driving. Our long-standing 'Road Scholars' scheme in the US continues to be a valuable channel for building awareness and improving driver skills. 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 and measures to be applied by each country. Performance is monitored centrally and low-score markets are targeted for increased support on implementation.

AstraZeneca employees: cases of occupational illness per million hours worked

2010	0.78	
2009		1.37
2008	1.04	4

AstraZeneca employees: accidents with serious injuries per million hours worked

2010	2.27
2009	2.24
2008	2.28

We continue to provide a wide range of health and wellbeing improvement programmes across AstraZeneca, designed to help people understand their personal health risks and support them in proactively managing these risks. Our new Health and Wellbeing strategy in particular focuses on Personal Energy Management Training, Health Screening and Essential Health Activities, such as improving physical fitness and managing workplace pressure.

Work-related stress remains our greatest single category of occupational illness with high workloads, interpersonal issues and organisational change 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.

#### **Community investment**

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 sustainable difference. Our investment is focused on improving health and promoting science skills.

In 2010, we spent a total of \$1.41 billion (2009: \$882 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 patient assistance programmes in the US contributed to \$1.38 billion worth of product donations, valued at an average wholesale price (2009: \$786 million). The increase over 2009 was due to an increasing number of people accessing our US patient assistance programmes due, we believe, to the economic recession, and to the types of medicines that they were requesting.

#### AstraZeneca Young Health Programme

In November, we launched the AstraZeneca Young Health Programme. This community programme is designed to help disconnected young people around the world understand and deal with the health issues they face. Adolescent health remains an underserved part of the healthcare agenda and this long-term investment programme aims to make a measurable and sustainable difference for disadvantaged young people. We are working with expert partners, Plan Ltd and Johns Hopkins School of Public Health, to identify the needs in our local communities and to help address these needs with a combination of work on the ground, research and advocacy. We will also be providing employees with the opportunity to contribute through local volunteering, donations and fund raising.

#### **Building capabilities**

AstraZeneca's contribution to helping improve health in the developing world centres on our dedicated research of new and effective treatments for tuberculosis (TB), which still claims over 5,000 lives every day. For further information about our research effort see the Tuberculosis section on page 60. Alongside this, we continue to work in partnership to strengthen healthcare capabilities in vulnerable communities.

In 2007, AstraZeneca and the African Medical and Research Foundation (AMREF) began a five-year partnership in Uganda to develop an integrated model for the management of malaria, HIV/ AIDS and TB, the leading causes of ill health and death in the country. For further information on this project, see page 49.

AstraZeneca and the British Red Cross have been in partnership since 2002 tackling TB and TB/HIV in Kyrgyzstan, Turkmenistan and Kazakhstan and, more recently, in South Africa, Lesotho and Liberia. Over 13,000 people have been directly supported to complete their TB treatment across all our partnership countries and TB mortality and morbidity rates continue to fall in our partnership countries in Central Asia. Community education initiatives continue to be delivered with a recent example in Liberia of a house-to-house TB education programme which reached nearly 32,000 people.

Our partnership with Axios International on the Ethiopia Breast Cancer Project completed in 2010, with a much broader impact than originally anticipated for a small pilot project. In 2005, the country had only one cancer specialist, no mammography, no easy access to chemotherapy or hormonal agents, no cancer screening and no national treatment protocols. Our partnership programme focused on strengthening diagnosis and treatment capabilities at Tikur Anbessa University Hospital in Addis Ababa, where the country's only cancer specialist was based. The hospital has now become a centre of reference for breast cancer treatment across Ethiopia. Other activities included the creation of treatment protocols and standardised reporting guidelines; strengthening the referral system; setting up an institutional-based cancer registry; raising awareness of the facilities among healthcare professionals; and physician training. The project was implemented in collaboration with the Ethiopian Ministry of Health and other health institutions and we also worked with the Ethiopian Cancer Association to help strengthen awareness and fundraising capabilities. The pilot has created a sustainable model that can be successfully replicated in other countries and other disease areas and we are reviewing where else it might be applied.

#### **Disaster relief**

We continue to contribute to disaster relief efforts.

As reported in our 2009 annual report, in January 2010, following the earthquake in Haiti, we donated medicines and contributed \$500,000 to the British Red Cross Emergency Appeal and a further \$100,000 to support their ongoing work to provide shelter and sanitation for those people made homeless. We also made a donation of \$400,000 to Partners In Health towards the building of a new teaching hospital. Following the Chilean earthquake in March 2010, we provided medicines to hospitals in need through the Chile Ministry of Health. We donated \$100,000 to Teleton, a major national Chilean charity, to support a recovery and rebuilding campaign, and \$75,000 to the British Red Cross to provide relief resources and shelter across the population.

Following the floods in Pakistan, we donated \$100,000 to the British Red Cross Emergency Appeal, as well as sending medicines. We also continued to support the British Red Cross disaster response centre in Kuala Lumpur with a further \$100,000. This has enabled them to replenish vital stocks used in response to the Pakistan floods and means they will be able to continue to respond quickly and efficiently to emergencies in the Asia Pacific region.

We are developing an enhanced protocol for working with the British Red Cross to ensure we are best placed to respond in a timely, consistent and effective way to future emergencies as and when they arise.





TB is the leading cause of death in people living with HIV. Together, the two diseases are a deadly combination. In Uganda, there is the added burden of malaria, which causes more illness and death than any other single disease. The diseases are linked but Ugandans with TB/HIV, malaria and other conditions have to attend separate health services for treatment.

Our partnership with the African Medical and Research Foundation (AMREF) is focused on developing a model for the integrated management of TB, HIV/AIDS and malaria that provides a framework for effective and efficient healthcare at local and national levels.

Working in collaboration with the Ugandan government in the districts of Luwero and Kiboga in central Uganda, the partnership has focused on increasing laboratory diagnostic capacity and improving community-based healthcare management. Progress to date includes the completion and handover to local district management teams of four new laboratories and the establishment of 328 village health teams with over 1,300 people trained in health promotion in their local communities. In addition, a study of drug logistics management revealed significant knowledge gaps and out of stock supply problems. Subsequently, 108 health workers have been trained in drug logistics management to help prevent shortages.

## Who is improving my healthcare?





Because health connects us all For more information on our work with AMREF and other partnerships in the developing world go to our website, astrazeneca.com/responsibility.

# Which therapy areas do we focus on? We discover, develop and commercialise medicines for six areas of healthcare:

- > Cardiovascular
- > Gastrointestinal
- > Infection
- > Neuroscience
- > Oncology
- > Respiratory & Inflammation

#### Sales by Therapy Area

	2010				2009		2008
	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m
Cardiovascular	9,403	12	11	8,376	20	25	6,963
Gastrointestinal	6,088	1	_	6,011	(5)	(2)	6,344
Infection and Other	2,176	(17)	(18)	2,631	7	10	2,451
Neuroscience	6,704	7	7	6,237	7	10	5,837
Oncology	4,045	(10)	(12)	4,518	(9)	(7)	4,954
Respiratory & Inflammation	4,099	(1)	(1)	4,132	-	6	4,128
Other businesses	754	(16)	(15)	899	(3)	1	924
Total	33,269	1	-	32,804	4	7	31,601

# **Business Review**

**Financial Statements** 

Additional Information

## **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 to society.

For a list of all our potential new products and product life-cycle developments see the Pipeline by Therapy Area at 27 January 2011 table below and the Development Pipeline table from page 206. For details of patent expiries of our key marketed products, see the Patent expiries section on page 31.

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 178. Details of relevant risks are set out in the Principal risks and uncertainties section from page 96.

Pipeline by Therapy Area at 27 January 2011						
	Phase I	Phase II	Phase III/ Registration	Line extensions		
Cardiovascular	> AZD6714 ▲ > AZD8329 ▲ > AZD7687 ▲ > AZD5658 ◆ > AZD4017 ▲	> AZD1656 ▲	> <i>Brilinta/Brilique</i> ♦ > Dapagliflozin <sup>#</sup>	<ul> <li>&gt; Kombiglyze<sup>™</sup> XR ◆ / Onglyza<sup>™</sup>/metformin IR FDC<sup>#</sup>★</li> <li>&gt; Dapagliflozin/ metformin FDC<sup>#</sup>▲</li> <li>&gt; Onglyza<sup>™</sup> SAVOR<sup>#</sup> ◆</li> <li>&gt; Brilinta PEGASUS-TIMI ◆</li> <li>&gt; Crestor (elevated CRP) ◆</li> <li>&gt; Axanum ▶</li> </ul>		
Gastrointestinal				> Nexium ▲ (peptic ulcer bleeding) > Nexium ◆ (GERD)		
Infection	<ul> <li>&gt; MEDI-534 ▲</li> <li>&gt; MEDI-550 ▲</li> <li>&gt; MEDI-559 ▲</li> <li>&gt; AZD5847 ▲</li> <li>&gt; AZD9742 ▲</li> </ul>	> AZD9773 <sup>#</sup> ▲ > CAZ104 <sup>#</sup> ▲ > Motavizumab <sup>#</sup> ● > CXL104 <sup>#</sup> ★ (CEF104)	> MEDI-3250 + > Zinforo# > (ceftaroline)	> FluMist/Fluenz ▲		
Neuroscience	> AZD3241 ▲ > AZD3043# ▲ > MEDI-578 ◆ > AZD5213 ◆	> AZD3480 <sup>#</sup> ▲ > TC-5214 <sup>#</sup> ◆ > AZD6765 ▲ > TC-5619 <sup>#</sup> ▲ > AZD2066 ▲ > AZD1446 <sup>#</sup> ▲ (chronic neuropathic pain) > AZD2423 + > AZD2066 (MDD) ◆ > NKTR-118 <sup>#</sup> ▲	> <i>Vimovo</i> <sup>#</sup> ♦ > TC-5214 <sup>#</sup> ♥	> Seroquel XR ♦ > Diprivan <sup>#</sup> � > EMLA <sup>#</sup> �		
Oncology	<ul> <li>&gt; AZD2461 ◆</li> <li>&gt; AZD3514 ◆</li> <li>&gt; AZD8055 ▲</li> <li>&gt; AZD7762 ▲</li> <li>&gt; MEDI-573<sup>#</sup> ▲</li> <li>&gt; AZD8330<sup>#</sup> ▲</li> <li>&gt; AZD1480 ▲</li> <li>(ARRY-424704)</li> <li>&gt; AZD24547 ▲</li> <li>&gt; CAT-8015 ▲</li> <li>&gt; AZD2014 ▲</li> <li>&gt; Selumetinib ▲</li> <li>(ARRY-424704)</li> <li>&gt; AZD2014 ▲</li> <li>&gt; MEDI-565 ◆</li> </ul>	> Recentin ▲ > AZD8931 + > Selumetinib <sup>#</sup> ▲ > MEDI-575 <sup>#</sup> + (AZD6244) (ARRY-142886) > Olaparib ▲ > AZD1152 ▲	<ul> <li>&gt; Vandetanib ► (Zactima)</li> <li>&gt; Zibotentan ▲</li> </ul>	> Iressa ▲ > Faslodex ♦		
Respiratory & Inflammation	> AZD9819 <b>*</b> > MEDI-546# ▲ > MEDI-551 <b>*</b> > MEDI-577 ▲	<ul> <li>&gt; AZD1981 ▲</li> <li>&gt; MEDI-528<sup>#</sup> ▲</li> <li>&gt; CAT-354 ▲</li> <li>&gt; AZD8848 ▲</li> <li>&gt; CAM-3001<sup>#</sup> +</li> <li>&gt; AZD3199 ▲</li> <li>&gt; AZD3199 ▲</li> <li>&gt; AZD8683 +</li> <li>&gt; AZD5423 +</li> <li>&gt; MEDI-545<sup>#</sup> ▲</li> <li>&gt; AZD5069 +</li> </ul>	> Fostamatinib#	> Oxis > Symbicort (COPD) > Symbicort (SMART)		

Key Movements since 27 January 2010

- \* Addition
- ▲ No change
- + Progression

# Partnered product Kombiglyze<sup>™</sup> XR in the US; Onglyza<sup>™</sup>/metformin IR FDC in the EU

- New filing Launched Reclassified
- AstraZeneca Annual Report and Form 20-F Information 2010

## Cardiovascular

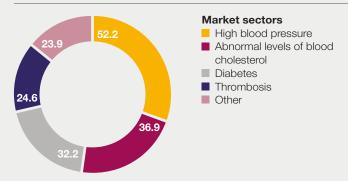


# \$170bn

Cardiovascular is the single largest therapy area in the global healthcare market. Worldwide market value of \$170 billion.

#### Therapy area world market

(MAT/Q3/10) (\$bn)



#### In brief

> Crestor sales up 24% to \$5.7 billion.

- > New indications were approved for *Crestor* in the US and the EU based on data from the landmark JUPITER clinical trial.
- In June, the US District Court for the District of Delaware, decided in AstraZeneca's favour the consolidated ANDA infringement case involving eight ANDA filers seeking approvals for generic *Crestor*. The defendants have appealed the Court's judgment and decision of our patent's infringement, validity and enforceability to the US Court of Appeals for the Federal Circuit.
- > In September, we received a Paragraph IV Certification notice-letter from Watson Laboratories, Inc. (Watson), informing us of its filing of a 505(b)(2) NDA for rosuvastatin zinc tablets and challenging the substance and formulation patents protecting *Crestor*. We commenced a patent infringement action against Watson in October in the US District Court for the District of Delaware.
- > Torrent do Brasil launched its generic versions of *Crestor* in October. AstraZeneca was granted an injunction ordering Torrent do Brasil to discontinue the sale and marketing of these generic products and recall products already on the market. This injunction has subsequently been suspended and the matter is now awaiting the decision of the Court of Appeal which is expected in the first quarter of 2011.
- > Atacand sales up 3% to \$1.5 billion.
- > Toprol-XL US sales down 29% as a result of increased generic competition.

- In December, the European Commission granted a marketing authorisation for *Brilique* (ticagrelor tablets) for the prevention of atherothrombotic events in adult patients with acute coronary syndromes. The decision is applicable to the 27 member states and the three European Economic Area countries of the EU. In the same month, the FDA issued a Complete Response Letter for the *Brilinta* (ticagrelor) NDA. AstraZeneca announced that it had replied to the Complete Response Letter on 21 January 2011.
- > In December, AstraZeneca notified Abbott that it would discontinue development of *Certriad*, a fixed dose combination of the active ingredient in *Crestor* (rosuvastatin calcium) and Abbott's Trilipix<sup>™</sup> (fenofibric acid), which was being co-developed with Abbott for the treatment of mixed dyslipidemia.
- In May, AstraZeneca received a Complete Response Letter from the FDA for the NDA for Axanum, a single capsule of low-dose acetylsalicylic acid (ASA) and esomeprazole. In June, AstraZeneca filed an MAA for Axanum in several countries in the EU for prevention of cardio- and cerebro-vascular events in patients requiring continuous low-dose ASA treatment who are at risk of developing ASA associated gastric and/or duodenal ulcers.
- > In November, AstraZeneca and BMS received FDA approval for Kombiglyze™ XR, a fixed-dose combination of Onglyza™ plus metformin hydrochloride extended-release tablets.
- In December, AstraZeneca and BMS filed regulatory submissions in the US and the EU seeking approval for dapagliflozin, a first-inclass sodium-glucose cotransporter-2 inhibitor, as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes.

#### **Our marketed products**

- > Crestor<sup>1</sup> (rosuvastatin calcium) is a statin used for the treatment of dyslipidaemia and hypercholesterolemia. In some markets it is also indicated to slow the progression of atherosclerosis and to reduce the risk of first cardiovascular (CV) events.
- > Atacand<sup>2</sup> (candesartan cilexetil) is an angiotensin II antagonist used for the 1st line treatment of hypertension and symptomatic heart failure.
- > Seloken/Toprol-XL (metoprolol succinate) is a beta-blocker once-daily tablet used for 24-hour control of hypertension and for use in heart failure and angina.
- > Tenormin (atenolol) is a cardioselective beta-blocker used for hypertension, angina pectoris and other CV disorders.
- > Zestril<sup>3</sup> (lisinopril dihydrate) is an angiotensin-converting enzyme inhibitor used for the treatment of a wide range of CV diseases, including hypertension.
- > Plendil (felodipine) is a calcium antagonist used for the treatment of hypertension and angina.
- > Onglyza<sup>™4</sup> (saxagliptin) is a dipeptidyl peptidase IV inhibitor used 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.
- <sup>4</sup> Co-developed and co-commercialised with BMS.

#### **Our financial performance**

		World			US		estern Euro	ре	Est	ablished R	ow	Eme	erging Mark	tets	Prior year
2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Crestor	5,691	26	24	2,640	26	1,111	15	20	1,332	37	25	608	31	26	4,502
Atacand	1,483	3	3	216	(18)	736	-	4	224	21	8	307	21	17	1,436
Seloken/															
Toprol-XL	1,210	(16)	(17)	689	(29)	91	(11)	(9)	39	(7)	(14)	391	17	13	1,443
Tenormin	276	(7)	(9)	13	(13)	61	(13)	(9)	127	(5)	(10)	75	(4)	(8)	296
Plendil	255	6	4	15	7	27	(34)	(32)	14	8	-	199	15	13	241
Zestril	157	(15)	(14)	10	(44)	81	(23)	(19)	17	(11)	(21)	49	17	14	184
Onglyza™	69	n/m	n/m	54	n/m	10	n/m	n/m	2	n/m	n/m	3	n/m	n/m	11
Others	262	-	(1)	15	(25)	113	(14)	(11)	26	(7)	(14)	108	29	25	263
Total	9,403	12	11	3,652	7	2,230	4	8	1,781	28	16	1,740	22	18	8,376
2009															
	4 500	05	00	0.100	05	000	10	04	070	40	4.4	40.4	10	00	0.507
Crestor	4,502	25	29	2,100	25	968	16	24	970	40	44	464	18	32	3,597
Atacand	1,436	(2)	5	263	-	734	(4)	2	185	(2)	8	254	(1)	13	1,471
Seloken/ Toprol-XL	1,443	79	84	964	227	102	(25)	(18)	42	(13)	(8)	335	2	11	807
	, -					70	( )	( )		( )	( )	78			
Tenormin	296	(5)	(5)	15	(17)		(11)	(6)	133	5	(6)		(12)	-	313
Plendil	241	(10)	(7)	14	(44)	41	(29)	(24)	13	(35)	(30)	173	5	7	268
Zestril	184	(22)	(17)	18	(10)	105	(27)	(22)	19	(21)	(21)	42	(14)	(4)	236
Onglyza™	11	n/m	n/m	11	n/m	-	-	-	-	-	-	-	-	-	-
Others	263	(3)	3	20	n/m	131	(13)	(6)	28	(7)	(10)	84	(7)	2	271
Total	8,376	20	25	3,405	48	2,151	(1)	6	1,390	23	26	1,430	4	15	6,963

#### **Our strategic objectives**

AstraZeneca is one of the world leaders in cardiovascular (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 (cardiac arrhythmia). Despite improvements in the quality of diagnosis and treatment, the unmet medical needs remain high and these disease areas, and their complications, continue to grow worldwide (both in developed and emerging markets) as a consequence of the spread of a westernised lifestyle, resulting in significant healthcare spend and recognised societal consequences.

#### **Cardiovascular diseases**

Hypertension (high blood pressure) and dyslipidaemia (abnormal levels of blood cholesterol) damage the arterial wall which may lead to atherosclerosis. CV events driven by atherosclerotic disease remain the leading cause of death in the western world. Lipidmodifying therapy, primarily statins, is a cornerstone for the treatment of atherosclerosis.

Acute coronary syndromes (ACS) is an umbrella term for sudden chest pain and other symptoms due to insufficient blood supply (ischaemia) to the heart muscle. 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

#### Our key marketed products

Since its launch in 2003, *Crestor* has continued to gain market share based on its differentiated profile in managing cholesterol levels and its more recent label indications for slowing the progression of atherosclerosis and reducing the risk of CV events in some markets. *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.

Fewer than half of the people thought to have high levels of low-density lipoprotein cholesterol (LDL-C) 'bad cholesterol' are diagnosed and treated. Of treated patients, only about half reach their doctor's recommended cholesterol targets using existing treatments. Study data has shown that the usual 10mg starting dose of *Crestor* is more effective at lowering LDL-C and produces greater achievement of LDL-C goals than commonly prescribed doses of other statins. *Crestor* also produces an increase in high-density lipoprotein cholesterol (HDL-C) 'good cholesterol' across the dose range.

In February 2010, the FDA approved *Crestor* to reduce the risk of stroke, myocardial infarction (heart attack) and arterial revascularisation procedures in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease (CVD) based on age (men  $\geq$ 50 and women  $\geq$ 60), high-sensitivity C-reactive protein  $\geq$ 2mg/L, and the presence of at least one additional CVD risk factor, such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease. This approval was based on data from the landmark JUPITER study which evaluated the impact of *Crestor* 20mg on reducing major CV events.

*Crestor* also received approval from 19 countries within the EU for the prevention of major CV events in patients who are at high risk of having a first CV event. This new indication was also based on subgroup data from the JUPITER study. A *post hoc* analysis of this subgroup data showed a significant reduction in the combined endpoint of heart attacks, strokes and CV deaths among the high risk patients who participated in the JUPITER study.

Atacand continues to be an important treatment option for patients with hypertension and symptomatic heart failure. Atacand is approved for the treatment of hypertension in over 105 countries and for symptomatic heart failure in more than 70 countries. Most patients with hypertension fail to reach their treatment goals with the use of a single anti-hypertensive treatment and fixed-dose combinations of two or more anti-hypertensives are commonly prescribed for patients to improve efficacy and attainment of treatment goals. 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 antihypertensive therapy. Atacand Plus is approved in 88 countries.

### **Therapy Area Review**

#### 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.

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 2009. A paediatric indication was also granted in the EU in March 2010.

The SATURN study is ongoing and is designed to measure the impact of *Crestor* 40mg and atorvastatin (Lipitor<sup>™</sup>) 80mg on the progression of atherosclerosis in high-risk patients. We expect to report the results of this study in the fourth quarter of 2011.

The PLANETS I and II studies, which evaluated the effects of *Crestor* 10mg, *Crestor* 40mg and atorvastatin (Lipitor<sup>™</sup>) 80mg on urinary protein excretion in patients with proteinuric renal disease in diabetics and non-diabetics, respectively, have been completed and publication is progressing with initial data from the PLANETS studies being reported in May.

#### In the pipeline

*Brilinta/Brilique* (ticagrelor) is an oral antiplatelet treatment for ACS. Ticagrelor is a direct-acting P2Y12 receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines and is the first reversibly-binding oral adenosine diphosphate (ADP) receptor antagonist.

Results from the Phase III study, PLATO, were announced in August 2009. With 18,624 randomised patients at 864 sites in 43 countries, PLATO ranks as one of AstraZeneca's largest clinical trials ever. It was designed to reflect current medical practice by randomising patients within 24 hours of the index event and following them whether they were medically managed or underwent invasive procedures. PLATO compared ticagrelor to clopidogrel (Plavix™/ Iscover™). The overall PLATO results demonstrated the superiority of ticagrelor versus clopidogrel in reducing heart attacks and CV death in patients with ACS treated for 12 months. The study provided the basis for regulatory filings worldwide.

In December, the European Commission granted marketing authorisation to *Brilique* (ticagrelor tablets) for the prevention of atherothrombotic events in adult patients with ACS. The decision is applicable to the 27 member states and the three European Economic Area countries of the EU.

In the same month, the FDA issued a Complete Response Letter for the *Brilinta* (ticagrelor) NDA. In the Complete Response Letter, the FDA requested further analyses of the PLATO data. The agency did not request that additional studies, including clinical studies, be conducted as a prerequisite for approval of the ticagrelor NDA. AstraZeneca announced that it had replied to the Complete Response Letter on 21 January 2011. The FDA is in the process of reviewing AstraZeneca's response to determine whether the information submitted is complete and whether to designate the review as Class 1, which would start a two-month review, or as Class 2, which would start a six-month review.

*Brilinta* remains under regulatory review in 21 countries, including the US. It has been approved in 30 countries, including in the EU, lceland and Norway, under the trade name *Brilique* and in Brazil under the trade name *Brilinta*. Additional marketing authorisations and regulatory submissions are planned for 2011. In October, AstraZeneca initiated PEGASUS TIMI-54, a 21,000 patient study in over 30 countries. The study examines the ability of ticagrelor plus aspirin to prevent adverse CV events safely compared to aspirin alone in higher-risk patients one to three years after a heart attack. Enrolment for PEGASUS began in December.

Axanum is a single capsule of low-dose acetylsalicylic acid (ASA) and esomeprazole (the active ingredient in Nexium). Low-dose ASA is a mainstay of therapy for patients at high risk of having a CV event such as a heart attack or stroke. Upper gastrointestinal (GI) problems (including ulcers and ulcer-related complications) are the most common reason for discontinuation of low-dose ASA therapy. Up to 30% of patients with upper GI problems discontinue or take deliberate breaks from their low-dose ASA treatment, placing them at risk of a potentially life-threatening CV event as early as eight to 10 days after discontinuation. AstraZeneca filed an MAA for Axanum in June, for prevention of cardio- and cerebro-vascular events in patients requiring continuous low-dose ASA treatment who are at risk of developing ASA associated gastric and/or duodenal ulcers, in several countries in the EU. The submission was based on the results of the OBERON and ASTERIX studies evaluating the efficacy and safety of Nexium in reducing the risk of gastric and/or duodenal ulcers in patients taking continuous low-dose ASA.

In May, AstraZeneca received a Complete Response Letter from the FDA for the NDA for *Axanum*. The Complete Response Letter is currently being evaluated and AstraZeneca will continue discussions with the FDA to determine the next steps with respect to the *Axanum* NDA.

In March 2010, AstraZeneca and Abbott received a Complete Response Letter based on the *Certriad* NDA submission made in June 2009. In December, AstraZeneca notified Abbott that it would discontinue development of *Certriad*, which was being co-developed with Abbott, for the treatment of mixed dyslipidemia. This decision was reached after careful review and consideration of the Complete Response Letter and the ongoing delay in the regulatory review of the *Certriad* NDA which made continuing the development of *Certriad* commercially unattractive. The co-development and licence agreement with Abbott subsequently ended in January 2011.

#### **Diabetes**

The number of people affected by Type 2 diabetes continues to grow, predominantly as a result of 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 biguanides and sulfonylureas. However, newer classes such as oral dipeptidyl peptidase IV (DPP-IV) inhibitors are successfully entering the market by offering effective blood sugar control and improved tolerability. Several new classes of drugs are in development in this area, including sodium-glucose cotransporter-2 inhibitors (SGLT2). CV safety has been given particular emphasis in recent regulatory reviews and guidance documents provided by the FDA and other regulatory authorities.

#### Our focus

#### Our key marketed products

The collaboration on a worldwide basis¹ between AstraZeneca and BMS to develop and commercialise two compounds discovered by BMS (Onglyza™ (saxagliptin) and dapagliflozin) for the treatment of Type 2 diabetes continues to make good progress.

Since its first approval in the US in July 2009, Onglyza<sup>™</sup> has been approved in 48 countries and launched in 34. The MAA for a fixed-dose combination of Onglyza<sup>™</sup> and metformin immediate release tablets as a treatment for adults with Type 2 diabetes remains under review by the EMA.

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

Overview

In November, AstraZeneca and BMS received FDA approval for Kombiglyze™ XR, a fixed-dose combination of Onglyza™ plus metformin hydrochloride extended-release tablets. Kombiglyze™ XR is the first and only once-a-day metformin extended release plus DPP-IV inhibitor combination tablet providing strong comprehensive glycaemic control across glycosylated haemoglobin levels (HbA1c), fasting plasma glucose and post-prandial glucose. Full commercial launch is anticipated to take place in the first quarter of 2011.

#### In the pipeline

Dapagliflozin, an investigational compound, is a potential first-inclass SGLT2 inhibitor under joint development with BMS as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes. Our extensive global Phase III programme evaluated dapagliflozin as initial therapy and as an add-on to other widely used anti-diabetic treatments. Reported data from five pivotal Phase III studies now in the public domain suggest a product profile that is encouraging, consistent, and with differentiated patient benefits, including the potential to be the first oral agent to provide HbA1c reduction, along with secondary benefits of weight loss and a reduction in blood pressure. In the Phase III studies, genital infections and urinary tract infections were generally higher in the dapagliflozin group but mild or moderate in nature, responded to an initial course of standard treatment and rarely led to discontinuation.

In December, AstraZeneca and BMS filed an NDA and an MAA with the FDA and the EMA for dapagliflozin as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes.

Our activities in the glucokinase activator (GKA) area continued during 2010 and Phase II studies for AZD1656 are ongoing. The GKA mechanism of action is believed to induce insulin release from the pancreas and reduce glucose output from the liver resulting in marked reductions in blood glucose in hyperglycaemic Type 2 diabetics. During 2010, we also progressed our AZD8329 and AZD7687 projects in 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.

#### **Atrial fibrillation**

Atrial fibrillation (AF) is the most common cardiac arrhythmia. Rhythm-control therapy to manage 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.

#### 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 activities in this area are in pre-clinical development.

Development of AZD0837, a direct thrombin inhibitor that was in Phase II testing for the prevention of strokes and other embolic events in AF patients, has been discontinued.

#### Financial performance 2010/2009

#### Performance 2010

#### Reported performance

CV sales grew by 12% to \$9,403 million in 2010 from \$8,376 million in 2009, driven by the continuing growth in *Crestor*.

#### Performance – CER growth rates

CV sales were up 11%.

Global sales of *Crestor* were up 24%. US sales for *Crestor* increased by 26% to \$2,640 million. *Crestor* sales outside the US were up 23% to \$3,051 million, with sales in Established ROW up 25%, including good growth in Canada (25%), Japan (25%) and Other Established ROW (23%). Sales in Western Europe were up 20%, driven by good growth in France, Italy and Spain. Sales in Emerging Markets were up 26%.

Sales of *Seloken/Toprol-XL* decreased 17%. US sales of the *Toprol-XL* product range, which includes sales of the authorised generic, decreased by 29% to \$689 million as a result of further generic competition, although this was partially offset by 13% growth in Emerging Markets to \$391 million.

*Atacand* sales were up 3%, despite US sales being down 18%, as a result of strong growth in Established ROW (8%) and Emerging Markets (17%).

Alliance revenue from the Onglyza<sup>™</sup> collaboration with BMS totalled \$69 million, comprising \$54 million in the US and \$15 million in other markets.

#### Performance 2009

#### **Reported performance**

CV sales were up 20% 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.

*Crestor* sales increased by 29% to \$4,502 million. US sales for *Crestor* 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% 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 sales growth in Established ROW markets up 44% 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.

Sales of *Atacand* in the US were unchanged from 2008 at \$263 million and accounted for 18% of global *Atacand* sales. *Atacand* sales were up 13% in Emerging Markets.

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

## Gastrointestinal

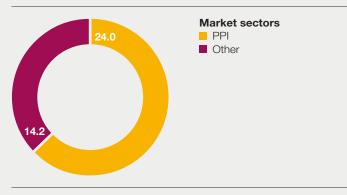


# \$38bn

The gastrointestinal market is valued at \$38 billion, with the proton pump inhibitor market accounting for \$24 billion.

#### Therapy area world market

(MAT/Q3/10) (\$bn)



#### In brief

- > Sales of Nexium \$5 billion, unchanged from the previous year.
- > Losec/Prilosec sales up 1% to \$986 million.
- In February 2010, AstraZeneca submitted Nexium for approval in Japan, the only major market yet to launch, and in October, we entered into an agreement with Daiichi Sankyo for the co-promotion and supply of Nexium in Japan.
- > AstraZeneca received a Complete Response Letter from the FDA in May for the sNDA for *Nexium* for the risk reduction of low-dose aspirin-associated peptic ulcers.
- In October, AstraZeneca filed requests for preliminary injunctions to restrain six companies from marketing and selling generic forms of *Nexium* in Germany. The court rejected the requests in December. The decision has not yet been published. AstraZeneca has four weeks from the date of publication of the decision to determine whether or not it will appeal the decision.

- In January 2010, AstraZeneca entered into an agreement with Teva Pharmaceutical Industries Ltd. and affiliates (Teva) to settle patent litigation regarding Teva's ANDA submission for a generic version of *Nexium* delayed-release capsules. Under the agreement, AstraZeneca has granted Teva a licence for its ANDA product to enter the US market, subject to regulatory approval, on 27 May 2014.
- In June, the Federal Court of Canada dismissed AstraZeneca's request to prohibit the Canadian Minister of Health from issuing a Notice of Compliance for the regulatory applications for generic esomeprazole magnesium submitted by Apotex Inc. (Apotex). In October, AstraZeneca commenced a patent infringement action against Apotex alleging infringement of five Canadian patents related to Nexium.
- In January 2011, AstraZeneca entered into a settlement agreement with Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (together, DRL) regarding DRL's ANDA submission for a generic version of *Nexium* delayed-release capsules. Under the agreement, AstraZeneca has granted DRL a licence for its ANDA product to enter the US market, subject to regulatory approval, on 27 May 2014.
- > Thirteen third parties have opposed the grant of a European patent covering Nexium, which is due to remain in force until 2014. The patent includes claims to Nexium of very high optical purity and has been asserted by AstraZeneca in litigation against generic companies in Europe. While the European Patent Office has not yet set a date for the oppositions to be heard, a hearing could occur in the first half of 2011.

#### **Our marketed products**

- > Nexium (esomeprazole) is the first proton pump inhibitor (PPI) used 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 used for the treatment of inflammatory bowel disease.

#### **Our financial performance**

		World			US		Western Europe			ablished R	ow	Eme	Prior year		
2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Nexium	4,969	-	-	2,695	(5)	1,202	(2)	2	453	17	4	619	21	18	4,959
Losec/Prilosec	986	4	1	47	(28)	253	(3)	(2)	437	6	(1)	249	19	16	946
Others	133	25	26	76	49	45	-	2	6	-	(17)	6	50	75	106
Total	6,088	1	-	2,818	(4)	1,500	(2)	1	896	12	1	874	20	17	6,011
2009															
Nexium	4,959	(5)	(1)	2,835	(9)	1,225	(1)	7	386	-	10	513	7	15	5,200
Losec/Prilosec	946	(10)	(10)	64	(63)	261	(12)	(3)	411	6	(1)	210	3	6	1,055
Others	106	19	24	51	55	45	(2)	4	6	-	-	4	-	25	89
Total	6,011	(5)	(2)	2,950	(11)	1,531	(3)	5	803	3	4	727	6	13	6,344

#### **Our strategic objectives**

We aim to develop our position in gastrointestinal (GI) treatments by continuing to focus on our existing proton pump inhibitors.

#### Our focus

#### Our key marketed products

Nexium is marketed in approximately 120 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. In the EU 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 EU and other markets for the maintenance of haemostasis and prevention of re-bleeding of gastric or duodenal ulcers.

*Nexium i.v.* is used when oral administration is not suitable for the treatment of GERD and upper GI side effects induced by NSAIDs. It is 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. *Nexium i.v.* has been submitted to the EMA and the FDA for use in children one to 17 years of age inclusive and their review is ongoing.

In May, AstraZeneca received a Complete Response Letter for the sNDA for *Nexium* which was submitted for the risk reduction of low-dose aspirin-associated peptic ulcers. AstraZeneca is currently evaluating the Complete Response Letter and will continue discussions with the FDA to determine the next steps with respect to the *Nexium* sNDA.

*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 with antacids and H2 receptor antagonists.

#### Clinical studies of key marketed products

The Japanese new drug application for *Nexium* was submitted in February 2010 and the regulatory review process is ongoing. In October, AstraZeneca entered into an agreement with Daiichi Sankyo for the co-promotion and supply of *Nexium* in Japan. Under the terms of the agreement, AstraZeneca and Daiichi Sankyo will co-promote the product after it has been approved for use in Japan. AstraZeneca will manufacture and develop the product and Daiichi Sankyo will be responsible for its distribution. Daiichi Sankyo has made an initial payment of \$100 million to AstraZeneca and will pay further sums when the product is approved and sales target milestones are achieved.

#### In the pipeline

Our research activities have focused on reflux inhibitors and hypersensitivity therapy. Our lead compound, lesogaberan (AZD3355) was terminated because of dose-finding data showing insufficient efficacy to deliver a meaningful clinical improvement in the study population for which the treatment was intended. Based on the findings in the lesogaberan programme, our discovery and development activities in the GERD area that are based on reflux inhibition will be terminated.

#### Financial performance 2010/2009

#### Performance 2010 Reported performance

GI sales grew by 1% to \$6,088 million in 2010 from \$6,011 million in 2009.

#### Performance – CER growth rates

Global GI sales were unchanged. This was due to *Nexium* sales being unchanged from 2009 at \$4,969 million and *Losec/Prilosec* sales showing a small increase of 1% to \$986 million. *Nexium* sales in the US were down 5% to \$2,695 million, although this was offset by sales outside the US which were up 6% to \$2,274 million.

#### Performance 2009

#### Reported performance

GI sales for 2009 were down 5% to \$6,011 million from \$6,344 million in 2008.

#### Performance – CER growth rates

GI sales fell by 2%.

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 Established ROW (10%), Western Europe (7%) and Emerging Markets (15%).

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 unchanged.

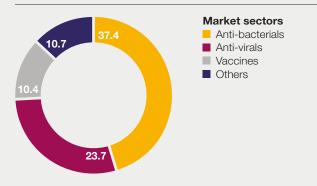
## Infection



# **\$82bn**

The world infection market is valued at \$82 billion, with anti-bacterials accounting for approximately 46%, anti-virals for 29% and vaccines 13%.

## Therapy area world market (MAT/Q3/10) (\$bn)



#### In brief

- > Synagis sales of \$1 billion; in the US \$646 million, down 17%.
- > Merrem/Meronem sales of \$817 million, down 7%.
- > FluMist sales of \$174 million, up 20%.
- > In December, the biological license application submitted to the FDA relating to motavizumab was withdrawn and AstraZeneca recorded a financial impairment charge of \$445 million.
- > Zinforo (ceftaroline) was submitted for marketing approval in the EU in December for the treatment of complicated skin and soft tissue infections as well as for community acquired pneumonia.
- > Initiation of Phase IIb study with AZD9773 (formerly known as CytoFab<sup>™</sup>).

#### **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/Fluenz (influenza vaccine live, intranasal) is an intranasal live, attenuated, trivalent influenza vaccine.
- > 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.
- <sup>2</sup> Licensed from Cubist Pharmaceuticals, Inc.

#### **Our financial performance**

		World			US		stern Euro	ре	Esta	ablished R	ow	Eme	erging Marl	kets	Prior year
2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Synagis	1,038	(4)	(4)	646	(17)	392	31	31	-	-	-	-	-	-	1,082
Merrem	817	(6)	(7)	127	(28)	328	(9)	(7)	57	10	(4)	305	8	4	872
FluMist	174	20	20	173	19	-	-	-	-	-	-	1	-	-	145
Non Seasonal Flu	39	(90)	(90)	39	(90)	_	-	_	-	_	_	_	-	_	389
Others	108	(24)	(25)	68	(16)	-	(100)	(93)	20	(5)	(43)	20	54	92	143
Total	2,176	(17)	(18)	1,053	(33)	720	4	6	77	5	(15)	326	11	8	2,631
2009															
Synagis	1,082	(12)	(12)	782	(15)	300	(2)	(2)	-	-	-	-	-	-	1,230
Merrem	872	(3)	5	177	(14)	361	5	13	52	8	19	282	(5)	6	897
FluMist	145	3	9	<b>9</b> 45	39	-	-	-	-	-	_	-	_	-	104
Non Seasonal															
Flu	389	n/m	n/m	389	n/m	-	-	-	-	-	-	-	-	-	-
Others	143	(35)	(31)	82	(29)	27	(61)	(55)	19	19	31	15	(25)	(15)	220
Total	2,631	7	10	1,575	17	688	(5)	-	71	11	22	297	(6)	5	2,451

#### **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/Meronem*, *FluMist/Fluenz* and Cubicin<sup>TM</sup>, as well as through the development of products in the pipeline such as *Zinforo* (ceftaroline). We also aim to make effective use of our structural and genomic-based discovery technologies and antibody platforms, vaccines and continued research into novel approaches in areas of unmet medical need.

#### **Resistant bacterial infections**

World demand for antibiotics remains high and will continue to grow 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.

#### Our focus

#### Our key marketed products

*Merrem/Meronem* remains the leading carbapenem anti-bacterial across AstraZeneca licensed territories, maintaining over a 7% share of the global intravenous antibiotic market (by value), despite experiencing loss of market exclusivity in the US in June. Generic growth across the carbapenem class is anticipated over the next 12 months following the patent expiries for *Merrem/Meronem* in Europe and the US.

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, Europe and the Middle East.

#### In the pipeline

Zinforo (ceftaroline) is a novel injectable cephalosporin with the potential to provide coverage against Gram-positive organisms and commonly susceptible Gram-negative organisms associated with community-acquired bacterial pneumonia (CABP) and complicated skin and soft tissue infections. In particular, ceftaroline is active against methicillin-resistant staphylococcus aureus (MRSA). Ceftaroline is being developed in collaboration with Forest and it received FDA approval for ceftaroline in October for the treatment of acute bacterial skin and skin structure infections and CABP caused by designated susceptible bacteria. Forest will use the brand name Teflaro<sup>™</sup> (ceftaroline) in the US. AstraZeneca is responsible for registration and marketing outside the US, Canada and Japan and filed an MAA for the 27 member states of the EU in December. We expect to make further submissions in other jurisdictions during 2011. In the first half of 2010, we completed the acquisition of Novexel and we are working with our partner, Forest, on future joint global development programmes, including CAZ-104 (a combination of ceftazidime and NXL-104). CAZ-104 is currently in Phase II evaluation for the treatment of complicated intra-abdominal infection and complicated urinary tract infection and a decision whether to proceed into Phase III will be taken during 2011.

To meet the high and growing need for new and better therapies for resistant bacterial infections we have built an anti-bacterials discovery capability which will ensure that AstraZeneca has the resource to create novel mechanism anti-bacterials. Out of this work, a candidate anti-bacterial drug, AZD9742, with a novel mechanism of action, completed Phase I testing late in 2010 and Phase II plans are under evaluation. A second candidate antibacterial drug, AZD5099, is expected to enter Phase I in the first half of 2011.

#### **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. 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 increased risk of contracting severe RSV disease than full-term healthy 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 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

Motavizumab is an investigational MAb that was being considered to help prevent RSV disease. In December, we discontinued further development of motavizumab for the prophylaxis of serious RSV disease and requested the withdrawal of the biological license application (BLA) which was pending at the FDA. As a result of this decision, AstraZeneca incurred a financial impairment charge of \$445 million. Although we have discontinued certain motavizumab development paths and withdrawn the prophylaxis BLA from the FDA, motavizumab remains in development for RSV treatment.

### **Therapy Area Review**

We are developing a live intranasal vaccine for the prevention of lower respiratory tract illness caused by RSV in otherwise healthy infants. Two vaccine candidates are in clinical development: MEDI-559 and MEDI-534.

#### Influenza virus

Influenza is the most common vaccine-preventable 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 a trivalent live, attenuated nasally delivered vaccine approved for the prevention of disease caused by influenza virus subtypes A and B in eligible children and adults. *FluMist* is now approved for eligible individuals in the US, South Korea, Canada, Hong Kong, Israel, Macau and Brazil.

#### In the pipeline

We are developing a quadrivalent live, attenuated influenza vaccine to include a fourth virus strain to provide additional seasonal protection and are expecting to submit the BLA for regulatory approval in the US in 2011.

In October, *Fluenz* (the trade name for *FluMist* in the EU) received a positive opinion in the EU from the CHMP for marketing the product in Europe for children from 24 months to less than 18 years of age. The Committee's positive opinion is now referred for a final decision by the European Commission, which is anticipated in early 2011.

#### Sepsis

Sepsis is a life-threatening condition resulting from uncontrolled severe infections. It remains a significant problem in medical management, with approximately three million annual worldwide incidents and a 30% mortality rate. Current treatment options for patients with severe sepsis or septic shock are extremely limited and, although industry pipelines are focused on the development of products specifically for registration for the treatment of sepsis or septic shock, there are few products in late stage development.

#### In the pipeline

The development programme for AZD9773 (formerly known as CytoFab<sup>™</sup>), an anti-TNF α polyclonal antibody, our potential treatment for severe sepsis licensed from Protherics Inc. (now part of the BTG plc group), continues in Phase II development with the initiation of a global Phase IIb trial in October. We also submitted a separate Phase II study of AZD9773 in Japan. AZD9773 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 new, improved treatments for TB. We have a dedicated research facility in Bangalore, India focused on finding drugs that will act on multi-resistant strains, will 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 work 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.

TB remains a complex research area in which collaborations play a very important role. This year, a discovery collaboration was signed with the Global Alliance for TB Drug Development towards progressing suitable compounds through to the lead optimisation stage. Additionally, we were awarded a Wellcome Trust grant under the 'R&D for Affordable Healthcare in India' initiative, which will be used to identify novel lead molecules for the treatment of TB. Our most advanced programme, AZD5847 (a novel oxazolidinone antibiotic), continues in Phase I studies, although single- and multiple-ascending dose studies in healthy volunteers are complete.

#### Financial performance 2010/2009

#### Performance 2010 Reported performance

Infection sales were down 17% to \$2,176 million from \$2,631 million in 2009.

#### Performance – CER growth rates

Infection sales were down 18% as the sales of the H1N1 pandemic influenza vaccine in 2009 were not repeated in 2010. There were only \$39 million of sales recorded in 2010 for US government orders for the H1N1 pandemic influenza vaccine. These sales were recorded in the first quarter of 2010 and compare with \$389 million of sales in 2009. This strain has now been incorporated into the traditional seasonal influenza vaccine.

FluMist sales were \$174 million, a 20% increase over last year.

Global Synagis sales were down 4%, with sales in the US down 17% to \$646 million being partially offset by strong growth in Western Europe where sales were up 31% to \$392 million.

#### Performance 2009

#### Reported performance

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

#### Performance – CER growth rates

Infection sales were up 10%. This was driven by sales of \$389 million for the H1N1 pandemic 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 was 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.

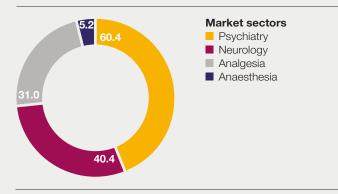
## Neuroscience



# **\$137bn**

The neuroscience world market totals \$137 billion.

#### Therapy area world market (MAT/Q3/10) (\$bn)



### In brief

- > Total Seroquel sales up 9% to \$5.3 billion.
- > In August, the European Commission approved Seroquel XR as an add-on treatment of major depressive episodes in patients with major depressive disorder (MDD) who have had sub-optimal response to anti-depressant monotherapy.
- > Seroquel XR submissions for generalised anxiety disorder (GAD) were withdrawn in the US in July and from the European Mutual Recognition Procedure in October.
- > The first patients were enrolled in the MDD Adjunct Phase III clinical development programme for TC-5214, a neuronal nicotinic receptor modulator, being developed with Targacept, in June.
- In April 2010, the FDA approved Vimovo (naproxen/esomeprazole magnesium) for arthritis patients at risk of developing NSAIDassociated gastric ulcers. In October, EU approval was received for Vimovo for the symptomatic treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients who are at risk of developing NSAID-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient.
- > As previously disclosed, in 2010, AstraZeneca reached a civil settlement with the US Attorney's Office (Department of Justice) and the state attorneys general National Medicaid Fraud Control Unit (NMFCU) to resolve an investigation relating to the marketing of Seroquel, pursuant to which AstraZeneca paid to the United States Federal Government a fine of \$302 million plus accrued interest and to participating states a proportional share of up to \$218 million

plus accrued interest. In September, AstraZeneca entered into individual settlement agreements with 41 states and Washington, D.C. for an aggregate amount of approximately \$210 million.

- In 2010, AstraZeneca reached agreements in principle on monetary terms with attorneys representing 24,591 Seroquel product liability claimants. AstraZeneca has made provisions in the year totalling \$592 million in respect of the ongoing Seroquel product liability litigation and state attorney general investigations into sales and marketing practices in the aggregate. For further details relating to Seroquel product liability claims and state attorney general investigations into Seroquel sales and marketing practices, see Note 25 to the Financial Statements from page 178.
- In January 2011, the US District Court for the District of New Jersey scheduled a trial date of 3 October 2011 in the consolidated seven ANDA patent litigations relating to Seroquel XR. The District Court also entered a stipulation and consent order concerning US Patent No. 4,879,288 (the '288 patent), one of the two patents-in-suit, staying litigation between AstraZeneca and Handa Pharmaceuticals, LLC (Handa) concerning the '288 patent, until and including 26 March 2012, the date AstraZeneca's paediatric exclusivity relating to its '288 patent expires. After expiration of the stay, AstraZeneca's infringement claims against Handa relating to the '288 patent, and Handa's related counterclaims, will be dismissed as moot. Under the stipulation, Handa agrees not to engage in the commercial sale of its generic extended release quetiapine fumarate products until after 26 March 2012.

#### **Our marketed products**

- Seroquel IR (quetiapine fumarate) is an atypical anti-psychotic drug generally 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, MDD and in some territories for GAD. Approved use for Seroquel IR and Seroquel XR varies based on territory.
- > Vimovo (naproxen/esomeprazole magnesium) is a fixed-dose combination of enteric-coated naproxen (an NSAID) with the gastroprotection of immediate release esomeprazole (a proton pump inhibitor) approved for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.
- > 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 used as 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 used as a local anaesthetic for topical application.

### **Therapy Area Review**

#### Our financial performance

	World			U	S	We	stern Euro	ре	Esta	ablished R	ow	Eme	rging Marl	ets	Prior year
2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Seroquel IR	4,148	(1)	(1)	3,107	1	560	(14)	(11)	223	10	1	258	7	-	4,171
Seroquel XR	1,154	66	67	640	87	359	30	36	61	85	67	94	114	109	695
Local Anaesthetics	605	1	(1)	29	(28)	265	(4)	(1)	186	9	(1)	125	13	8	599
Zomig	428	(1)	(2)	176	(3)	172	(4)	(2)	69	17	8	11	(15)	(23)	434
Diprivan	322	11	8	45	-	50	(19)	(16)	76	29	20	151	22	17	290
Others	47	(2)	(4)	6	(25)	27	(7)	(7)	3	-	-	11	38	25	48
Total	6,704	7	7	4,003	8	1,433	(3)	-	618	17	7	650	20	14	6,237
2009															
Seroquel	4,866	9	12	3,416	13	928	9	17	236	(24)	(24)	286	6	18	4,452
Local Anaesthetics	599	(1)	4	40	18	277	(4)	3	171	5	4	111	(7)	5	605
Zomig	434	(3)	_	182	(3)	180	(5)	3	59	2	2	13	(7)	7	448
Diprivan	290	4	6	45	15	62	(19)	(14)	59	_	(7)	124	20	26	278
Others	48	(11)	(4)	8	(11)	29	(12)	(3)	3	(25)	(25)	8	-	13	54
Total	6,237	7	10	3,691	12	1,476	2	10	528	(11)	(12)	542	5	16	5,837

#### **Our strategic objectives**

There is still significant unmet medical need in the areas of chronic pain, cognitive disorders and other serious central nervous system disorders. Our aim is to strengthen our position in neuroscience through further growth of *Seroquel IR* and *Seroquel XR* and to discover and develop new drug candidates with meaningful therapeutic advantages primarily in Alzheimer's disease, pain control and cognition.

#### **Psychiatry**

The depression market is currently dominated by selective serotonin re-uptake inhibitors and serotonin norepinephrine re-uptake inhibitors. With increasing payer pressure and the need to demonstrate clear value, new medicines must either show superior efficacy over current treatments, or clear efficacy in well-defined patient segments, such as treatment-resistant depression. 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 for depression.

We continue to pursue projects in clinical development aiming to address present unmet medical needs. While no further internal discovery projects, beyond support to existing development projects, are planned, we continue to pursue additional opportunities through external alliances.

#### Our focus

#### Our key marketed products

Seroquel IR is an atypical anti-psychotic drug with anti-depressant properties. It is approved for the treatment of schizophrenia and bipolar disorder (mania, depression and maintenance). Its overall clinical efficacy and tolerability profile make it one of the leading atypical anti-psychotics in terms of global value share in the atypical anti-psychotic market segment.

To date, *Seroquel XR* has been approved in 72 countries for schizophrenia, 57 countries for bipolar mania, 49 countries for bipolar depression, 33 countries for bipolar maintenance, six countries for major depressive disorder (MDD) and three countries for generalised anxiety disorder (GAD). Following referral to the CHMP, *Seroquel XR* was approved as an add-on treatment for major depressive episodes in patients with MDD who have had sub-optimal response to anti-depressant monotherapy. The first EU approvals were granted in August and launches have already occurred in key markets such as Germany and the UK. Local

approval processes continue to progress in the remaining EU member states that took part in the original Mutual Recognition Procedure with other EU member states to follow.

The Seroquel XR GAD submissions were withdrawn in the US in July and from the European Mutual Recognition Procedure in October.

#### In the pipeline

With our development partner, Targacept, we have commenced the Phase III clinical development programme for TC-5214, a neuronal nicotinic receptor modulator. The programme is designed to support filing of an NDA in the second half of 2012 for TC-5214 as an adjunct treatment for MDD in patients with an inadequate response to 1st line anti-depressant treatment. An MAA in Europe is currently planned for 2015.

Decisions on the further development of AZD2066 will be determined following subsequent analyses of data from a Phase II study in depression. AZD6765 remains in Phase II development to address the needs of patients with severe treatment resistant depression. Development of AZD6280, AZD8418 and AZD7268 has been discontinued.

#### Analgesia and anaesthesia (pain control)

The small number of currently approved products in the neuropathic pain market will become generic between 2014 and 2017. However, few new products are in development and the unmet medical need for improvements in both efficacy and tolerability is such that the market remains highly attractive. In Asia, neuropathic pain drugs are gaining approval, shifting cultural and medical treatment barriers. It is believed that advances in the understanding of the mechanisms which lead to neuropathic pain will allow for improved patient segmentation, potentially increasing the success rate of research in this condition.

The chronic nociceptive pain market, including osteoarthritis (OA) and chronic low back pain, is steadily growing due to ageing populations combined with longer life expectancy across all regions, including Asia. Opioids are considered the gold standard for efficacy for moderate to severe pain across pain segments. However, opioid pain control comes with unwanted side effects such as bowel dysfunction. There remains a high unmet medical need for products that enable continued opioid pain control by reducing or eliminating side effects. Led by the anti-nerve growth factor MAbs, biologics are an emerging treatment option for pain control and this is an area in which we have an active interest through our biologics capabilities.

#### Our focus

#### Our key marketed products

*Vimovo* (naproxen/esomeprazole magnesium), co-developed by AstraZeneca and Pozen Inc., is a fixed-dose combination of enteric-coated naproxen (an NSAID) with the gastroprotection of immediate release esomeprazole (a proton pump inhibitor) approved for the relief of signs and symptoms of OA, rheumatoid arthritis (RA), and ankylosing spondylitis (AS), and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. Following approval by the FDA in April 2010, *Vimovo* was launched in the US in July.

In October 2009, AstraZeneca filed an MAA in the EU via the Decentralised Procedure and in October 2010, received positive agreement for approval in 23 countries. *Vimovo* is indicated for the symptomatic treatment of OA, RA and AS in patients who are at risk of developing NSAID-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient. Each EU member state is now pursuing pricing and reimbursement and national approvals.

#### In the pipeline

NKTR-118, an oral peripherally-acting 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, and 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. The NKTR-118 Phase III programme is planned to start in the first half of 2011.

AZD2066 has progressed through Phase IIa studies and AZD2423 has progressed into Phase IIa studies for the treatment of neuropathic pain.

#### 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 doctors consider inadequate, target the symptoms, not the underlying cause, of the disease. This area continues to grow, 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' (as well as 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 stimulants (mostly amphetamines and methylphenidate). We continue to work on treatment options that would offer strong efficacy without the challenges that current treatments bring or which would target symptoms not addressed by today's medications. We also hope to offer new options to adult ADHD patients, many of whom remain undiagnosed or untreated today.

#### In the pipeline

The current portfolio of potential medicines in this area includes three compounds in Phase II development for 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.

<sup>1</sup> Decision Resources 2008.

Through our collaboration with the Karolinska Institute in Sweden, the Banner Alzheimer's Institute in the US, the National Institute of Radiological Sciences in Japan 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 one F-18 and two C-11 amyloid PET ligands which are being developed as research biomarkers. Additionally, collaboration with the Mental Health Research Institute in Australia is ongoing to develop new ways of identifying AD patients at early stages of the disease.

Compounds in Phase II development include products deriving from our relationship with Targacept (AZD3480, AZD1446 and the option compound TC-5619). AZD3480, an  $\alpha$ 482 neuronal nicotinic receptor (NNR) agonist, 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. Non-clinical assessment of therapeutic margin is ongoing, with a decision whether to advance as a treatment for ADHD expected in the first quarter of 2011. AZD1446, another  $\alpha$ 482 NNR agonist, is in development for AD but it is not progressing in ADHD due to failure to meet the primary outcome measure in a recent Phase IIa study in adult ADHD. The option compound from Targacept, TC-5619 (an  $\alpha$ 7 NNR agonist), is in Phase IIa studies in CDS and ADHD and studies are in the process of being designed for AD.

#### Financial performance 2010/2009

#### Performance 2010

#### **Reported performance**

Neuroscience sales were up 7% to \$6,704 million, up from \$6,237 million in 2009.

#### Performance - CER growth rates

Neuroscience sales were up 7%.

Seroquel sales were up 9% to \$5,302 million, with Seroquel XR sales up 67% to \$1,154 million, partially offset by a 1% decline in Seroquel IR sales to \$4,148 million. US sales of Seroquel were \$3,747 million, 10% ahead of last year, with Seroquel XR sales up 87% to \$640 million and Seroquel IR up 1% to \$3,107 million. For 2010, Seroquel sales outside the US increased by 7% to \$1,555 million.

#### Performance 2009

#### Reported performance

Neuroscience sales grew by 7% to \$6,237 million in 2009 from \$5,837 million in 2008.

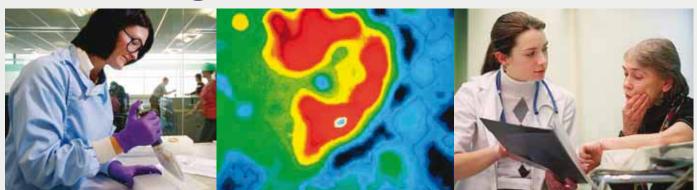
#### Performance – CER growth rates

Neuroscience sales grew by 10% to \$6,237 million from \$5,837 million last year.

US sales for *Seroquel* were \$3,416 million, 13% ahead of last year. *Seroquel* sales outside the US increased by 8% to \$1,450 million. Outside the US and Canada, value and volume growth for *Seroquel* were well ahead of the atypical anti-psychotic market.

Sales of *Zomig* were down 3% in the US to \$182 million. Sales outside the US were up 3% to \$252 million.

## Oncology

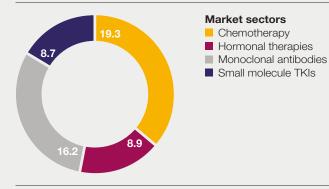


# \$53bn

The world market value for cancer therapies is \$53 billion and continues to grow.

#### Therapy area world market

(MAT/Q3/10) (\$bn)



#### In brief

- > Arimidex sales down 22% to \$1.5 billion, impacted by patent expiry in the US in June. However, market exclusivity has been extended in many EU markets from August 2010 to February 2011.
- > Zoladex sales \$1.1 billion, unchanged from the previous year.
- > Casodex sales \$579 million, down 34%, as a result of generic competition in the US, Western Europe and Japan.
- > Iressa sales \$393 million, up 28%, having been launched in the EU as the first approved personalised medicine for the treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of the epidermal growth factor receptor-tyrosine kinase (EGFR-TK). In January 2011, AstraZeneca informed the FDA that it will be withdrawing the accelerated approval NDA for *Iressa*.
- > Vandetanib has been submitted for regulatory approval for the treatment of unresectable, locally advanced medullary thyroid cancer in the US and the EU. In January 2011, the FDA extended the time to complete its review of the vandetanib NDA by three months to 7 April 2011.
- > Recentin (cediranib) did not meet its primary endpoints in two pivotal studies examining cediranib in 1st line metastatic colorectal cancer (mCRC) and a third pivotal study in recurrent glioblastoma (rGBM) and therefore no regulatory submissions will be filed in 1st line mCRC or rGBM. However, studies continue in NSCLC.
- > Zibotentan (ZD4054) did not demonstrate a significant improvement in overall survival in a Phase III study in patients with metastatic castration resistant prostate cancer (CRPC). Therefore, no regulatory submissions for zibotentan are planned at this time. However, clinical studies continue in other CRPC settings.
- > Olaparib (AZD2281) is in ongoing Phase II studies for the treatment of certain types of breast and ovarian cancer and a decision in relation to Phase III studies has been delayed until later in 2011.

#### **Our marketed products**

- > Arimidex (anastrozole) is an aromatase inhibitor used for the treatment of early breast cancer.
- > Zoladex (goserelin acetate implant), in one- and three-month depots, is a luteinising hormone-releasing hormone agonist used for the treatment of prostate cancer, breast cancer and certain benign gynaecological disorders.
- > Casodex (bicalutamide) is an anti-androgen therapy used for the treatment of prostate cancer.
- Iressa (gefitinib) is used as 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 used for the treatment of hormone receptor-positive metastatic breast cancer for post menopausal women whose disease has spread following treatment with an antioestrogen medicine.
- > Nolvadex (tamoxifen citrate) remains a widely used breast cancer treatment outside the US.

#### **Our financial performance**

		World		U	S	We	stern Euro	ре	Esta	ablished R	wc	Eme	erging Mark	kets	Prior year
2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Arimidex	1,512	(21)	(22)	494	(44)	580	(7)	(4)	287	10	2	151	(3)	(6)	1,921
Zoladex	1,115	3	-	46	(15)	276	(19)	(17)	451	8	-	342	24	23	1,086
Casodex	579	(31)	(34)	16	(89)	113	(39)	(37)	347	(14)	(18)	103	(6)	(8)	844
Iressa	393	32	28	4	(20)	49	600	643	182	15	9	158	24	20	297
Others	446	21	21	161	27	135	14	19	61	9	4	89	29	25	370
Total	4,045	(10)	(12)	721	(41)	1,153	(10)	(7)	1,328	3	(4)	843	15	12	4,518
2009															
Arimidex	1,921	3	7	878	16	626	(9)	-	261	5	-	156	(8)	3	1,857
Zoladex	1,086	(5)	-	54	(25)	341	(10)	1	416	6	-	275	(6)	6	1,138
Casodex	844	(33)	(34)	148	(49)	185	(60)	(56)	402	6	(5)	109	(12)	(1)	1,258
Iressa	297	12	8	5	(29)	7	250	250	158	22	9	127	1	4	265
Others	370	(15)	(13)	127	(37)	118	2	9	56	4	(7)	69	6	20	436
Total	4,518	(9)	(7)	1,212	(9)	1,277	(22)	(15)	1,293	7	(1)	736	(5)	5	4,954

#### **Our strategic objectives**

We aim to build on our position as one of the world leaders in cancer treatment established with brands such as *Arimidex* and the growing brands *Faslodex* and *Iressa*. Our future growth will be driven through targeting the right treatments, both small molecules and biologics, to the right patients, using companion diagnostics where appropriate. This approach is driving the growth of *Iressa* and is a key focus in the development of our early stage portfolio.

#### **Our focus**

#### Our key marketed products

*Arimidex*, first launched in 1995, remains the leading hormonal therapy for patients with early breast cancer globally. 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. In Europe, supplementary protection certificate extensions were applied for under the EU paediatric regulation and subsequently granted in all 12 applicable EU countries, including France, Germany, Italy and the UK. The extension provides for an additional six months of market exclusivity from August 2010 to February 2011.

*Faslodex* 500mg is now approved in the EU and the US, replacing the 250mg dose for most patients. It offers an additional, more efficacious, hormonal therapy option for patients with hormonereceptor positive advanced breast cancer, delaying the need for cytotoxic chemotherapy. It is given by once-monthly injections and is approved for the 2nd line treatment of hormone-receptor positive advanced breast cancer in post-menopausal women. In other markets where 250mg is approved, plans are in place to replace the dose with 500mg and, in markets where *Faslodex* is not approved, plans are to seek approval for the 500mg dose as the first registration.

*Casodex* and *Zoladex* are both leading endocrine therapies for the treatment of prostate cancer. *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 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. In breast cancer, *Zoladex* is widely approved for use in advanced breast cancer in pre-menopausal 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 2011, with further launches of generic goserelin (the active ingredient in *Zoladex*).

*Iressa* is approved in 76 countries and is one of the leading epidermal growth factor receptor-tyrosine kinase (EGFR-TK) inhibitors in Japan and the Asia Pacific region where it is marketed for pre-treated advanced non-small cell lung cancer (NSCLC). Outside the EU, indications are being sought or expanded from the pre-treated setting to include 1st line patients whose tumours harbour activating mutations of the EGFR–TK inhibitor.

Mature data from the IPASS study showed that overall survival was similar between *Iressa* and carboplatin/paclitaxel (doublet chemotherapy) and confirmed that *Iressa* may be a potential option for the 1st line treatment of EGFR mutation positive patients with advanced NSCLC. In the EU, *Iressa* has been launched as the first personalised medicine for the treatment of adults with locally advanced or metastatic NSCLC with activating mutations.

In January 2011, AstraZeneca informed the FDA that it will be withdrawing the accelerated approval NDA for *Iressa*, effective 30 September 2011. AstraZeneca does not plan to pursue approval for *Iressa* in the US.

#### In the pipeline

Vandetanib blocks the development of a tumour's blood supply (anti-angiogenesis) influencing the growth and survival of the tumour itself (RET- (rearranged during transfection) and anti-EGFR-kinase activity). Vandetanib is under regulatory review in the US and the EU for the treatment of patients with unresectable, locally advanced medullary thyroid cancer (MTC). The FDA had granted priority review status for the NDA and set a Prescription Drug User Fee Act (PDUFA) action date of 7 January 2011. However, as part of the review process in the US, the FDA required that we submit a Risk Evaluation and Mitigation Strategy (REMS). A proposed REMS was submitted by AstraZeneca in December 2010 and the FDA accordingly extended the original PDUFA date by three months to 7 April 2011. The submissions are supported by the results from the ZETA Phase III study which showed that treatment with vandetanib significantly extended progression-free survival (PFS), the primary endpoint of the study, in patients with advanced MTC. Results from a Phase II study also showed that vandetanib significantly improved PFS, when compared to placebo, for patients with locally advanced or metastatic papillary or follicular thyroid cancer.

**Business Review** 

Overview

### **Therapy Area Review**

*Recentin* (cediranib) is an anti-angiogenic compound being evaluated across a range of tumour types. The outcomes of two pivotal studies examining cediranib in 1st line metastatic colorectal cancer (mCRC) were reported in the first half of 2010 and a third pivotal study in recurrent glioblastoma (rGBM) was reported in July. The trials suggest that cediranib has clinical activity but limited clinical utility in these settings. AstraZeneca does not intend to file regulatory submissions in 1st line mCRC or rGBM. There are ongoing Phase II studies in NSCLC and other solid tumours.

Zibotentan (ZD4054) is an oral once-daily potent and specific endothelin A-receptor antagonist. Data from a randomised Phase II study suggested that zibotentan 10mg had the potential to improve survival with a generally well tolerated safety profile in men with metastatic castration resistant prostate cancer (CRPC). However, data from a Phase III study in the same population did not show a significant improvement in overall survival. Therefore, no regulatory submissions for zibotentan are planned at this time. The full results of these studies are expected to be published in 2011. The remaining Phase III ENTHUSE studies, investigating efficacy in metastatic CRPC in combination with docetaxel, and in non-metastatic CRPC, are ongoing.

Olaparib (AZD2281) is an oral poly-ADP-ribose-polymerase inhibitor, a new class of drug which potentially offers an innovative therapeutic approach to treating cancers by targeting weaknesses 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. Progression to Phase III studies has been delayed while a patient-friendly formulation is under investigation. A decision on Phase III studies will be taken in 2011 when the new formulation becomes available.

Our early oncology pipeline includes a range of novel compounds that target signalling pathways believed to be pivotal in cancer cell growth and survival, tumour immunology and DNA repair mechanisms. AZD8931, a pan-erb kinase inhibitor, has commenced Phase II testing targeting the treatment of metastatic breast cancer. Also in Phase II is AZD6244, a potent MEK (mitogen-activated protein kinase 1) inhibitor licensed from Array BioPharma, Inc., which has shown biological activity in both lung cancer and melanoma. The Phase I combination studies for AZD6244 with the Merck AKT inhibitor, MK2206, are nearing completion with tumour specific Phase II studies planned for 2011.

AZD8055, AZD7762, AZD1480 and AZD4547 are all completing Phase I studies while AZD3514, AZD2461 and AZD5363 all entered Phase I clinical trials this year. In September, we entered into a collaboration with Cancer Research UK to conduct Phase I testing of AZD3965, an inhibitor of cancer cell metabolism. In June, we entered into a partnership with Dainippon Sumitomo for the co-development through Phase I of AZD3016, an immune modulator.

We are also developing potential new cancer drugs using a variety of biologic approaches. Our investigational biologics are directed towards molecular targets with a strong role in cancer progression and incorporate innovative technologies, providing the potential to eliminate cancer cells in more effective ways. Within biologics, we continue to progress a discovery and clinical pipeline that is balanced across different anti-tumour approaches, including impacting cancer cells directly (growth factor and survival signalling), modulating the blood supply that tumours need to grow (vascular modulation) and activating a patient's own immune system to eliminate cancer cells (immune-mediated killing). Our biologics pipeline includes investigational treatments for cancers of the blood as well as for a variety of solid tumours. We currently have five investigational drugs in Phase I trials which are currently planned to progress to Phase II studies in 2011. Additional drug candidates are expected to begin Phase I trials in 2011.

#### Financial performance 2010/2009

#### Performance 2010

#### Reported performance

Oncology sales were down 10% to \$4,045 million compared with \$4,518 million in the prior year.

#### Performance – CER growth rates

Oncology sales were down 12%.

Sales of *Arimidex* were down 22%. This was mainly due to sales in the US which were down 44% to \$494 million, reflecting the inroads made by generics since their approval at the end of June. *Arimidex* sales outside the US were down 3% to \$1,018 million.

*Casodex* sales were down 34% with sales in the US down 89% to \$16 million as a result of generic competition that began in the third quarter 2009. Sales outside the US were also down 22% to \$563 million.

*Iressa* sales increased by 28% to \$393 million, including \$49 million of sales in Western Europe. Sales in Japan were up 8%. Sales in Emerging Markets were up 20%, including a 23% increase in China.

Faslodex sales for the full year increased by 35% in the US and grew by 32% outside the US.

#### Performance 2009

#### Reported performance

Oncology sales decreased by 9% to \$4,518 million down from \$4,954 million in 2008.

#### Performance - CER growth rates

Oncology sales were down 7%. *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 unchanged 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.

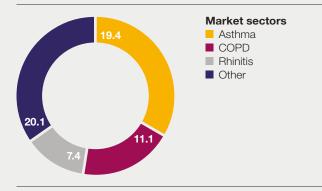
## **Respiratory & Inflammation**



# \$58bn

The prescription respiratory world market value is \$58 billion.

#### Therapy area world market (MAT/Q3/10) (\$bn)



### In brief

- > Total Symbicort sales \$2.7 billion, up 20%.
- > Total Pulmicort sales \$872 million, down 34%.
- In November, the US Court of Appeals for the Federal Circuit affirmed the US District Court, District of New Jersey's issuance of a preliminary injunction barring Apotex, Inc. and Apotex Corp. (Apotex) from launching a generic version of *Pulmicort Respules*. Apotex has petitioned the appellate court for a rehearing of its appeal, *en banc*.
- > Fostamatinib (previously known as R788) was in-licensed from Rigel in February 2010 and in September, the first patient was enrolled in a Phase III clinical development programme for rheumatoid arthritis.

#### **Our marketed products**

- > Symbicort pMDI (budesonide/formoterol in a pressurised metered-dose inhaler) is used for the treatment of asthma and chronic obstructive pulmonary disease (COPD) in the US.
- > 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. It is also approved for maintenance and reliever therapy (SMART) in persistent asthma.
- > Pulmicort (budesonide) is a corticosteroid anti-inflammatory inhalation drug that is used to help prevent the symptoms of and improve the control of asthma.
- > Pulmicort Respules (budesonide inhalation suspension) is a first nebulised corticosteroid used for the treatment of asthma in both children and adults. Approved use for Pulmicort Respules varies based on territory.
- > Rhinocort (budesonide) is a nasal steroid used as a treatment for allergic rhinitis (hay fever), perennial rhinitis and nasal polyps.
- > Oxis (formoterol) is a fast onset, long-acting beta-agonist used for the treatment of asthma and COPD.
- > Accolate (zafirlukast) is an oral leukotriene receptor antagonist used for the treatment of asthma.

### **Therapy Area Review**

#### Our financial performance

		World			s	We	stern Euro	ре	Est	ablished R	ow	Eme	rging Marl	Prior year	
2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Symbicort	2,746	20	20	721	48	1,367	2	5	286	75	59	372	25	23	2,294
Pulmicort	872	(33)	(34)	305	(62)	215	(6)	(4)	114	13	5	238	35	32	1,310
Rhinocort	227	(14)	(16)	93	(28)	39	(13)	(11)	16	14	-	79	4	-	264
Others	254	(4)	(5)	41	(15)	118	(4)	(3)	22	(4)	(13)	73	4	1	264
Total	4,099	(1)	(1)	1,160	(21)	1,739	-	3	438	46	33	762	23	20	4,132
2009															
Symbicort	2,294	14	23	488	91	1,345	2	11	163	3	13	298	8	21	2,004
Pulmicort	1,310	(12)	(10)	804	(18)	229	(8)	(1)	101	9	4	176	2	12	1,495
Rhinocort	264	(18)	(15)	129	(29)	45	(6)	2	14	(7)	-	76	(1)	6	322
Others	264	(14)	(7)	48	(9)	123	(16)	(7)	23	(12)	(8)	70	(15)	(4)	307
Total	4,132	-	6	1,469	_	1,742	(1)	8	301	3	8	620	2	14	4,128

#### **Our strategic objectives**

We aim to build on our strong position in the respiratory and inflammation 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 through our biologics pipeline and targeted small molecule approaches.

#### **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 impact of medication on the course of the disease is small and 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 moderate 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. Over recent years, studies employing patient-centric tools, such as the asthma control questionnaire, have revealed a surprisingly low asthma control at all severities, highlighting an underestimated medical need.

#### Our focus

#### Our key marketed products

*Symbicort* improves symptoms and provides a clinically important improvement in the health of many patients with either asthma or COPD by providing effective and rapid control of the symptoms.

Symbicort pMDI (pressurised metered-dose inhaler) is indicated, in the US, for the treatment of asthma in patients 12 years of age and older. The COPD indication was approved and launched in the US in early 2009. In June, the US Prescribing Information was updated to include the FDA's new recommendations for appropriate use of asthma medications containing LABAs. The class label changes for all LABA-containing products are specific to the treatment of asthma and do not apply to the treatment of COPD.

*Symbicort Turbuhaler* was launched in Japan for the treatment of adult asthma in January 2010 and is co-promoted in Japan together with Astellas. *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* is one of the world's leading inhaled corticosteroids for the treatment of asthma and is available in several forms. Teva has had an exclusive licence to sell a generic version of *Pulmicort Respules* in the US since 2009.

#### Clinical studies of our key marketed products

The EUROSMART study, including more than 8,000 patients, compared the two *Symbicort* maintenance doses within the SMART concept in asthma to identify possible patient characteristics at baseline which would predict a better response to a higher than standard maintenance dose in a real life setting. The results from the study showed that *Symbicort SMART* at the 2x2 maintenance dose did prolong time to first severe exacerbation and reduced symptoms. Patients with low lung function benefited most from the higher maintenance dose.

#### In the pipeline

Building on our capabilities in combinations and device development demonstrated through our experience with *Symbicort*, we are aiming to further improve the mainstay of treatment for COPD patients by combining bronchodilators such as the LABA (AZD3199) and the LAMA (AZD8683, being developed in collaboration with Pulmagen Therapeutics (Synergy) Limited), with inhaled anti-inflammatory compounds such as inhaled selective glucocorticoid receptor agonists (AZD5423, being developed in collaboration with Bayer Schering Pharma), which recently commenced Phase II studies. Additionally, we are targeting inflammation in COPD using oral routes of administration and have commenced a Phase II study of AZD5069, a CXCR2 antagonist that targets neutrophils. AZD9668, an oral inhibitor of neutrophil elastase, has been discontinued for the treatment of COPD based on Phase IIb study data.

We are targeting uncontrolled asthma/asthma exacerbations though small molecule approaches such as AZD1981, a CRTh2 receptor antagonist, and AZD8848, a toll-like receptor 7 agonist (being developed in collaboration with Dainippon Sumitomo) as well as biological approaches such as benralizumab (MEDI-563), a MAb that blocks the binding of interleukin-5 to its receptor, tralokinumab (CAT-354), a MAb that targets interleukin-13 and MEDI-528 (an anti-IL-9 MAb), which are all in Phase II.

## Overview

#### Rheumatology

Rheumatoid arthritis (RA) is currently treated with generic diseasemodifying 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. We anticipate that the RA market will experience modest annual growth over the next decade, as sales increase from \$9 billion to \$12 billion<sup>1</sup>. Sales of the biologic tumour necrosis factor (TNF) alpha blockers accounted for 75% of major-market RA sales and the launch in 2010 of two new TNF blockers is likely to sustain the TNF class sales. Use of other biologic approaches, currently reserved for TNF blocker failures, is expected to increase due to new entrants, new subcutaneous formulations and use earlier in the treatment pathway. Targeted novel oral drugs that provide anti-TNF-like efficacy with safety benefits and more convenient dosing will likely be used ahead of the TNF blockers, especially in patients that currently choose not to take, are ineligible for, or do not respond to TNF blockers and other RA biologics.

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.

#### In the pipeline

Fostamatinib (previously known as R788) was in-licensed from Rigel in February 2010. Fostamatinib is the first oral syk inhibitor in development as a novel therapeutic approach for RA. It is thought to reversibly block signalling in multiple cell types involved in inflammation and tissue degradation in RA. In September, the first patient was enrolled in the fostamatinib Phase III clinical development programme, called OSKIRA. The first anticipated regulatory filings based on the OSKIRA programme are currently planned for 2013. Under the terms of the agreement with Rigel, AstraZeneca will make an upfront payment to Rigel of \$100 million with up to an additional \$345 million payable if specified development, regulatory and first commercial sale milestones are achieved. Rigel will also be eligible to receive up to an additional \$800 million of specified sales-related milestone payments if the product achieves considerable levels of commercial success, as well as significant stepped double-digit royalties on net sales worldwide. AstraZeneca is responsible for all development, regulatory filings, manufacturing and global commercialisation activities in all licensed indications under the agreement.

In 2010, we invested in several novel multi-functional MAbs in inflammatory and autoimmune conditions. Sifalimumab (MEDI-545), which targets interferon-alpha, is being prepared for a Phase IIb dose-ranging study in patients with SLE. Mavrilimumab (CAM-3001, licensed from CSL Limited) which targets the alpha sub-unit of the granulocyte-macrophage colony stimulating factor receptor, successfully completed a Phase I study to assess the tolerability and preliminary pharmacokinetics and pharmacodynamics of single intravenous doses of CAM-3001 in subjects with RA. A Phase II randomised, double-blind, placebo-controlled, multiple ascending dose study evaluating the efficacy and safety of CAM-3001 in subjects with RA is also in progress.

<sup>1</sup> Decision Resources 2010.

#### Financial performance 2010/2009

#### Performance 2010

#### **Reported performance**

Respiratory & Inflammation (R&I) sales were down 1% to \$4,099 million compared with \$4,132 million in 2009.

#### Performance - CER growth rates

R&I sales were down 1%.

Total sales of Symbicort were up 20% to \$2,746 million with strong growth both in the US which was up 48% to \$721 million and outside the US which was up 13% to \$2,025 million.

Sales of Pulmicort were down 34%, mainly as a result of US sales which decreased 62% to \$305 million as a result of the launch, under licence from AstraZeneca, of the Teva generic budesonide inhaled suspension product in December 2009. Sales of Pulmicort outside the US were up 10% to \$567 million.

#### Performance 2009

#### **Reported performance**

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%.

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 was led by doctors' 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 was 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.

**Financial Statements** 

How is our business performing around the world? **Revenue** growth in markets outside the US in 2010 broadly offset the loss of revenue in the US

This section contains further information about the performance of our products within the geographical areas in which our sales and marketing efforts are focused.

For more information regarding our products, see the Therapy Area Review from page 50. Details of material legal proceedings can be found in Note 25 to the Financial Statements from page 178 and details of relevant risks are set out in the Principal risks and uncertainties section from page 96.

See the Market definitions table on page 217 for information about AstraZeneca's market definitions.

#### 2010 in brief

- > In the US, combined sales of our key growth brands of Crestor, Onglyza™, Seroquel, Symbicort and Vimovo were up 19% to \$7,167 million (2009: \$6,014 million). Despite this strong performance, overall sales decreased by 7% to \$13,727 million as a result of increased generic competition for Arimidex, Casodex, Pulmicort Respules and Toprol-XL and its authorised generic and the absence of the H1N1 pandemic influenza (swine flu) vaccine revenue.
- > Western Europe reported a strong performance in the context of increased competition and governmental controls over healthcare expenditure. *Crestor* outperformed the statin market in Western Europe with double-digit growth by volume and *Seroquel* grew three times as fast as the atypical anti-psychotic market segment in Western Europe by value.
- > Established ROW sales were up 7%, driven by the strong performance for Crestor as well as the successful launch for Symbicort Turbuhaler in Japan.
- > Emerging Markets delivered strong double-digit sales growth of 16% to \$5,198 million, with sales growth in China of 28%, Russia of 26% and Brazil of 17%.
- > AstraZeneca is the third largest pharmaceutical company in the US, with a 6% share of US prescription pharmaceutical sales and the seventh largest prescription-based pharmaceutical company in Western Europe, with a 4.8% market share of prescription sales by value.

#### **Our financial performance**

	2010				2008		
	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m
US	13,727	(7)	(7)	14,777	9	9	13,510
Western Europe	9,168	(1)	2	9,252	(5)	3	9,743
Canada	1,510	26	14	1,203	(6)	3	1,275
Japan	2,617	11	4	2,367	20	7	1,957
Other Established ROW	1,049	23	6	853	1	12	843
Established ROW	5,176	17	7	4,423	8	7	4,075
Emerging Europe	1,165	7	6	1,091	(10)	7	1,215
China	1,047	29	28	811	29	27	627
Emerging Asia Pacific	890	14	7	780	(3)	6	802
Other Emerging ROW	2,096	26	20	1,670	3	13	1,629
Emerging Markets	5,198	19	16	4,352	2	12	4,273
Total	33,269	1	-	32,804	4	7	31,601

#### **Geographical Review**

#### US

AstraZeneca is the third largest pharmaceutical company in the US, with a 6% share of US prescription pharmaceutical sales.

Sales in the US decreased 7% to \$13,727 million (2009: \$14,777 million), as strong performance from our key growth brands was offset by the impact of increased generic competition experienced by our mature brands. Combined sales of our key growth brands, namely, *Crestor*, Onglyza<sup>™</sup>, *Seroquel*, *Symbicort* and *Vimovo*, were up 19% to \$7,167 million (2009: \$6,014 million). Increased generic competition for *Arimidex*, *Pulmicort Respules* and *Toprol-XL* and its authorised generic, resulted in a sales decline in these brands of 46% to \$1,377 million (2009: \$2,534 million).

*Crestor* achieved sales of \$2,640 million (2009: \$2,100 million) and a total prescription growth of 12.2% within the statin market. This growth significantly outpaced the market by 9.5% and the growth of total generic statins by 1.3%.

Seroquel continued to be the most prescribed atypical antipsychotic, with sales up 10% to \$3,747 million (2009: \$3,416 million). Seroquel grew total prescriptions by 132,400. This was driven by strong Seroquel XR prescription volume growth of 92%, following the promotional launch of the adjunct major depressive disorder indication in the first quarter of 2010. Seroquel XR was the fastest growing branded atypical anti-psychotic, accounting for 15.9% of the Seroquel total prescription volume in the US, up from 11.1% at the end of 2009.

Symbicort pMDI continued to deliver steady growth in the US, with sales up 48% to \$721 million (2009: \$488 million) and prescription growth of 44%, leading the fixed combination class in total prescription growth. It achieved an 18% total prescription share and a 19.5% new prescription share of the inhaled corticosteroid/ long-acting beta-agonist market.

Onglyza<sup>™</sup> is presently capturing one in four new dipeptidyl peptidase patient treatment decisions and achieved over an 8% total prescription share gain in 2010, ending the year with a total prescription share of 10% of the dipeptidyl peptidase IV inhibitor market. Sales in the US were \$54 million (2009: \$11 million).

*Nexium* remained the third most prescribed branded pharmaceutical in the US. In the face of continuing generic, OTC and pricing pressures, *Nexium* sales were down 5% to \$2,695 million (2009: \$2,835 million). Generic lansoprazole and Prevacid OTC 24 Hour were introduced in late 2009, leaving *Nexium* as the only branded pharmaceutical product with significant market share by volume in the proton pump inhibitor class.

Sales of *Toprol-XL* and its authorised generic, which is marketed and distributed by Par Pharmaceutical Companies, Inc., decreased 29% to \$689 million (2009: \$964 million), with further generic competition from Watson Pharmaceuticals Inc. and Wockhardt Ltd, which entered the market in 2010.

Patent protection in the US for *Arimidex* expired in June, following which multiple generic formulations of *Arimidex* were approved by the FDA and entered the market. As a result, sales of *Arimidex* declined 44% to \$494 million (2009: \$878 million). Generic competition also caused *Casodex* sales to decline by 89% to \$16 million (2009: \$148 million).

Sales for *Pulmicort Respules* were down 72% to \$194 million (2009: \$692 million) as a result of sales of Teva's generic product which entered the market under an exclusive licence from AstraZeneca in December 2009.

In 2010, sales of *Synagis* in the US were down 17% to \$646 million (2009: \$782 million). Sales in the 2009-2010 respiratory syncytial virus (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.

Revenue from the sale of the H1N1 pandemic influenza (swine flu) vaccine to the US government fell to \$39 million (2009: \$389 million) as the order for the US Department of Health and Human Services was fulfilled in the first quarter of 2010 and this strain has now been incorporated into the traditional seasonal influenza vaccine.

Sales for Aptium Oncology, Inc. fell by 44% to \$219 million (2009: \$393 million) and sales for Astra Tech AB rose by 22% to \$101 million (2009: \$83 million).

In March 2010, the Affordable Care Act came into force. It has had and is expected to have a significant impact on our US sales and the US healthcare industry as a whole. For further information, see the Pricing pressure section from page 11.

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. This is 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 2010, 78% of the prescriptions dispensed in the US were generic. 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.

#### **Rest of World**

Sales performance outside the US in 2010 was strong, up 7% to \$19,542 million (2009: \$18,027 million), despite the continuing challenging economic environment. Combined sales of key products (*Arimidex, Crestor, Nexium, Seroquel* and *Symbicort*) were up 11% with sales of \$9,923 million (2009: \$8,824 million). Emerging Markets delivered particularly strong sales, up 16% with sales of \$5,198 million (2009: \$4,352 million).

#### Western Europe

AstraZeneca is the seventh largest prescription-based pharmaceutical company in Western Europe, with a 4.8% market share of prescription sales by value.

Total sales in Western Europe were up 2% (Reported: down 1%) to \$9,168 million (2009: \$9,252 million) as volume growth exceeded the negative impact from price reductions chiefly related to government interventions. Much of the volume growth was attributable to *Crestor, Seroquel XR* and *Symbicort*.

*Crestor* outperformed the statin market with strong double-digit sales growth by volume. Likewise, *Seroquel* outperformed the atypical anti-psychotics market segment by three times, in value, with strong growth of *Seroquel XR*, primarily driven by the bipolar indication. *Symbicort* defended its position in the inhaled corticosteroid/beta-agonist market well, despite a highly competitive environment. Generic versions of *Nexium* are now available in several markets but overall sales were up 2% to \$1,202 million (Reported: down 2%) (2009: \$1,225 million).

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 criteria for cost-effectiveness evaluations of medicines, which has reduced access to medicines for European patients in areas of high unmet medical need. These and other measures all contribute to an increasingly difficult environment for branded pharmaceuticals in Europe.

Further, in 2010, we experienced a number of government interventions in our markets which, combined with the current economic conditions, had a negative impact on our sales. In particular, sales growth in Germany slowed to 1% (Reported: down 3%) to \$1,235 million (2009: \$1,278 million), principally owing to an increase of compulsory rebates for *Symbicort* and *Seroquel* and reference pricing for *Crestor*. However, *Seroquel, Symbicort* and *Atacand* all showed a strong performance on an underlying volume basis. As a result of the debt crisis in Greece, the Greek government implemented significant price cuts in 2010 which resulted in an overall sales decline of 14% to \$322 million (2009: \$1,056 million) was caused, in part, by a 1.9% price cut across the portfolio although this was partially offset by strong performance of *Crestor* and *Symbicort*.

Overall sales in France increased by 7% to \$1,848 million (2009: \$1,810 million), driven by double-digit growth of *Crestor* and *Nexium* and continued strong growth of *Symbicort* despite very aggressive competition. Sales in Italy were up 4% (Reported: unchanged) to \$1,198 million (2009: \$1,199 million). *Crestor* showed particularly strong growth of 24%. However, from August, performance was impacted by a general price cut in sales to the private sector of 1.8%.

#### **Established ROW**

Sales in Established ROW increased by 7%. The key products driving sales growth in 2010 were *Crestor, Symbicort, Nexium* and *Seroquel*.

#### Canada

AstraZeneca remains the second largest research-based pharmaceutical company in Canada by sales value. In 2010, total Canadian sales increased by 14% to \$1,510 million (2009: \$1,203 million), compared to a year-on-year increase of 3.6% for the Canadian pharmaceutical industry. Combined sales of *Crestor, Nexium, Symbicort* and *Atacand* were \$1,133 million (2009: \$872 million), with *Crestor* and *Nexium* the second and fifth largest prescription products in Canada by sales. An established product in the Canadian marketplace, *Crestor* sales grew by 25% to \$600 million (2009: \$434 million). Despite limited formulary access, *Nexium* sales reached \$271 million (2009: \$217 million), representing year-on-year growth of 13%. The Canadian provinces continue to adopt provincial and regional approaches to pharmaceutical funding, from one end of the continuum in Quebec, with more open access, to more restricted access in British Columbia. In 2010, there was a reduction in generic prices, led by Ontario, and changes to the pharmacy reimbursement model. Overall, the trend in Canada indicates that provinces will continue to introduce policy changes that drive cost savings, while providing reasonable patient access to innovative medicines.

#### Japan

Sales in Japan increased by 4% to \$2,617 million (2009: \$2,367 million). Strong volume gains of 7.3% were driven mainly by the continued growth of Crestor and Losec, as well as the launch of Symbicort Turbuhaler, which is co-promoted with Astellas. By the end of 2010, Symbicort Turbuhaler had a 14% share (by volume) of the market for inhaled corticosteroid/beta-agonists. AstraZeneca's oncology business remains one of the leaders in Japan and delivered growth from Iressa (+8%), Arimidex (+4%) and Zoladex (+1%), partially offset by the decline of Casodex (-19%) which has faced generic competition since 2009. This was achieved despite the biennial reimbursement price reductions by the Ministry of Health, Labour and Welfare which were imposed in April 2010. As expected, the price reductions were accompanied by the introduction of a new system to exempt certain products from the biennial price reductions. The system was introduced on a temporary basis linked to industry and company commitments to seek registration for products and indications not currently available in Japan.

#### Other Established ROW

Sales in Other Established ROW showed robust growth of 6% to \$1,049 million (2009: \$853 million). Double-digit volume growth in Australia for our key products was partially offset by price cuts imposed in April 2010 on *Crestor* and *Nexium*. *Crestor* continued to perform particularly strongly and had a 22% volume share in the Australian statin market.

#### **Emerging Markets**

In the Emerging Markets, sales increased by 16% to \$5,198 million (2009: \$4,352 million), accounting for nearly 57% of total sales growth outside the US. This was driven by growth in China and Latin America.

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 the introduction of measures to reduce the cost of prescriptions in line with the systems in Europe, Canada and Australia.

#### **Emerging Europe**

Sales in Emerging Europe were up 6% to \$1,165 million (2009: \$1,091 million) driven by increased sales in Russia and Romania, which more than offset a reduction in sales in Turkey.

We have continued to build our presence in Russia, where sales were up 26% to \$232 million (2009: \$180 million), mainly driven by sales of *Zoladex* (+38%), *Symbicort* (+41%), *Nexium* (+109%) and *Crestor* (+43%).

#### **Geographical Review**

In Romania, we delivered a strong performance with sales up 36% to \$119 million (2009: \$92 million). This was driven by sales of *Crestor* (+41%), *Seroquel* (+48%) and *Symbicort* (+97%). In 2010, the government imposed a claw back system to finance the healthcare budget deficit. In addition, the government imposed extended payment terms for distributors to drug manufacturers.

In late 2009, the Turkish government imposed unprecedented levels of price reductions on the pharmaceutical industry. As a result, our 2010 sales were down 13% to \$304 million (2009: \$339 million), despite an underlying 4.9% volume growth.

#### China

In 2010, our business in China (excluding Hong Kong) increased by 28% to \$1,047 million (2009: \$811 million), becoming AstraZeneca's eighth market to pass the \$1 billion mark. We continue to be one of the fastest growing multinational pharmaceutical companies in China and the second largest in the prescription market by value. *Crestor, Symbicort, Nexium i.v.* and *Betaloc Zok (Seloken/Toprol-XL)* were listed on the National Reimbursement Drug list in November 2009 and provincial level listings are being finalised.

#### Emerging Asia Pacific

Sales in Emerging Asia Pacific showed strong growth of 7% to \$890 million (2009: \$780 million). This was driven by double-digit sales growth in South Korea, India, Malaysia and Vietnam. Growth was more subdued in markets which were more significantly impacted by government interventions on pricing or by measures which promoted local generic penetration, primarily in Taiwan, Thailand, the Philippines and Indonesia.

#### Other Emerging ROW

In Latin America, sales were up 19% to \$1,391 million (2009: \$1,118 million) mainly due to continued sales growth in Brazil and Mexico. In Brazil, our overall sales grew by 17% to \$605 million (2009: \$457 million). *Atacand, Crestor, Nexium* and *Seroquel* showed strong performance, with overall sales up 28% to \$314 million (2009: \$216 million). *Seroquel* was our number one prescription product, with sales up 34% to \$103 million (2009: \$68 million), followed by *Crestor*, with overall sales up 33% to \$102 million (2009: \$67 million).

Sales in Mexico were strong, increasing by 17% to \$325 million (2009: \$261 million). Overall sales of *Atacand, Crestor, Nexium, Symbicort* and *Seroquel* were up 33% to \$140 million (2009: \$100 million). *Nexium* increased sales by 35% to \$58 million (2009: \$41 million). Overall sales of *Crestor* were up 37% to \$38 million (2009: \$27 million).

In the Middle East and Africa, we further accelerated our growth with sales up 28% and continued to gain market share, by value, in the region. Our largest markets in the region were Saudi Arabia, the United Arab Emirates and Egypt, and growth in 2010 has mainly been driven by Maghreb. In South Africa, sales were up 15%, mainly driven by growth of *Symbicort* (+22%), *Seroquel* (+29%) and *Crestor* (+27%).

Prior year

924

## Other Businesses

Astra Tech AB (Astra Tech) is engaged in the research, development, manufacture and marketing of dental implants and medical devices for use primarily in urology and surgery. 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 urology and surgery 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 Russia, the US, Japan and Emerging Asia Pacific.

Astra Tech

All product lines showed continued good sales growth in 2010. Despite the current economic downturn, the dental implant market is estimated to have grown by 3% during 2010 and Astra Tech Dental grew its implant sales and increased its market share in several key markets. 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 were launched in the first quarter of 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.

us

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In November, AstraZeneca formally commenced a review of its strategic options for Astra Tech. AstraZeneca continues to evaluate all alternatives for value maximisation from this business and any final decision will only be made when the results of the review have concluded. During the period of this review, AstraZeneca remains committed to supporting Astra Tech's business, customers and stakeholders.

#### 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 access to a network of over 140 doctors 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 2010, Aptium Oncology continued to refine its business model to adapt to the ever-changing dynamics of the US healthcare industry, while continuing to perform well in its cancer centre management business with positive profit and cash flow contributions. It remains focused on growth and its consultancy business continues to lay the groundwork for new management relationships. For example, in the second guarter of 2010, Aptium Oncology entered into a long-term management agreement with Beth Israel Medical Center in New York, a member of the Continuum Health Network, to manage its West Side Cancer Center.

Clinical research is an integral part of care delivery at Aptium Oncology's cancer centres and an area of strategic strength for the company. In addition to Aptium Oncology's Gastrointestinal Cancer Consortium, which 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, Aptium Oncology created a similar consortium in 2010 focused on multiple myeloma.

Emerging Markets

Established ROW

36

10

20

#### Our financial performance

World

2010	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World sales \$m
Aptium															
Oncology	219	(44)	(44)	219	(44)	-	-	-	-	-	-	-	-	-	393
Astra Tech	535	6	7	101	22	393	2	4	38	6	(3)	3	200	100	506
Total	754	(16)	(15)	320	(33)	393	2	4	38	6	(3)	3	200	100	899
2009															
Aptium															
Oncology	33	9 (1)	(1)	33	9 (1)	-	-	-	-	-	-	-	-	-	395
Astra Tech	506	(4)	2	83	4	386	(6)	2	36	10	20	1	-	-	529

(6)

386

Western Europe

(3)

899

Total



# What is being done to improve health in China?



AstraZeneca is one of the country's fastest growing multinational pharmaceutical companies. At present, most of our business comes from big hospitals in 200 of the largest cities that have a population of more than one million. We are investing to improve our sales capabilities in these and in a further 100 large cities.

At the same time, nearly 900 million people live outside big cities and the Chinese government is investing \$125 billion between 2009 and 2011 to support healthcare reform by expanding basic healthcare insurance and upgrading community and rural hospitals. We have plans to build a sustainable business in this broader market.

We are also supporting the Chinese Ministry of Health in improving patient health with an innovative programme to increase the capacity of community healthcare services by strengthening the training of general practitioners. In collaboration with the China Medical Association, which will be providing the training, AstraZeneca is sponsoring a three-year programme. It will help train some 30,000 community general practitioners so that they can better treat some common chronic diseases.





Because health connects us all For more information go to the Geographical Review from page 70.

How did the business perform financially in 2010? **Our performance** in 2010 underlines the resilience and strength of **AstraZeneca's** business



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Our performance in 2010 enabled us to deliver increased earnings, increase the dividend and return residual cash to shareholders through share repurchases

Despite government pricing pressures and anticipated patent expiries in the US and Western Europe, revenue in 2010 remained in line with the prior year in constant currency terms, as a result of an excellent performance for key brands and continued growth in Emerging Markets.

Core operating profit was also unchanged in constant currency terms. Core earnings per share increased by 5%, benefiting from lower net finance expense, a lower tax rate and fewer shares outstanding as a result of share repurchases.

Our extensive efforts to reshape the cost base to maintain competitiveness continue. The first phase of our restructuring programme is now complete, and it has delivered exactly as planned. We have achieved annual benefits of \$2.4 billion by the end of 2010 at a total programme cost of \$2.5 billion incurred over the 2007 to 2009 period. The second phase of restructuring, announced in January 2010, is expected to deliver a further \$1.9 billion in annual benefits by the end of 2014, at a planned cost of \$2.0 billion, of which \$1.2 billion was charged in 2010.

Our cash generation remains strong, enabling us to invest for future growth and value by funding research and development and capital expenditures while also providing \$5.5 billion in cash returns to shareholders by way of dividends and share repurchases: a nearly two-fold increase compared with 2009.

Driving operating execution in line with our mid-term planning assumptions for revenue and pre-R&D operating margin will generate the requisite cash flow to provide for the needs of the business while providing attractive shareholder returns, as evidenced by the 11% increase in the dividend for 2010 and the planned \$4 billion in net share repurchases for 2011.

Marharst:

Simon Lowth Chief Financial Officer

The purpose of this Financial Review is to provide a balanced and comprehensive analysis of the financial performance of the business during 2010, 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 constant exchange rates 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 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 2010 Reconciliation of Reported results to Core results table on page 82 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 2010 Reported operating profit table on page 82.
- > Core pre-R&D operating margin. This is a non-GAAP measure of our Core financial performance. A reconciliation of Core pre-R&D operating margin to our operating profit is provided on pages 82 and 88.
- > 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 cash and cash equivalents, current investments and derivative financial instruments less interest-bearing loans and borrowings.

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 2010 Reconciliation of Reported results to Core results table on page 82, 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.

Core pre-R&D operating margin is our operating margin before research and development costs recorded in the year. This measure reflects Core operating performance before reinvestment in internal research and development.

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 between different kinds of costs and they should not be used in isolation. You should also refer to our Reported financial information in the 2010 Reported operating profit table on page 82, our reconciliation of Core financial measures to Reported financial information in the Reconciliation of Reported results to Core results table on page 82, and to the Results of operations - summary analysis of year to 31 December 2009 section from page 87 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-by-case basis to ensure clear accountability and consistency for each cost category.

## **Business Review**

## **Financial Statements**

#### 2010 Business background and results overview

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

As described earlier in our Annual Report, 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, such as:

- > The adverse impact on pharmaceutical prices as a result of the macroeconomic and regulatory environment. For instance, although there is no direct governmental control on prices in the US, action from federal and 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. In 2010, we saw the introduction of the US healthcare reform legislation and government imposed price reductions in Western Europe (as detailed in the Pricing pressure section from page 11).
- > 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 in 2010, our performance was affected by generic competition in the US for Arimidex, Pulmicort Respules and Toprol-XL. Further details of the impact of patent expiry on our revenue streams are included in the Patent expiries section on page 31.
- > 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 2010 are:

- > Reported revenue of \$33,269 million was unchanged (Reported: up 1%).
- > Strong revenue growth in markets outside the US broadly offset the loss of more than \$1.6 billion of revenue in the US from generic competition on several products and the absence of H1N1 pandemic influenza vaccine revenue.
- > Strong double-digit sales growth at CER for Crestor, Symbicort and Seroquel XR. Crestor and Seroquel franchise sales now exceed \$5 billion each for the full year.
- > Revenue in Emerging Markets grew to over \$5.1 billion, a 16% increase (Reported: 19%). Sales in China increased to over \$1.0 billion.
- > Core operating profit for the full year was unchanged on both a Reported and a CER basis at \$13,603 million. Operating profit decreased by 1% (Reported: unchanged).
- > Excluded from Core results were specific legal provisions of \$612 million (which impacted Reported results in the year) mainly in respect of the ongoing *Seroquel* product liability litigation and state attorney general investigations into sales and marketing practices, and a gain of \$791 million arising from changes made to benefits under certain of the Group's post-retirement plans, chiefly the Group's UK pension plan.
- > Basic EPS of \$5.60 represented an increase of 7% (Reported: 8%). Core EPS for the full year increased by 5% to \$6.71 (Reported: 6%).
- > Net cash inflow from operating activities was \$10,680 million (2009: \$11,739 million).
- > Dividends paid increased to \$3,361 million (2009: \$2,977 million).
- > Net funds at 31 December were \$3,653 million, an improvement of \$3,118 million on \$535 million in the previous year.
- > Total restructuring costs associated with the global programme to reshape the cost base of the business were \$1,202 million in 2010 (2009: \$659 million). This brings the total restructuring costs charged to date to \$3,708 million.

#### Results of operations – summary analysis of year to 31 December 2010

#### 2010 Reported operating profit

			2010	2009	Percer	ntage of sales	2010 compare	ed with 2009
	Reported \$m	CER growth \$m	Growth due to exchange effects \$m	Reported \$m	Reported 2010 %	Reported 2009 %	CER growth %	Reported growth %
Revenue	33,269	164	301	32,804			-	1
Cost of sales	(6,389)	(497)	(117)	(5,775)	(19.2)	(17.6)	9	11
Gross profit	26,880	(333)	184	27,029	80.8	82.4	(1)	(1)
Distribution costs	(335)	(31)	(6)	(298)	(1.0)	(0.9)	10	12
Research and development	(5,318)	(871)	(38)	(4,409)	(16.0)	(13.5)	20	21
Selling, general and administrative costs	(10,445)	955	(68)	(11,332)	(31.4)	(34.5)	(8)	(8)
Other operating income and expense	712	159	_	553	2.1	1.7	29	29
Operating profit	11,494	(121)	72	11,543	34.5	35.2	(1)	-
Net finance expense	(517)			(736)				
Profit before tax	10,977			10,807				
Taxation	(2,896)			(3,263)				
Profit for the period	8,081			7,544				
Basic earnings per share (\$)	5.60			5.19				

#### 2010 Core operating results

			2010	2009	2010 compared with 2009	
	Core \$m	CER growth \$m	Growth due to exchange effects \$m	Core \$m	CER growth %	Total Core growth %
Gross margin	27,024	(386)	193	27,217	(1)	(1)
Distribution costs	(335)	(30)	(7)	(298)	10	12
Research and development	(4,219)	176	(61)	(4,334)	(4)	(3)
Selling, general and administrative costs	(9,777)	190	(77)	(9,890)	(2)	(1)
Other operating income and expense	910	(16)	-	926	(2)	(2)
Operating profit	13,603	(66)	48	13,621	-	-
Net finance expense	(517)			(736)		
Profit before tax	13,086			12,885		
Taxation	(3,416)			(3,703)		
Profit for the period	9,670			9,182		
Basic earnings per share (\$)	6.71			6.32		

#### 2010 Reconciliation of Reported results to Core results

			Mercka	& MedImmune			
	2010 F Reported \$m	Restructuring costs \$m	Amortisation \$m	Intangible impairments \$m	Legal provisions \$m	Post- retirement plan amendments \$m	2010 Core \$m
Gross margin	26,880	144	-	-	-	-	27,024
Distribution costs	(335)	-	-	-	-	-	(335)
Research and development	(5,318)	654	-	445	-	-	(4,219)
Selling, general and administrative costs	(10,445)	404	443	-	612	(791)	(9,777)
Other operating income and expense	712	-	75	123	-	-	910
Operating profit	11,494	1,202	518	568	612	(791)	13,603
Add back: Research and development	5,318	(654)	-	(445)	-	-	4,219
Pre-R&D operating margin	16,812	548	518	123	612	(791)	17,822
Net finance expense	(517)	-	-	-	-	-	(517)
Profit before tax	10,977	1,202	518	568	612	(791)	13,086
Taxation	(2,896)	(317)	(100)	(150)	(162)	209	(3,416)
Profit for the period	8,081	885	418	418	450	(582)	9,670
Basic earnings per share (\$)	5.60	0.62	0.29	0.29	0.31	(0.40)	6.71

Revenue was unchanged (Reported: up 1%). Revenue benefited from strong growth of *Crestor, Symbicort* and *Seroquel* offset by lower revenues for *Pulmicort, Arimidex* and *Casodex* and the absence of H1N1 vaccine revenue. Emerging Markets sales growth of 16% (Reported: 19%) and Established ROW 7% (Reported: 17%) was offset by a decline in US sales of 7% (Reported: 7%) with sales in Western Europe up 2% (Reported: down 1%). Further details of our sales performance are contained in the Performance 2010 sections of the Therapy Area Review from page 50 and the Geographical Review from page 70.

Core gross margin of 81.2% declined 1.6 percentage points (Reported: 1.8 percentage points). The impairment of lesogaberan (AZD3355), the 2009 benefit from the release of a provision with respect to the resolution of an issue related to a third party supply contract, higher royalties and adverse regional and product mix were only partially offset by lower payments to Merck.

Core R&D expenditure was \$4,219 million, 4% lower than last year (Reported: 3%). Increased investment in biologics was more than offset by lower project costs and operational efficiencies. The lower project costs are the result of several late stage projects completing their trials, partially offset by the commencement of Phase III programmes for TC-5214 and fostamatinib.

Core SG&A costs of \$9,777 million were 2% lower than the previous year (Reported: 1%). Investment in Emerging Markets and recently launched brands were more than offset by operational efficiencies across Established Markets.

Core other income of \$910 million was \$16 million less than the previous year. 2009 benefited from disposal gains related to Abraxane<sup>™</sup> and the Nordic OTC business and 2010 included royalties from sales of Teva's generic version of *Pulmicort Respules*.

Core pre-R&D operating margin was 53.5%, down 1.0 percentage points (Reported: 1.2 percentage points), with the lower gross margin only partially offset by efficiencies within selling, general and administrative areas.

Core operating profit was \$13,603 million, unchanged at CER. Core operating margin declined by 0.4 percentage points to 40.8%, with lower R&D expense and operational efficiencies only partially offsetting the decline in the gross margin.

Core earnings per share were \$6.71, up 5% (Reported: 6%), with the operating performance boosted by lower net finance expense, the benefit of a lower average number of shares outstanding and a lower effective tax rate.

Core adjustments were broadly in line with last year's level with increased restructuring costs and intangible impairments offset by gains chiefly attributable to changes in the Group's UK pension arrangements. Excluded from Core were:

> impairment charges of \$568 million, arising from impairments in respect of motavizumab (\$445 million) and our HPV cervical cancer vaccine income stream (\$123 million), both capitalised as part of the MedImmune acquisition. Total impairment charges relating to intangible fixed assets were \$833 million in the year.

- > \$612 million of legal provision charges, of which \$592 million is in respect of the ongoing *Seroquel* product liability litigation and state attorney general investigations into sales and marketing practices in aggregate. In line with prior years these have been excluded from our Core performance and full details of these matters are included in Note 25 to the Financial Statements from page 178.
- > restructuring costs totalling \$1,202 million, incurred as the Group continues its previously announced efficiency programmes.
- > amortisation totalling \$518 million relating to assets capitalised as part of the Medlmmune acquisition and the Merck exit arrangements.
- > a credit of \$791 million chiefly attributable to a curtailment gain related to changes made to benefits under the Group's UK pension arrangements. In 2010, we amended our UK defined benefit fund. Pensionable pay was frozen at its 30 June 2010 level but the defined benefit fund remains open to existing members. Members of the pension fund were given the option of remaining in the fund or leaving the fund. Those that chose to leave the fund were offered funding which they could contribute to a new Group Self Invested Personal Pension Plan. This change to the UK defined benefit scheme represented an accounting curtailment of certain pension obligations and, in accordance with IAS 19 'Employee Benefits', these obligations were revalued by the scheme actuaries immediately prior to the curtailment and the assumptions updated at that date.

Operating profit was down 1% at CER (Reported: unchanged) at \$11,494 million. Basic earnings per share were \$5.60, up 7% (Reported: 8%), as a result of the factors affecting Core earnings per share.

Net finance expense was \$517 million, versus \$736 million in 2009. Fair value gains of \$5 million were recorded on the long-term bonds in the year, versus fair value losses of \$145 million for 2009. In addition to this, there is reduced interest payable on lower debt balances, and slightly increased returns from higher cash and cash equivalent balances.

The 2010 taxation charge of \$2,896 million (2009: \$3,263 million) consists of a current tax charge of \$3,435 million (2009: \$3,105 million) and a credit arising from movements on deferred tax of \$539 million (2009: charge of \$158 million). The current year tax charge includes a prior period current tax adjustment of \$370 million (2009: \$251 million) relating mainly to an increase in provisions for tax contingencies and double tax relief partially offset by a benefit of \$342 million arising from a number of tax settlements (including the UK matters described in Note 25 to the Financial Statements on page 195) and tax accrual to tax return adjustments. The 2009 prior period current tax adjustments related 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 effective tax rate for the year was 26.4% (2009: 30.2%, 28.8% excluding the impact of legal provisions). A description of our tax exposures is set out in Note 25 to the Financial Statements on page 195.

Total comprehensive income for the year increased by \$616 million from 2009. This was driven by the increase in profit for the year of \$537 million and an increase of \$79 million in other comprehensive income.

#### Cash flow and liquidity - 2010

All data in this section is on a Reported basis.

#### Net funds/(debt)

	2010 \$m	2009 \$m	2008 \$m
Net funds/(debt) brought forward at 1 January	535	(7,174)	(9,112)
Earnings before interest, tax, depreciation, amortisation and impairment	14,235	13,630	11,764
Movement in working capital and provisions	82	1,329	(210)
Tax paid	(2,533)	(2,381)	(2,209)
Interest paid	(641)	(639)	(690)
Other non-cash movements	(463)	(200)	87
Net cash available from operating activities	10,680	11,739	8,742
Purchase of intangibles (net)	(1,180)	(355)	(2,944)
Other capital expenditure (net)	(708)	(824)	(1,057)
Acquisitions	(348)	-	-
Investments	(2,236)	(1,179)	(4,001)
Dividends	(3,361)	(2,977)	(2,739)
Net share (repurchases)/issues	(2,110)	135	(451)
Distributions	(5,471)	(2,842)	(3,190)
Other movements	145	(9)	387
Net funds/(debt) carried forward at 31 December	3,653	535	(7,174)
Comprised of:			
Cash, short-term investments and derivatives (net)	12,875	11,598	4,674
Loans and borrowings	(9,222)	(11,063)	(11,848)

Cash generated from operating activities was \$10,680 million in the year to 31 December 2010, compared with \$11,739 million in 2009. The decline of \$1,059 million is primarily driven by legal settlements of \$709 million relating to *Seroquel* sales and marketing practices and product liability and Average Wholesale Price Litigation in the US, and the first instalment of \$562 million (£350 million) in respect of the UK tax settlement (for which the second instalment of £155 million is due in March 2011).

Investments cash outflows of \$2,236 million include the acquisition of Novexel (\$348 million), the payment of \$647 million to Merck (resulting in the Group acquiring Merck's interest in certain AstraZeneca products) and a further \$537 million paid out on other externalisation arrangements. Cash outflows on the purchase of tangible fixed assets amounted to \$791 million in the year. Further details of the Novexel business acquisition and our arrangements with Merck are included in Note 22 and Note 25 to the Financial Statements respectively.

Net cash distributions to shareholders increased from \$2,842 million in 2009 to \$5,471 million in 2010 through dividend payments of \$3,361 million and net share repurchases of \$2,110 million. At 31 December 2010, outstanding gross debt (interest-bearing loans and borrowings) was \$9,222 million (2009: \$11,063 million). The reduction in gross debt of \$1,841 million during the year was principally due to the repayment on maturity of Euro bonds of Euro 500 million and Euro 750 million. The first repayment was the Euro 500 million 18 month bond issued in July 2008 and maturing in January 2010, and the second was the Euro 750 million 3 year bond issued in November 2007 and maturing in November 2010. Of the gross debt outstanding at 31 December 2010, \$125 million is due within one year (2009: \$1,926 million). Strong business cash flows have improved net funds by \$3,118 million since 31 December 2010.

#### Off-balance sheet transactions and commitments

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

#### 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	646	2,691	2,532	10,095	15,964
Operating leases	161	137	105	103	506
Contracted capital expenditure	259	-	-	-	259
Total	1,066	2,828	2,637	10,198	16,729

#### Financial position – 2010

All data in this section is on a Reported basis.

#### Summary statement of financial position

	2010 \$m	Movement \$m	2009 \$m	Movement \$m	2008 \$m
Property, plant and equipment	6,957	(350)	7,307	264	7,043
Goodwill and intangible assets	22,029	(86)	22,115	(82)	22,197
Inventories	1,682	(68)	1,750	114	1,636
Trade and other receivables	7,847	138	7,709	448	7,261
Trade and other payables	(9,034)	(103)	(8,931)	(1,604)	(7,327)
Provisions	(1,938)	(252)	(1,686)	(544)	(1,142)
Net income tax payable	(3,855)	(1,002)	(2,853)	(885)	(1,968)
Net deferred tax liabilities	(1,670)	285	(1,955)	(65)	(1,890)
Retirement benefit obligations	(2,472)	882	(3,354)	(622)	(2,732)
Non-current other investments	211	27	184	28	156
Net funds/(debt)	3,653	3,118	535	7,709	(7,174)
Net assets	23,410	2,589	20,821	4,761	16,060

In 2010, net assets increased by \$2,589 million to \$23,410 million. The increase in net assets as a result of the Group profit of \$8,081 million was offset by dividends of \$3,494 million and share repurchases of \$2,604 million. Shares issued in the year increased net assets by \$494 million.

#### Property, plant and equipment

Property, plant and equipment decreased by \$350 million to \$6,957 million. Additions of \$808 million (2009: \$967 million) were offset by depreciation of \$1,076 million (2009: \$893 million).

#### Goodwill and intangible assets

Our goodwill of \$9,871 million (2009: \$9,889 million) 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 2010; the movement of \$18 million in 2010 being due to exchange rate movements.

Intangible assets amounted to \$12,158 million at 31 December 2010 (2009: \$12,226 million). Intangible assets additions were \$1,791 million in 2010 (2009: \$1,003 million), amortisation was \$810 million (2009: \$729 million) and impairments totalled \$833 million (2009: \$415 million).

Additions to intangible assets in 2010 included \$647 million paid to Merck under pre-existing arrangements under which Merck's interest in our products in the US will be terminated and \$548 million from our acquisition of Novexel (of which \$239 million of intangible assets acquired were subsequently sold to Forest as detailed in Note 22 to the Financial Statements).

Intangible asset impairment charges recorded in 2010 included \$445 million following our decision to withdraw our FDA biological license application for motavizumab detailed on page 156 and \$128 million related to our decision to discontinue further development of lesogaberan (AZD3355). The impairment balance also includes \$123 million following reassessment of the licensing income generated by the HPV cervical cancer vaccine and \$126 million written off other products in development.

#### Receivables, payables and provisions

Exchange rate movements contributed \$119 million of the overall increase of \$138 million in receivables with an increase in the trade receivables balance being offset by a reduction on other receivables mainly due to a reduction in our *Seroquel* related insurance

receivable balance during the year. Trade and other payables increased by \$103 million.

The movement in provisions of \$252 million in 2010 includes \$1,361 million of additional charges recorded in the year, offset by \$1,109 million of cash payments. Included within the \$1,361 million of charges in the year is \$592 million in respect of the ongoing *Seroquel* product liability litigation and state attorney general investigations into sales and marketing practices in aggregate and \$497 million for our global restructuring initiative. Further details of the charges made against our provisions are contained in Notes 17 and 25 to our Financial Statements. Cash payments of \$1,109 million include \$335 million against our global restructuring initiative and \$709 million related to legal provisions.

#### Tax payable and receivable

Net income tax payable has increased by \$1,002 million to \$3,855 million, principally due to an increase in accruals for tax contingencies, 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 on page 195). Net deferred tax liabilities reduced by \$285 million in the year. This movement includes a reclassification from deferred tax to current tax of amounts provided in relation to tax contingencies for prior periods.

#### **Retirement benefit obligations**

Net retirement benefit obligations reduced by \$882 million, principally as a result of recognising a gain of \$791 million arising from changes made to benefits under certain of the Group's post-retirement benefits plans, chiefly the Group's UK pension plan detailed on page 162. In 2010, approximately 96.5% of the Group's obligations were concentrated in the UK, the US, Sweden and Germany.

#### **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 Group Accounting Policies section from page 142. The Group also has taxation contingencies. These are described in the Taxation section in the Critical accounting policies and estimates section on page 93. These matters are explained fully in Note 25 to the Financial Statements from page 178. **Business Review** 

#### **Research and development collaboration payments**

Details of future potential research and development collaboration payments are also included in Note 25 to the Financial Statements from page 178. As detailed in Note 25, payments to our collaboration partners may not become payable because of the inherent uncertainty in achieving the development and revenue milestones linked to the future payments. As part of our overall externalisation strategy, we may enter into further collaboration projects in the future that may include milestone payments and, therefore, as certain milestone payments fail to crystallise due to, for example, development not proceeding, they may be replaced by potential payments under new collaborations.

#### Investments, divestments and capital expenditure

As detailed earlier in Research and Development from page 26, AstraZeneca views collaborations, including externalisation arrangements in the field of research and development, as a crucial element of the development of our business.

The Group has completed over 80 major externalisation transactions over the past three years, one of which was a business acquisition and all others were strategic alliances and collaborations. Details of our significant externalisation transactions are given below. The Group determines these to be significant using a range of factors. We look at the specific circumstances of the individual externalisation arrangement and apply several quantitative and qualitative criteria. Because we consider our externalisation strategy to be an extension of our research and development strategy, the expected total value of development payments under the transaction and its proportion in our annual R&D spend, both of which are proxies for overall research and development effort and cost, are important elements of the significance determination. Other quantitative criteria we apply include, without limitation, expected levels of future sales, the possible value of milestone payments and the resources used for commercialisation activities (for example, the number of staff). Qualitative factors we consider in our determination of whether an externalisation arrangement is significant include, without limitation, new market developments, new territories, new areas of research and strategic implications.

Based on the application of the quantitative and qualitative factors described above, we have determined that the following two externalisation arrangements are significant:

- > In January 2007, AstraZeneca signed an exclusive codevelopment and co-promotion agreement with BMS for the development and commercialisation of saxagliptin, a dipeptidyl peptidase IV inhibitor (DPP-IV) for the treatment of Type 2 diabetes, and dapagliflozin, a selective sodium-glucose cotransporter 2 (SGLT2) inhibitor. The agreement is global (with the exception of Japan) for saxagliptin. Under each agreement the two companies jointly develop the clinical and marketing strategy and share development and commercialisation expenses on a global basis. To date, AstraZeneca has made upfront and milestone payments totalling \$300 million for saxagliptin and \$50 million for dapagliflozin and may make future milestone payments of \$350 million on dapagliflozin contingent on achievement of regulatory milestones and launch in key markets. Following launch, profits and losses globally are shared equally and an additional \$300 million of sales-related payments for each product may be triggered based on worldwide sales success. The Group made milestone payments to BMS of \$50 million in 2010, \$150 million in 2009 and \$50 million in 2008.
- In December 2009, AstraZeneca and Targacept entered into an in-licence agreement for AstraZeneca to obtain exclusive global development and commercialisation rights to Targacept's investigational product for major depressive disorder (MDD), TC-5214. TC-5214, which recently completed a Phase IIb clinical trial, is a nicotinic channel blocker that is thought to treat depression by modulating the activity of various neuronal nicotinic receptor (NNR) subtypes. Under the deal, AstraZeneca made an upfront payment of \$200 million and may make milestone payments to a maximum of \$540 million up to launch. In addition, Targacept will be entitled to receive royalties on worldwide product sales and additional milestone payments linked to worldwide product sales.

Details of our business acquisitions in the last three years are contained in Note 22 to the Financial Statements from page 167.

In aggregate, milestones capitalised under the Group's other externalisation arrangements totalled \$337 million in 2010, \$306 million in 2009 and \$62 million in 2008, and the Group recognised other income in respect of other externalisation arrangements totalling \$82 million in 2010, \$440 million in 2009 and \$216 million in 2008.

#### Capitalisation and shareholder return Dividend for 2010

	\$	Pence	SEK	Payment date
First interim dividend	0.70	44.9	5.12	13.09.10
Second interim dividend	1.85	116.7	11.99	14.03.11
Total	2.55	161.6	17.11	

#### Summary of shareholder distributions

	Shares repurchased (million)	Cost \$m	Dividend per share \$	Dividend cost \$m	Shareholder distributions \$m
2000	9.4	352	0.70	1,236	1,588
2001	23.5	1,080	0.70	1,225	2,305
2002	28.3	1,190	0.70	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	1.30	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	3,339	3,339
2010	53.7	2,604	2.55	<b>3,617</b> <sup>1</sup>	6,221
Total	425.6	20,520	15.625	23,956	44,476

<sup>1</sup> Total dividend cost estimated based upon number of shares in issue at 31 December 2010.

#### Capitalisation

The total number of shares in issue at 31 December 2010 was 1,409 million. 11.8 million shares were issued in consideration of share option exercises for a total of \$494 million. Share repurchases amounted to 53.7 million ordinary shares at a cost of \$2,604 million. Shareholders' equity increased by a net \$2,553 million to \$23,213 million at the year end. Non-controlling interests increased to \$197 million (2009: \$161 million).

#### **Dividend and share repurchases**

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.

The Board has recommended an 8% increase in the second interim dividend to \$1.85 (116.7 pence, 11.99 SEK) to be paid on 14 March 2011. This brings the full year dividend to \$2.55 (161.6 pence, 17.11 SEK), an increase of 11%.

In 2010, the Group recommenced its share repurchase programme. The Group completed net share repurchases of \$2,110 million in 2010. The Board has announced that the Group intends to complete net share repurchases in the amount of \$4 billion during 2011.

In setting the distribution policy and the overall financial strategy, the Board's aim is to continue to strike a balance between the interests of the business, our financial creditors and our shareholders. After providing for business investment, funding the progressive dividend policy and meeting our debt service obligations, the Board will keep under review the opportunity to return cash in excess of these requirements to shareholders through periodic share repurchases.

#### **Future prospects**

As described earlier in our Annual Report, the coming 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 makes high level planning assumptions for revenue evolution, margins, cash flow and business reinvestment to help guide the management of the business. The planning outlook extends to 2014. AstraZeneca assumes that the global biopharmaceutical industry can grow at least in line with real GDP over the planning horizon. While downward pressure on revenue from government interventions in the marketplace remains a continuing feature of the challenging market environment, AstraZeneca's assessment remains that, as yet, these have not risen to a "step-change" in trend. The assumptions for revenue, margins and cash flow assume no material mergers, acquisitions or disposals. In addition, our plans assume no premature loss of exclusivity for key AstraZeneca products. It was also assumed that exchange rates for our principal currencies will not differ materially from the average rates that prevailed during January 2010, and AstraZeneca sees no basis for material changes to exchange rate assumptions.

It is expected that revenue growth from key franchises that retain exclusivity and continued growth in Emerging Markets will be pressured by the loss of market exclusivity on a number of products. Revenue for 2011 will continue to be affected by the loss of market exclusivity for *Arimidex* in the US, and for *Arimidex* in Europe and in Established ROW once exclusivity expires in February 2011. The extent of generic competition to *Nexium* in Europe is another variable that could influence 2011 revenue.

Over the last several years, the Group has undertaken significant restructuring initiatives aimed at reshaping the cost base to improve long-term competitiveness. The first phase of the restructuring programme is now complete at a cumulative cost of \$2.5 billion. The second phase of restructuring, which was announced in January 2010, is comprised of a significant change programme in R&D as well as additional productivity improvement initiatives in the supply chain and SG&A. Of the estimated \$2.0 billion in costs anticipated for this phase of the programme, \$1.2 billion was charged in 2010; the remainder will largely be taken in 2011. This programme will deliver annual benefits to the Group by 2014.

Planning assumptions remain that continued productivity improvements (including successful completion of restructuring initiatives), will aid the achievement of levels of revenue and margins to generate the requisite operating cash flow over the planning period to support the reinvestment needs of the business, debt service obligations and shareholder distributions.

#### **Results of operations – summary analysis of year to 31 December 2009** 2009 Reported operating profit

			2009	2008	Percer	ntage of sales	2009 compar	ed with 2008
	Reported \$m	CER growth \$m	Growth due to exchange effects \$m	Reported \$m	Reported 2009 %	Reported 2008 %	CER growth %	Reported growth %
Revenue	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				
Basic earnings per share (\$)	5.19			4.20				

#### 2009 Core operating results

			2009	2008	2009 compare	ed with 2008
	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 finance expense	(736)			(463)		
Profit before tax	12,885			10,495		
Taxation	(3,703)			(3,056)		
Profit for the period	9,182			7,439		
Basic earnings per share (\$)	6.32			5.10		

#### 2009 Reconciliation of Reported results to Core results

			Merck			
	2009 Reported \$m	Restructuring costs \$m	Amortisation \$m	Intangible impairments \$m	Legal provisions \$m	2009 Core \$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
Add back: Research and development	4,409	(68)	-	(7)	-	4,334
Pre-R&D operating margin	15,952	591	511	265	636	17,955
Net finance expense	(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
Basic earnings per share (\$)	5.19	0.32	0.27	0.13	0.41	6.32

In 2009, sales increased by 7% (Reported: 4%). 2009 revenues 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%. Further details of our 2009 sales performance are given in the Performance 2009 sections of the Therapy Area Review from page 50.

Core gross margin of 83% for 2009 was 2.4% higher than 2008 (Reported: 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 2009, 3% lower than the prior year (Reported: 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 2009 were 5% higher than the prior year (Reported: 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 operating income and expense 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 2009.

Impairment charges relating to intangible fixed assets totalled \$415 million during 2009. 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 were excluded from Core results.

Developments in several legal matters resulted in provisions totalling \$636 million in 2009.

2009 restructuring costs totalling \$659 million, incurred as the Group continued 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 in 2009, an increase of 23% (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 in 2009, versus \$463 million in 2008. The principal factors contributing to this increase were the continued reversal of a 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 (2008: \$130 million gain) as credit spreads reduced since the 2008 year end.

The effective tax rate for 2009 was 30.2%. Excluding the impact of the \$636 million legal provisions, the effective tax rate would have been 28.8% (2008: 29.4%).

2009 Core EPS were \$6.32, an increase of 23% from 2008, as the increase in Core operating profit was partially offset by increased net finance expense. 2009 Reported EPS increased 24% to \$5.19.

Total comprehensive income for 2009 increased by \$3,266 million from 2008. This was principally due to an increase in profit in 2009 of \$1,414 million, beneficial exchange rate impacts on consolidation of \$1,365 million and reduced actuarial losses of \$663 million compared with 2008.

#### Cash flow and liquidity - 2009

All data in this section is on a Reported basis.

Cash generated from operating activities was \$11,739 million in 2009, 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 2009.

Net cash outflows from investing activities were \$2,476 million in 2009 compared with \$3,896 million in 2008. The movement of \$1,420 million was 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 in 2009.

Gross debt (including loans, short-term borrowings and overdrafts) was \$11,063 million as at 31 December 2009 (2008: \$11,848 million). Of this debt, \$1,926 million was due within one year (2008: \$993 million).

Net funds of \$535 million improved by \$7,709 million from net debt of \$7,174 million at 31 December 2008.

#### Financial position – 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 in 2009. 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 2009.

#### Property, plant and equipment

In 2009, 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 increased by \$82 million to \$22,115 million.

Goodwill principally arose on the acquisition of Medlmmune and on the restructuring of our US joint venture with Merck in 1998. No goodwill was capitalised in 2009.

Intangible assets reduced by \$97 million in 2009 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.

#### Inventories

Inventories increased by \$114 million to \$1,750 million in 2009, 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 2009, legal defence costs of approximately \$656 million (2008: \$512 million) have been incurred in connection with *Seroquel*-related product liability claims. The first \$39 million is not covered by insurance. At 31 December 2009, AstraZeneca recorded an insurance receivable of \$521 million (2008: \$426 million), representing the maximum insurance receivable that AstraZeneca could recognise under applicable accounting principles at that time.

In 2009, trade and other payables increased by \$1,604 million primarily due to increases in US managed market accruals, accruals in respect of intangibles investments made in the fourth quarter and other accruals. Trade and other payables included \$2,618 million in respect of accruals relating to rebates and chargebacks in our US market.

During 2009 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 was 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.

#### Tax payable and receivable

Net income tax payable increased by \$885 million to \$2,853 million in 2009, principally due to tax audit provisions, cash tax timing differences and exchange rate movements.

#### **Retirement benefit 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. In 2009, approximately 97% of the Group's obligations were concentrated in the UK, the US and Sweden.

#### **Financial risk management**

#### Financial risk management policies Insurance

Our risk management processes are described in the Managing risk section from page 95. 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 while 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 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 23 to the Financial Statements from page 168 and in the Managing risk section from page 95.

Sensitivity analysis of the Group's exposure to exchange rate and interest rate movements is also detailed in Note 23 to the Financial Statements from page 168.

#### **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 Group Accounting Policies section in the Financial Statements from page 142. 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
- > Impairment testing of goodwill and intangible assets
- > Litigation
- > Post-retirement benefits
- > Taxation
- > Segmental reporting.

#### **Revenue recognition**

Revenue is recorded at the invoiced amount (excluding intercompany sales and value added taxes) less movements in estimated accruals for rebates and chargebacks given to managedcare 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, Public Health Service Covered Entities 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 with the US Department of Health and Human Services and with individual states, which include product usage and information on best prices and average market prices benchmarks.
- > Contractual, under which entities such as third party managedcare 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 revenue and the movements on US pharmaceuticals revenue provisions are set out opposite.

Accrual assumptions are built up on a product-by-product and customer-by-customer 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.

#### Gross to net sales

	2010 \$m	2009 \$m	2008 \$m
Gross sales	22,909	22,646	20,029
Chargebacks	(2,075)	(1,841)	(1,726)
Regulatory – US government and state programmes	(1,949)	(1,357)	(1,005)
Contractual – Managed-care and group purchasing organisation rebates	(4,755)	(4,752)	(3,658)
Cash and other discounts	(437)	(428)	(390)
Customer returns	(21)	(193)	(48)
Other	(265)	(196)	(167)
Net sales	13,407	13,879	13,035

#### Movement in provisions

	Brought forward at 1 January 2010 \$m	Provision for	Adjustment in respect of prior years \$m	Returns and payments \$m	Carried forward at 31 December 2010 \$m
Chargebacks	396	2,107	(32)	(1,948)	523
Regulatory – US government and state programmes	775	1,984	(35)	(1,602)	1,122
Contractual – Managed-care and group purchasing organisation rebates	1,447	4,826	(71)	(5,008)	1,194
Cash and other discounts	41	438	(1)	(437)	41
Customer returns	177	22	(1)	(65)	133
Other	59	269	(4)	(260)	64
Total	2,895	9,646	(144)	(9,320)	3,077

	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)	41
Customer returns	77	194	(1)	(93)	177
Other	57	198	(2)	(194)	59
Total	2,136	8,872	(105)	(8,008)	2,895

	Brought forward at 1 January 2008 \$m	Provision for current year \$m	Adjustment in respect of prior years \$m	Returns and payments \$m	Carried forward at 31 December 2008 \$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

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.

For products facing generic competition (such as Arimidex and *Merrem* 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.

## Overview

The closing adjustment in respect of prior years benefited 2010 net US pharmaceuticals revenue by 1.1% (2009: increased revenue by 0.8%; 2008: decreased revenue by 0.2%). However, taking into account the adjustments affecting both the current and the prior year, 2009 revenue benefited by 0.3% and 2008 revenue decreased by 1.0%.

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.

#### 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) while 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 profit 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. Further details of this policy are included in the Group Accounting Policies section of our Financial Statements on page 142. 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.

Details of the estimates and assumptions we make in our annual impairment testing of goodwill are included in Note 8 to the Financial Statements on page 154. No impairment of goodwill was identified.

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 and all intangible assets that have had indications of impairment during the year. Sales forecasts and specific allocated costs (which have both been subject to appropriate senior management sign-off) are discounted using appropriate rates based on AstraZeneca's risk-adjusted pre-tax weighted average cost of capital. In building to the range of rates used in our internal investment appraisal of future projects and capital investment decisions, we adjust our weighted average cost of capital for other factors, which reflect, without limitation, local matters such as risk on a case by case basis.

Intangible asset impairment charges recorded in 2010 included \$445 million following our decision to withdraw our FDA biological license application for motavizumab as detailed on page 156 and \$128 million related to our decision to discontinue further development of lesogaberan (AZD3355).

The majority of our investments in intangible assets and goodwill arose from the restructuring of the joint venture with Merck in 1998, the acquisition of MedImmune in 2007 and the payments to partially retire Merck's interests in our products in the US in 2008 and 2010, and we are satisfied that the carrying values at 31 December 2010 are fully justified by estimated future cash flows. The accounting for our arrangements with Merck is fully explained in Note 25 to the Financial Statements from page 178.

Further details of the estimates and assumptions we make in impairment testing of intangible assets are included in Note 9 to the Financial Statements from page 155.

#### 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 where we are unable to make a reasonable estimate of the liability, we treat them as contingent liabilities. These are not provided for but are disclosed in Note 25 to the Financial Statements from page 178.

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 (more than 50% assessed probability) 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 product liability and to drug marketing and pricing practices and in respect of which AstraZeneca has made an aggregate provision of \$612 million in the year. \$592 million of this provision has been made in respect of the ongoing *Seroquel* product liability litigation and state attorney general investigations into sales and marketing practices in aggregate. The current status of these matters is described more fully in Note 25 to the Financial Statements from page 178, including our position on recovery of legal defence costs on page 190. 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, or in the rare circumstances where the amount of the legal liability cannot be estimated reliably, 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 and we consider recovery to be virtually certain, then 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.

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 financial results in any particular period.

#### **Post-retirement benefits**

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. The benefits provided by the UK pension plan were modified during 2010. As detailed on page 83 and Note 18 to the Financial Statements from page 162, in accordance with IAS 19 'Employee Benefits', we recognised a gain of \$791 million in the year arising from changes made to benefits under certain of the Group's post-retirement plans, chiefly the freezing of future pensionable pay at 30 June 2010 levels under the Group's UK pension plan.

In applying IAS 19, 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 except in Sweden where we have used rates on government bonds as the market in high quality bonds is insufficiently deep.

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 country-specific 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.

Further details of the estimates and assumptions we make in determining our recorded liability for transfer pricing audits and other tax contingencies are included in the tax section of Note 25 of the Financial Statements on page 195.

#### Segmental reporting

In 2009, AstraZeneca 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. Further details of our consideration of IFRS 8 are given in our Group Accounting Policies from page 145.

#### **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 well-controlled business.

The Directors have concluded that our internal control over financial reporting is effective at 31 December 2010 and the assessment is set out in the Directors' Responsibilities for, and Report on, Internal Control over Financial Reporting on page 136. KPMG Audit Plc has audited the effectiveness of our internal control over financial reporting at 31 December 2010 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 137, their report is unqualified.

## What is our approach to risk management? We encourage clear decision making as to which risks we take and how we manage them

### **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 the Business Review section from page 24, where relevant.

#### Managing risk

As an innovation-driven, global, prescription-based biopharmaceutical business, 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 take as a business and how we manage those risks, in each case informed by an understanding of the commercial, financial, compliance, legal 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, emerging and changing 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 these risks and uncertainties is set out in the Principal risks and uncertainties section from page 96.

#### Embedded in business processes

We strive to ensure sound risk management is embedded within our strategy, planning, budgeting and performance management processes. The Board has defined the Group's risk appetite expressing the acceptable levels of risk for the Group using three key dimensions (earnings and cash flow, return on investment and reputation). This definition provides a clear statement of the Board's position on risk and enables, in quantitative and qualitative terms, the level of risk the Group is prepared to take in individual decisions, in pursuit of its overall objectives, to be taken into account.

Annually, the Group develops a long-term business plan to support the delivery of its strategy and the Board reviews and confirms that the business plan conforms to its risk appetite. Line management are accountable for identifying and managing risks, and for delivering business objectives within the Group's risk appetite. Each area for which a SET member is responsible (a SET function) is required to provide a comprehensive assessment of its risks as part of the annual business planning process. Identified risks are mapped to AstraZeneca's risk 'taxonomy', which provides a structured disaggregation of the potential strategic, operational, compliance and reputational risks facing the Group. The CEO and the CFO undertake quarterly business reviews (QBRs) with each SET function where the key risks are reviewed. Business managers within each SET function are required to provide quarterly updates on their key risks and these are consolidated to create the list of key risks for that SET function for review at the QBRs. The key risks for each SET function are then aggregated into a Group risk register. The purpose of the risk review is to identify and measure risks, and to define and review risk management and mitigation plans. Risk management standards, guidelines and supporting tools are in place to support the managers in the effective identification, reporting, management and mitigation of risk.

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 is to ensure that a culture of ethics and integrity is embedded in all business practices. 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.

For information about how we identify and manage the risks associated with 'responsible business', please see the Accountabilities and responsibilities section of the Responsible Business section on page 41.

#### 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 cross-functional 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 SET is responsible for overseeing and monitoring the effectiveness of the risk management processes implemented by management. Specialist risk and compliance functions support the SET by providing and advising on policy and standard setting, monitoring and auditing, communication and training, and reporting on the adequacy of line management processes as they apply to managing risk throughout the business.

#### Risk

Our compliance organisation is comprised of the Global Compliance function together with a wide range of specialist compliance functions. Global Compliance maintains our Code of Conduct and Global Policies and Standards and ensures that an effective compliance programme is in place to ensure compliance with the 16 Principles of our Code of Conduct and relevant policies and standards.

The specialist compliance functions support line management and SET to manage risk in specific regulated areas to ensure ongoing legal and regulatory compliance. These specialist groups include: Good Laboratory, Clinical and Manufacturing Compliance; Sales and Marketing Compliance; Medical and Regulatory Affairs; Financial Control and Compliance; Safety, Health and Environment; Information Security and Data Privacy; and Security.

When a potential compliance breach is identified, the compliance organisation undertakes an internal investigation. Should the investigation conclude that an actual compliance breach has occurred, the compliance organisation will consider whether the Company needs to make a disclosure and/or to report the findings to a regulatory or governmental authority. When appropriate, the compliance organisation will engage external advisers to conduct and/or advise on investigations.

#### Management reporting and assurance

The Audit Committee is comprised of five Non-Executive Directors and is accountable, among other things, for assessing the adequacy and effectiveness of the risk management systems and processes implemented by management. The Audit Committee receives regular reports from the external auditor and the following business functions:

- > Group Internal Audit (GIA) independent assurance reports on the Group's risk management and control framework.
- > Global Compliance compliance programme reports on key compliance risks, updates on key compliance initiatives, performance against the Global Compliance scorecard, compliance incidents and investigations including calls made by employees to the AZethics and MedImmune helplines.
- > Financial Control and Compliance Group reports on Sarbanes-Oxley Act compliance and the financial control framework.
- > Management the Group-level risk summary from the annual business planning process and QBRs and reports on the performance management and monitoring processes.

The Audit Committee reviews and reports to the Board following each Audit Committee 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 and other compliance matters. For further information on the Audit Committee, see the Audit Committee section from page 113.

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 Audit Committee meeting. A core part of the audit work carried out by GIA includes assessing how AstraZeneca is managing risk and reviewing the effectiveness of selected aspects of AstraZeneca's risk control framework, including the effectiveness of other assurance and compliance functions within the business. During 2010, 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 on 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 and differentiated 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 the manufacturing of biologics and their supply chain. manufacture, 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 and marketing, 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, certain 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 MAA can be obtained through a centralised procedure.

Difficulties of obtaining and maintaining regulatory approvals

for new products

In recent years, companies sponsoring new drug applications and regulatory authorities have been under increased public pressure to apply more conservative risk/benefit criteria and, in some instances, the applicable regulatory authorities require a company to develop plans to ensure safe use of a marketed product before a pharmaceutical product is approved, or after approval, if a new and significant safety issue is established. 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, the predictability of the outcome and timing of review processes remains challenging, particularly in the US, due to competing regulatory priorities and a continuing sentiment of risk aversion on the part of regulatory reviewers and management. Delays in regulatory reviews and approvals could impact the timing of a new product launch and the drive for public transparency of the review processes through the more extensive use of public advisory committees, which in the US, continue to add to the unpredictability of the process. For example, the approval of Brilinta and Axanum in the US has been delayed by Complete Response Letters which requested further data and/or analyses.

#### Failure to obtain effective intellectual property protection

Our policy and a key business priority is to protect our investment in R&D by securing appropriate intellectual property protection in respect of our inventions and innovations. Our ability to obtain and enforce 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.

A number of the countries in which we operate are still developing their intellectual property laws or may even be limiting the applicability of these laws to pharmaceutical inventions such that certain countries may seek to limit or deny effective patent protection for pharmaceuticals. Limitations on the availability of patent protection or the use of compulsory licensing 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 from page 30 and information about the risk of patent litigation and the early loss of intellectual property rights is contained in the Patent litigation and early loss of intellectual property rights section from page 98.

#### 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.

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 collaborations. 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 projects. If we are unsuccessful in establishing such projects in the future, this may have a material adverse effect on our financial condition and results of operations.

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#### 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 expires. 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/ Fluenz*. 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, it can be difficult, for a period following the launch of a new product, 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 the 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 will 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)
- > the need to impose developed market compliance standards in emerging markets
- > inadvertent breaches of local and international law/regulation
- > not being able to recruit sufficient personnel with appropriate skills and experience
- > identification of the most appropriate and effective sales channels and route to market 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 reputation, financial condition and results of operations.

#### Expiry of intellectual property rights

Pharmaceutical products are normally only protected from being copied during the period of protection under patent rights or related intellectual property rights such as Regulatory Data Protection or Orphan Drug status. Following expiry of such rights, the product is generally open to competition from generic versions. Products under patent protection or within the period of Regulatory Data Protection typically generate significantly higher revenues than those not protected by such rights. See the Intellectual Property section from page 30 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 asserted or challenged in intellectual property litigation initiated against or by alleged infringers. Such intellectual property rights may be affected by validity challenges in patent offices. In any event, we expect our most valuable products to receive the greater number of challenges. Despite our efforts to establish and defend robust patent protection for our products, we may not succeed in such litigation and 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, our revenue and margins could be materially adversely affected.

Generic drug manufacturers are seeking to market generic versions of many of our more important products prior to expiries of our patents and Regulatory Exclusivity periods. For example, we are currently facing challenges in the US from numerous generic drug manufacturers regarding certain of our patents for *Seroquel XR*, *Nexium* and *Crestor*, three of our best selling products. 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 2010, US sales for *Seroquel XR*, *Nexium* and *Crestor* were \$640 million, \$2,695 million, and \$2,640 million respectively. The more significant patent litigation relating to our products is described in Note 25 to the Financial Statements from page 178.

Additional Information

In addition to patent challenges by generic drug manufacturers seeking to market generic versions of our products, we bear the risk that we may be found to infringe patents owned or licensed exclusively by third parties, including research-based and generic pharmaceutical companies and individuals. Such third party patents may allegedly cover, for example, compositions, devices, products, processes, methods, biological materials, or research tools relating to our products. Infringement accusations may implicate, for example, our manufacturing processes, product intermediates or use of research tools. Managing or litigating infringement disputes over so-called 'freedom to operate' can be costly. We may be subject to injunctions against our products or processes and/or be liable for damages or royalties. We may need to obtain costly licences. These risks may be greater in respect of biologics and vaccines, where such infringement accusations relating to patents claiming processes, research tools, methods, and biological materials are frequently found. We may mitigate such risks successfully through, for example, acquiring licences, foregoing certain activities or uses, or modifying processes to avoid infringement claims and permit commercialisation of our products, but there is no certainty that any such action or modification will be possible; and any such action may entail significant cost. Details of significant infringement claims against AstraZeneca by third parties enforcing intellectual property rights can be found in Note 25 to the Financial Statements from page 178.

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 valid trade marks usually generate higher revenues than those without trade marks. 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.

#### Biosimilars

Various regulatory authorities are implementing or considering abbreviated approval processes for biosimilars (similar versions of existing biologics, also referred to as 'similar biological medicinal products' and 'follow-on biologics').

For example, in 2010, the US enacted the Biologics Price Competition and Innovation Act within the Affordable Care Act, which contains general directives for biosimilar applications. The FDA sought stakeholder input on specific issues and challenges in implementing an abbreviated biosimilar approval pathway and further guidance is expected to be issued. In Europe, the EMA published a draft guideline on similar biological medicinal products containing MAbs. This draft guideline will likely be finalised in 2011. In May 2010, the WHO published 'Guidelines for Evaluation of Similar Biotherapeutic Products', which are intended for national regulatory authorities in other markets.

While it is uncertain when any such processes may be fully adopted, particularly for complex protein molecules such as MAbs, any such processes could have a material adverse effect on the future commercial prospects for patented biologics.

#### Expiry or earlier loss of patents covering competing products

The expiry or earlier loss of patents covering other innovator companies' 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 financial condition and results of operations. For example, the loss of patent rights covering major products in the US, such as Advair Diskus<sup>™</sup> before 2012 or Celebrex<sup>™</sup> before 2014, or the early entry of generic versions of still-patented products, prior to the expiry of the patents protecting such products, such as Lipitor<sup>™</sup> (expected in 2011), may adversely affect the growth of our stillpatented products in the same product class (ie *Symbicort, Vimovo* and *Crestor*, respectively) in that market.

#### Competition, price controls and price reductions

All our products compete directly with other products marketed either by major research-based 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 the manufacturer does 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, including *Nexium*, *Crestor* and *Seroquel*, are subject to price pressure from competition from generic products in the same product class.

Industry consolidation has resulted in a small number of very large companies. This trend, if it continues, could materially adversely affect our competitive position, while consolidation among our customers may increase price pressures.

In most of our key markets there is continued economic, regulatory and political pressure to limit or reduce the cost of pharmaceutical products. Concurrently, many markets are adopting the use of Health Technology Assessment (HTA) to provide a rigorous evaluation of the clinical efficacy of a product, at or post-launch. HTA evaluations are also increasingly being used to assess the clinical as well as the cost effectiveness of products in a particular health system. This comes as payers and policy-makers attempt to drive increased efficiencies in the use and choice 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 70.

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, which require physicians to obtain prior approval for the use of a branded medicine where a generic version exists. 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 on to the individual via out-of-pocket 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, among 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.

#### Risk

In the US, new legislation is possible that may allow the commercial importation of medicines into the US from selected countries where these medicines are available at lower prices than in the US. 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 recently passed the Affordable Care Act, a comprehensive health reform package with provisions initially taking effect between 2010 and 2014. Among other things, the law expands insurance coverage, establishes new national entities focused on health system reforms, and calls on the pharmaceutical industry and other healthcare industries to offset spending increases through 'payfors'. In terms of specific provisions impacting our industry, the law mandates higher rebates and discounts on branded drugs for certain Medicare and Medicaid patients as well as an industry-wide excise tax. The law also includes several health system delivery reforms that will be implemented over the next four years, including the establishment of a new comparative effectiveness research organisation, the Patient-Centered Outcomes Research Institute and an Independent Payment Advisory Board with broad authority to propose to cut Medicare expenditures. The combined work of these two entities could lead to continued downward price pressure on pharmaceuticals. As the US continues to struggle with federal and state budget deficits, it is expected that there will be continued downward pressure on healthcare spending growth.

The health reform legislation expands the patient population eligible for Medicaid and provides new insurance coverage for individuals through state-operated health insurance exchanges. Large employers have typically offered generous health insurance benefits, but many are struggling with increasing health insurance premiums and may therefore opt to shift employee coverage into the health insurance exchanges, which will be operational by 2014. The pharmaceutical industry could be adversely impacted by such shifts if the health insurance exchanges do not offer a prescription drug benefit that is as robust as benefits historically provided by large employers.

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 continues to be exposed in Europe to a range of disparate pricing systems, ad hoc cost-containment measures and reference pricing mechanisms, which impact prices. This can lead to marked price differentials between markets, which increases the pricing pressure affecting the industry. 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, is already prevalent and may increase. In particular, as discussed in the Pricing pressure section from page 11, Germany, Spain, Portugal and Greece have introduced a number of short-term measures to lower healthcare spending, including price cuts or increased mandatory rebates. This could have a material adverse effect on our financial condition and results of operations.

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.

#### Increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation

There is an increasing focus globally on the implementation of legislation of an anti-bribery and anti-corruption nature and on the enforcement of such legislation. For example, in the UK, the new Bribery Act 2010 received Royal Assent in April 2010 and is expected to come into force in 2011. While there remains speculation as to the practical impact of the Bribery Act on companies, it has extensive extra-territorial application, implements significant changes to existing UK anti-bribery legislation and broadens the scope of statutory offences and the potential penalties applicable thereto, including, among others things, the creation of liability for any bribe paid on behalf of an organisation where the organisation failed to have adequate preventative procedures in place at the time of the offence. There is also an increase in the maximum applicable penalties for bribery, including up to ten years' imprisonment and unlimited fines. There have also been increased enforcement efforts in the UK by the Serious Fraud Office and, in the US, there has been significant enforcement activity in respect of the Foreign Corrupt Practices Act by the SEC and US Department of Justice against US companies as well as non-US companies listed in the US.

We devote significant resources to the considerable challenge of compliance with this legislation, including in emerging and developing markets, at considerable cost. AstraZeneca is the subject of current anti-corruption investigations and there can be no assurance that we will not, from time to time, continue to be subject to informal inquiries and formal investigations from governmental agencies. In the context of our business, governmental officials interact with us in a variety of roles that are important to our operations, such as in the capacity of a regulator, partner or healthcare payer, reimburser or prescriber, among others. Inquiries and investigations from governmental agencies require additional resources to be devoted and, notwithstanding the measures that we take to prevent breaches of applicable anti-bribery and anti-corruption laws by our personnel, breaches may result in the imposition of significant penalties, such as the payment of fines, the requirement to comply with monitoring or self-reporting obligations or debarment or exclusion from government sales or reimbursement programmes, any of which could have material adverse consequences on our business operations, financial condition and results of operations, and could cause damage to our reputation.

#### Any expected gains from productivity initiatives are uncertain

We continue to implement various productivity initiatives and restructuring programmes with the aim of enhancing the long-term efficiency of the business. However, anticipated cost savings and other benefits from these programmes are based on 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 initiatives can be lost through low employee engagement and hence productivity, increased absence and attrition 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, 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.

#### 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 95.

#### 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; for example, some R&D processes, information services and IT systems, facilities management, human resources, and finance and accounting services among other support functions. 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

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 (for example, the active pharmaceutical ingredient in some of our medicines), equipment, formulated drugs and packaging, all of which are key to our operations.

However, events beyond our control could result in the failure of supplies of goods which could have a material adverse effect on our financial condition and results of operations. For example, suppliers of some of the key goods we rely on may cease to trade. The consequence of this may be significant delays and/or difficulties in obtaining goods and services on commercially acceptable terms, if 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. Further information is contained in the Managing sourcing risk section on page 35.

#### 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 many 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

#### Risk

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 could have a material adverse effect on our financial condition and results of operations.

#### 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, litigation and government investigation. 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 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 nonmonetary remedies.

#### 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 Seroguel and further details about this are set out in Note 25 to the Financial Statements from page 178. Information about our approach to patient safety is set out in the Patient safety section from page 44.

#### 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 these 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 or pharmacovigilance (ie post-marketing safety surveillance) regulations for pharmaceutical products could arise and lead to loss of product licences, product recalls and seizures, interruption of production leading to product shortages, and delays in the approvals of new products pending resolution of the 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 are responsible could result in our 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 some cases, those governments most severely impacted by the economic downturn may seek alternative ways to settle their debts through, for example, the issuance of government bonds which might trade at a discount to the value of the debt. 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 an innovationdriven, global, prescription-based biopharmaceutical 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 90), 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 90.

#### 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 41% of our global 2010 sales were in the US, 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 28.5% 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 23 to the Financial Statements from page 168.

#### 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 90 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 Seroguel - product liability section on page 190.

#### 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 90 for tax risk management policies and Note 25 to the Financial Statements on page 195 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 asset values 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 as a result of a sustained low interest rate environment, there will be a strain on funding from the business. The likely increase in the IAS 19 accounting deficit generated by any of these factors may cause the ratings agencies to review our credit rating, with the potential to negatively affect our ability to raise debt. See Note 18 to the Financial Statements from page 162 for further details of the Group's pension obligations.

In a world where there is increasing pressure on healthcare budgets, we can be more effective if we can identify the patients likely to benefit most from particular medicines. We have experience of this personalised healthcare approach with our lung cancer therapy *Iressa*.

At one stage *Iressa* had its submissions withdrawn because its benefits failed to reach statistical significance in the overall population. However, it worked well on some patients and subsequent analysis of data from clinical studies showed that it was superior to conventional chemotherapy in 1st line treatment of lung cancer patients who had a mutation of the EGFR gene.

Identifying the right treatment for the right patient at the right time and to embed it as part of routine clinical practice was the major challenge for *Iressa*. We worked with a variety of healthcare professionals (HCPs) to improve education and best practice in EGFR testing. Workshops involving pathologists, oncologists and respiratory physicians were run around the world. These were complemented by digital activities, including websites, e-learning, and even iPhone applications, to promote best practice and facilitate routine diagnostic testing.

As the first personalised medicine in lung cancer, *Iressa* is pioneering, not just for the benefits it offers patients, but for the way in which it has brought together different groups of HCPs and changed the way patients are tested and treated as part of routine clinical practice.

## How do I find a cancer treatment that's right for me?





Because health connects us all For more information go to the website, egfr-mutation.com.

How is our business structured and managed? We have a clear structure in which the Board reserves and delegates its powers

### Board of Directors at 31 December



#### 1 Louis Schweitzer (68)

#### Non-Executive Chairman, Chairman of the Nomination and

**Governance Committee and member of the Remuneration Committee** Appointed as a Director in March 2004 and as Chairman in January 2005. Louis Schweitzer has extensive leadership experience at both executive and non-executive levels in large, multinational companies. He is Non-Executive Chairman of AB Volvo and a Non-Executive Director of BNP-Paribas, Veolia Environnement SA and L'Oréal SA. Previously he has held the roles of Non-Executive Chairman, Chairman and Chief Executive Officer of Renault SA.

#### 2 David Brennan (57)

#### **Executive Director and Chief Executive Officer**

Appointed as a Director in March 2005 and as CEO in January 2006. David Brennan is President of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and a member of the executive board of the European Federation of Pharmaceutical Industries and Associations (EFPIA). He is a past Chairman of the board of the Pharmaceutical Research and Manufacturers of America (PhRMA) and remains a member of the PhRMA board. From 2001 until January 2006, he was President and Chief Executive Officer of the Company's North American subsidiary. He was Chairman of the board of the Southeastern Pennsylvania Chapter of the American Heart Association 2004-2006. He 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.

#### 3 Simon Lowth (49)

#### **Executive Director and Chief Financial Officer**

Appointed as a Director and as CFO in November 2007. Simon Lowth is also a Non-Executive Director of Standard Chartered PLC. He was previously at ScottishPower where he was Finance Director, a position he left following completion of the sale of the company 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. He has an engineering degree from Cambridge University and an MBA from the London Business School.

#### 4 Michele Hooper (59)

Senior independent Non-Executive Director, Chairman of the Audit Committee and member of the Nomination and Governance Committee Appointed as a Director in July 2003 and as Senior independent Non-Executive Director in April 2007. Michele Hooper is a recognised corporate governance expert and has considerable healthcare industry expertise. She is President and Chief Executive Officer of The Directors' Council, a private company which she co-founded in 2003, that works with corporate boards to increase their independence, effectiveness and diversity, and a nonexecutive member of the boards of UnitedHealth Group Inc., PPG Industries, Inc. and Warner Music Group, Inc. Previously she was President and Chief Executive Officer of Stadtlander Drug Company, Inc. and Corporate Vice-President and President, International Businesses of Caremark International Inc.

#### **5 Bruce Burlington (62)**

**Non-Executive Director and member of the Science Committee** Appointed as a Director in August. Bruce Burlington is a pharmaceutical product development and regulatory affairs consultant and brings extensive experience in those areas to the Board. He is also a non-executive board member of Cangene Corporation and a member of the scientific advisory boards of the International Medica Foundation and H. Lundbeck A/S. Previously he spent 17 years with the FDA, serving as director of the FDA's Center for Devices and Radiological Health as well as holding a number of senior roles in the Center for Drug Evaluation and Research. After leaving the FDA he served in a series of senior executive positions at Wyeth (now part of Pfizer Inc.).

#### 6 Jean-Philippe Courtois (50)

#### Non-Executive Director and member of the Audit Committee Appointed as a Director in February 2008. Jean-Philippe Courtois has over 25 years' experience in the global technology industry and is President of Microsoft International, Senior Vice-President of Microsoft Corporation, a board member of PlaNet Finance and Microsoft's official representative at the Institut Montaigne. Previously he was Chief Executive Officer and President of Microsoft EMEA and has served as co-chairman of the World Economic Forum's Global Digital Divide Initiative Task Force and on the European Commission Information and Communication Technology Task Force. In 2009, he also served as an EU Ambassador for the Year of Creativity and Innovation.



#### 7 Jane Henney (63)

Non-Executive Director and member of the Audit Committee, the Nomination and Governance Committee and the Science Committee Appointed as a Director in September 2001. Jane Henney has extensive clinical and health policy expertise and is currently Professor of Medicine, University of Cincinnati, a non-executive member of the boards of AmerisourceBergen Corporation and CIGNA Corporation and a board member of The Commonwealth Fund and China Medical Board. Previous positions within the health industry include her role as Commissioner of Food and Drugs at the FDA and Senior Vice-President and Provost for Health Affairs, University of Cincinnati Academic Health Center.

#### 8 Rudy Markham (64)

# Non-Executive Director and member of the Audit Committee and the Remuneration Committee

Appointed as a Director in September 2008. Rudy Markham has significant international business and financial experience, having formerly held a number of senior commercial and financial positions worldwide with Unilever, culminating in his appointment as Chief Financial Officer of Unilever. He is currently Chairman and Non-Executive Director of Moorfields Eye Hospital NHS Foundation Trust and a non-executive member of the boards of United Parcel Services Inc., the UK Financial Reporting Council, Standard Chartered PLC and Legal & General plc. He is also a non-executive member of the board of the UK Foreign and Commonwealth Office, a Fellow of the Chartered Institute of Management Accountants and a Fellow of the Association of Corporate Treasurers.

#### 9 Dame Nancy Rothwell (55)

# Non-Executive Director, Chairman of the Science Committee and member of the Remuneration Committee

Appointed as a Director in April 2006 and has responsibility for overseeing Responsible Business. Nancy Rothwell is a distinguished life scientist and academic and is the President and Vice-Chancellor of the University of Manchester. She is also President of the Society of Biology. Previously she has served as President of the British Neuroscience Association and has been on the councils of the Medical Research Council, the Royal Society, the Biotechnology and Biological Sciences Research Council, the Academy of Medical Sciences and Cancer Research UK.

#### 10 John Varley (54)

Non-Executive Director, Chairman of the Remuneration Committee and member of the Nomination and Governance Committee Appointed as a Director in July 2006. John Varley was formerly Group Chief Executive of the Barclays Group, having held a number of senior positions with the bank during his career, including that of Group Finance Director. He brings additional international, executive business leadership experience to the Board. He is also a Non-Executive Director of BlackRock, Inc., Chairman of Business Action on Homelessness, President of the Employers' Forum on Disability, a member of the International Advisory Panel of the Monetary Authority of Singapore and Honorary President of the UK Drug Policy Commission.

#### 11 Marcus Wallenberg (54)

#### **Non-Executive Director and member of the Science Committee** Appointed as a Director in April 1999. Marcus Wallenberg has international business experience across a broad range of industry sectors, including the pharmaceutical industry from his directorship with Astra AB prior to 1999. He is the Chairman of Skandinaviska Enskilda Banken AB, AB Electrolux and Saab AB, Vice-Chairman of Telefonaktiebolaget LM Ericsson (publ) and a Non-Executive Director of Stora Enso Oyj and the Knut and Alice Wallenberg Foundation.

Other officers of the Company at 31 December included members of the Senior Executive Team, as set out on page 108, and Adrian Kemp, Company Secretary.

Shriti Vadera was appointed as a Non-Executive Director and a member of the Audit Committee with effect from 1 January 2011.

# Senior Executive Team at 31 December



#### 1 David Brennan

Chief Executive Officer See page 106.

#### 2 Simon Lowth

**Chief Financial Officer** See page 106.

#### **3 Martin Mackay**

#### President, Global R&D

Martin Mackay joined AstraZeneca in July. He was previously at Pfizer Inc. where he was Head of PharmaTherapeutics R&D and a member of the Pfizer Inc. executive leadership team. Prior to joining Pfizer Inc. in 1995, he held several discovery and development roles culminating in his appointment as Head of Molecular and Cell Biology, CNS Research at Ciba-Geigy. He has a degree in microbiology from Heriot-Watt University and a PhD in molecular genetics from the University of Edinburgh.

#### 4 Jeff Pott

#### **General Counsel**

Jeff Pott was appointed General Counsel in January 2009 and has overall responsibility for all aspects of AstraZeneca's Legal and Intellectual Property function. He joined AstraZeneca in 1995 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, he spent five years at the US legal firm Drinker Biddle and Reath LLP, where he specialised in pharmaceutical product liability litigation and anti-trust advice and litigation. He received his bachelor's degree in political science from Wheaton College and his Juris Doctor Degree from Villanova University School of Law.

#### **5 David Smith**

#### **Executive Vice-President, Global Operations and Information Services** David Smith joined AstraZeneca in 2006 as Executive Vice-

President, Operations. He leads AstraZeneca's global manufacturing and supply organisation and is also responsible for the Safety, Health and Environment; Regulatory Compliance; Procurement; and Engineering functions and has overall responsibility for Information Services. He 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 and Timberland in senior supply chain roles. In 2003, he returned to the pharmaceutical sector and joined Novartis in Switzerland.

#### 6 Lynn Tetrault

**Executive Vice-President, Human Resources and Corporate Affairs** Lynn Tetrault was appointed Executive Vice-President, Human Resources and Corporate Affairs in 2007, having previously been Vice-President, Corporate Affairs. She has also held the role of Vice-President HR, Global Drug Development and Vice-President, HR for the US subsidiary of AstraZeneca following the merger between Astra and Zeneca. She 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. She received her bachelor's degree from Princeton University and her law degree from the University of Virginia Law School.

#### 7 Tony Zook

#### **Executive Vice-President, Global Commercial Operations**

Tony Zook was appointed Executive Vice-President of AstraZeneca's global Commercial organisation in January 2010. He has responsibility for worldwide sales and marketing activities, as well as the commercial infrastructure in support of those efforts. Prior to his current role, he was President and CEO for AstraZeneca's US business and headed AstraZeneca's Global Marketing function. He was also President of Medlmmune. He has held various other positions in AstraZeneca's sales and marketing organisation. He joined Astra USA in 1997 as Vice-President, Marketing and Sales, having begun his pharmaceutical career at Berlex Laboratories. He 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.

Additional Information



Louis Schweitzer Chairman and Chairman of the Nomination and Governance Committee

"The Board regards the setting, maintenance and review of high standards of corporate governance as an essential part of our work. During 2010, we reviewed the revised UK Corporate Governance Code and no significant changes were required to our corporate governance practices as a result."

In this part of the Annual Report, we explain our approach to corporate governance and describe, in general terms, how our business is organised and managed.

#### Corporate governance

We have prepared this Annual Report with reference to the Combined Code published by the UK Financial Reporting Council (FRC) in June 2008 and the new UK Corporate Governance Code published by the FRC in May 2010 (together, the UK Corporate Governance Codes). This Report (together with other sections of this Annual Report) describes how we apply the main principles of good governance in the UK Corporate Governance Codes. We have complied throughout the accounting period with the provisions of the Combined Code. Although the new UK Corporate Governance Code only applies for accounting periods beginning on or after 29 June 2010, we have taken the decision to comply with the new provisions, in line with best practice, since its publication in May 2010. Both the Combined Code and UK Corporate Governance Code are available on the FRC's website, frc.co.uk.

#### Leadership

The roles of Chairman and CEO are split. Louis Schweitzer, our Non-Executive Chairman, is responsible for leadership of the Board. Our CEO, David Brennan, leads the SET and has executive responsibility for running our business. The Board comprises 10 Non-Executive Directors, including the Chairman, and two Executive Directors – the CEO and the CFO, Simon Lowth.

All Directors are collectively responsible for our long-term success. In addition, the Non-Executive Directors are responsible for exercising independent, objective judgement in respect of Board decisions and for scrutinising and challenging the actions of executive management. The Board holds an annual strategy review day, which is attended by all SET members. The CEO, the CFO and the SET take the lead in developing our strategy, which is then reviewed, constructively challenged and approved by the Board at the strategy review day.

Michele Hooper, who joined the Board as a Non-Executive Director in 2003, was appointed as our Senior independent Non-Executive Director in April 2007. The role of the Senior independent Director is to provide a sounding board for the Chairman and to serve as an intermediary for the other Directors when necessary. The Senior independent Director is also available to shareholders if they have concerns that contact through the normal channels of Chairman or Executive Directors has failed to resolve, or for which such contact is inappropriate.

There are four principal Board Committees – the Audit Committee, the Remuneration Committee, the Nomination and Governance Committee and the Science Committee. The membership and work of these Committees is described below. In addition, there may from time to time be constituted *ad hoc* Board Committees for specific projects or tasks. In these cases, the scope and responsibilities of the Committee are documented. The Board provides adequate resources to enable each Committee to undertake its duties.

#### Reserved matters and delegation of authority

The Board maintains and periodically reviews a list of matters that are reserved to, and can only be approved by, the Board. These include: the appointment, termination and remuneration of any Director; approval of 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; the raising of capital or loans by the Company (subject to certain exceptions); the giving of 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 our business in relation to those matters in respect of which he has been delegated authority from the Board.

Although the CEO retains full responsibility for the authority delegated to him by the Board, he has established and chairs the SET, which is the vehicle through which he exercises certain of that authority in respect of our business.

The roles of the Board, the Board 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.

#### Operation of the Board

The Board is responsible for setting our strategy and policies, oversight of risk and corporate governance, and also monitors progress towards meeting our objectives and annual plans. The Board discharges these responsibilities through a programme of meetings that includes regular reviews of financial performance and critical business issues, and the formal, annual strategy review day. The Board also aims to ensure that a good dialogue with our shareholders takes place and that their issues and concerns are understood and considered.

# **Corporate Governance Report**

The Board held six meetings and its annual strategy review day in 2010. All the meetings took place in London, UK. The Board is currently scheduled to meet six times and hold a strategy review day in 2011, and will meet at such other times as may be required to conduct business.

As part of the business of each Board meeting, the CEO typically submits a progress report on each key business area, giving details of progress against the goals the Board has approved. 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 Board members regularly meet other senior executives throughout the year. The Board also receives accounting and other management information about our resources, and presentations from internal and external speakers on legal, governance and regulatory developments. At the end of Board meetings, the Non-Executive Directors 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.

#### **Board effectiveness**

#### **Composition of the Board**

The Nomination and Governance Committee and, where appropriate, the full Board regularly review the composition of the Board and the status of succession to both senior executive management and Board-level positions. Directors have regular contact with, and access to, succession candidates for senior executive management positions.

The Board aims to maintain a balance in terms of the range of experience and skills of individual Board members, which includes relevant international business, pharmaceutical industry and financial experience, as well as appropriate scientific and regulatory knowledge. The biographies of Board members set out on pages 106 to 107 give more information about current Directors in this respect. The Board views gender, nationality and cultural diversity among Board members as important considerations when reviewing the composition of the Board. The following changes to the composition of the Board have occurred during the period covered by this Annual Report:

- > Bo Angelin and John Buchanan, both Non-Executive Directors, retired from the Board on 29 April 2010.
- > Bruce Burlington was appointed as a Non-Executive Director and member of the Science Committee with effect from 1 August 2010.
- > Shriti Vadera was appointed as a Non-Executive Director and a member of the Audit Committee with effect from 1 January 2011.

#### Independence of the Non-Executive Directors

During 2010, the Board considered the independence of each Non-Executive Director for the purposes of the UK Corporate Governance Codes and the corporate governance listing standards of the NYSE (Listing Standards). 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 UK Corporate Governance Codes, 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 3.7% interest in the issued share capital of the Company as at 27 January 2011. 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 UK Corporate Governance Codes. 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 on Michele Hooper resigning from the board of UnitedHealth Group in the event of a conflict 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.

#### **Conflicts of interest**

The Articles enable the Directors to authorise any situation in which a Director has an interest that conflicts or has the potential to conflict 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-conflicted 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 conflicts maintained by the Company Secretary and reviewed annually by the Board. The Board considers that this system continues to operate effectively.

#### Appointments to the Board

The Nomination and Governance Committee section on page 115 gives information about the appointment process for new Directors.

Newly appointed Directors are provided with comprehensive documentation containing information about the Group and their role as Non-Executive Directors. They also typically attend tailored induction programmes that take account of their individual skills and experience.

#### **Time commitment**

Our expectation is that Non-Executive Directors should be prepared to commit about 15 days per annum, as a minimum, to the Group's business. In practice, Board members' time commitment usually exceeds this minimum expectation when all the work that they undertake for the Group is considered, particularly in the case of the Chairman of the Board and the Chairmen of the Board Committees. As well as their work in relation to formal Board and Board Committee meetings, the Non-Executive Directors also 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.

#### Board and Board Committee meeting attendance in 2010

Name	Board	Audit	Remuneration	Nomination and Governance
Bo Angelin <sup>1</sup>	2 (2)	-	-	-
David Brennan	6 (6)	-	-	-
John Buchanan <sup>2</sup>	2 (2)	2 (2)	1 (3)	-
Bruce Burlington <sup>3</sup>	3 (3)	_	-	-
Jean-Philippe Courtois	5 (6)	3 (4)	-	-
Jane Henney	5 (6)	4 (4)	-	4 (6)
Michele Hooper	6 (6)	4 (4)	-	6 (6)
Simon Lowth	6 (6)	-	-	-
Rudy Markham⁴	6 (6)	3 (4)	4 (4)	-
Nancy Rothwell	5 (6)	-	6 (7)	-
Louis Schweitzer	6 (6)	-	7 (7)	6 (6)
John Varley	5 (6)	-	7 (7)	5 (6)
Marcus Wallenberg⁵	4 (6)	-	-	-

<sup>1</sup> Bo Angelin retired from the Board on 29 April 2010.

<sup>2</sup> John Buchanan retired from the Board on 29 April 2010.

<sup>3</sup> Bruce Burlington was appointed as a Director with effect from 1 August 2010.

<sup>4</sup> Rudy Markham was appointed as a member of the Remuneration Committee with effect from 29 April 2010.
<sup>5</sup> Marcus Wallenberg was appointed as a member of the Science Committee with effect from 28 April 2010.

Marcus Wallshoerg was appointed as a memoer of the oblence committee with enect norm 20 April 2010

On occasions when a Director is unavoidably absent from a Board or Board Committee meeting, for example through illness or where a meeting clashes with his or her existing commitments, he or she still receives and reviews the papers for the meeting and typically provides verbal or written input ahead of the meeting, usually through the Chairman of the Board or the Chairman of the Board Committee, so that his or her views are made known and considered at the meeting. In addition, given the nature of the business to be conducted, some Board meetings are convened at short notice, which can make it difficult for some Directors to attend due to prior commitments.

#### Information and support

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 Company maintained directors' and officers' liability insurance cover throughout 2010. 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 us attract and retain high-quality, skilled Directors.

#### **Performance evaluation**

Prior to the publication of this Annual Report, the Board conducted the annual evaluation of its own performance and that of its committees and individual Directors. 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 flows to the Board from management, and the way in which it flows; 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 to demonstrate commitment to the role.

The last occasion on which the Board's annual performance evaluation was externally facilitated was in 2008 and the Board intends to comply with the UK Corporate Governance Code guidance that the evaluation should be externally facilitated at least every three years.

#### **Re-election of Directors**

In accordance with Article 66 of the Articles, all Directors retire at each AGM and may offer themselves for re-election by shareholders. Accordingly, all the Directors will retire at the AGM in April 2011. The Notice of AGM will give details of those Directors seeking re-election.

#### Accountability

#### **Risk management and internal control**

The Non-Executive Directors have various responsibilities concerning the integrity of financial information, internal controls and risk management.

The Board has overall responsibility for our system of internal controls and risk management policies and is also responsible for reviewing their effectiveness. During 2010, the Directors have continued to review the effectiveness of our system of controls, risk management and our high-level internal control arrangements. These reviews have included an assessment of internal controls, and in particular, financial, operational and compliance controls and risk management and their effectiveness, supported by management assurance of the maintenance of controls reports from Group Internal Audit (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.

# **Corporate Governance Report**

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 our 'continuous assurance' process.

The internal control framework has been in operation for the whole of 2010 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 about the ways in which we manage our business risks is set out in the Risk section from page 94, which also contains a list of the principal risks and uncertainties that we face.

#### Remuneration

Information about our approach to remuneration and the role and work of the Remuneration Committee, including our policy on executive remuneration, is set out in the Directors' Remuneration Report from page 119.

#### **Relations with shareholders**

In our financial and business reporting to shareholders and other interested parties by means of quarterly, half-yearly and annual reports, we aim to present a balanced and understandable assessment of our strategy, financial position and prospects.

We make information about the Group available to shareholders through a range of media, including a fully integrated html corporate website, astrazeneca.com, containing a wide range of data of interest to institutional and private investors. We consider our website to be an important means of communication with our shareholders.

The Company has been authorised by shareholders to place shareholder communications (such as the Notice of AGM and this Annual Report) on the corporate website in lieu of sending paper

copies to shareholders (unless specifically requested by shareholders). While recognising and respecting the fact that some of our stakeholders may have different preferences about how they receive information from us, 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 provided and the consequent cost savings and reduction in environmental impact associated with reduced printing and distribution costs.

We have frequent discussions with institutional shareholders on a range of issues. These include individual meetings with some of our largest institutional shareholders to seek their views. Board members are kept informed of any issues and receive regular reports and presentations from executive management and our brokers in order to assist them to develop an understanding of major shareholders' views about the Group. From time to time, we conduct an audit of institutional shareholders to ensure that we are communicating clearly with them and that a high-quality dialogue is being maintained. The results of this audit are reported to and discussed by the full Board.

We also respond to individual ad hoc requests for discussions from institutional shareholders and analysts. Our Investor Relations team acts as the main point of contact for investors throughout the year. As discussed above, the Senior independent Non-Executive Director, currently Michele Hooper, is also available to shareholders if they have concerns that contact through the normal channels of Chairman, CEO and/or CFO 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 about our operation and performance. Formal notification of the AGM is sent to shareholders at least one month in advance. The Chairmen of the Board Committees ordinarily attend the AGM to answer questions raised by shareholders. In line with the UK Corporate Governance Code, details of proxy voting by shareholders, including votes withheld, are given at the AGM and are posted on our website following the AGM.

#### **Board Committee membership**

		1	Nomination and		
Name	Audit	Remuneration	Governance	Science	Independent
Bo Angelin <sup>2</sup>				1	1
David Brennan					n/a
John Buchanan <sup>3</sup>	Chair <sup>3</sup>	1			1
Bruce Burlington				1	1
Jean-Philippe Courtois	✓				1
Jane Henney	1		1	1	1
Michele Hooper <sup>4</sup>	Chair <sup>3</sup>		1		1
Simon Lowth					n/a
Rudy Markham	/	√5			1
Nancy Rothwell		1		Chair	1
Louis Schweitzer		1	Chair		n/a <sup>e</sup>
John Varley		Chair	1		1
Marcus Wallenberg				✓7	×

<sup>1</sup> As determined by the Board for UK Corporate Governance Codes purposes

<sup>2</sup> Bo Angelin retired from the Board on 29 April 2010.

<sup>3</sup> John Buchanan retired from the Board on 29 April 2010. Michele Hooper was appointed Chairman of the Audit Committee with effect from 29 April 2010.

<sup>4</sup> Michele Hooper is the Senior independent Non-Executive Director.
 <sup>5</sup> Rudy Markham was appointed as a member of the Remuneration Committee with effect from 29 April 2010.

<sup>6</sup> Louis Schweitzer was considered independent by the Board upon his appointment as Chairman; in accordance with the UK Corporate Governance Codes, the test of independence is not

appropriate in relation to the Chairman after his appointment.

Marcus Wallenberg was appointed as a member of the Science Committee with effect from 28 April 2010.

#### **Audit Committee**

The members of the Audit Committee are Michele Hooper (Chairman of the Audit Committee), Jane Henney, Jean-Philippe Courtois, Rudy Markham and, with effect from her appointment to the Board on 1 January 2011, Shriti Vadera. They are all Non-Executive Directors. The Board considers each member to be independent under the UK Corporate Governance Codes and under the general guidance and specific criteria of the Listing Standards concerning the composition of audit committees applicable to non-US companies. John Buchanan ceased to be a member and Chairman of the Audit Committee upon his retirement from the Board at the 2010 AGM. In April 2010, we submitted the required annual written affirmation to the NYSE confirming our full compliance with those standards. For the purposes of the UK Corporate Governance Codes, the Board remains satisfied that at least one member of the Committee has recent and relevant financial experience. At its meeting in December, 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 the Audit Committee.

The core terms of reference of the Audit Committee 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.
- > Our overall framework for internal control over financial reporting and for other internal controls and processes.
- > Our overall framework for risk management, particularly financial risks.
- > Our accounting policies and practices.
- > Our annual and quarterly financial reporting.
- > Compliance with the Corporate Integrity Agreement.

The Audit Committee is responsible for notifying the Board of any significant concerns of the external auditor or the Vice-President, 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 our internal control over financial reporting or other internal controls, and any serious issues of non-compliance. It oversees the establishment, implementation and maintenance of our Code of Conduct and other related policies. It monitors the Company's response to letters requesting information and investigations initiated by regulatory and governmental authorities such as the SEC and the US Department of Justice pertaining to matters within the ambit of the Committee's work. 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 Committee reviews and approves the appointment and 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 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 Committee in the first instance. A standing agenda item at Committee meetings covers the operation of the pre-approval procedures and regular reports are provided to the full Committee.

The Audit Committee held four scheduled meetings in 2010. The individual attendance record of members of the Committee is set out in the Board and Board Committee meeting attendance in 2010 table on page 111. Following each Committee meeting, the Chairman of the 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 2010, members of the Audit Committee met individual managers or groups of managers on a number of occasions in order to gain a deeper insight into areas relevant to the Committee's work and to provide an opportunity to discuss specific areas of interest. In particular, members of the Committee travelled to the US to meet senior leaders of the US business and to learn what steps the business has taken and is taking to ensure compliance with the Corporate Integrity Agreement there.

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 Committee members and those individuals, separately from the main sessions of the Committee, which were attended by the CEO, the CFO and the Senior Vice-President, Group Finance.

During 2010 and January 2011, the business considered and discussed by the Audit Committee included the matters referred to below:

- > Our 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 our system of internal controls and, in particular, our internal control over financial reporting. This included review and discussion of the results of the 'continuous assurance' and annual 'letter of assurance' processes. The 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 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 93.
- > 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 inquiries into these matters.

# **Corporate Governance Report**

- > Quarterly reports were received from the compliance officer responsible for monitoring the US business's compliance with the Corporate Integrity Agreement.
- > 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 2010. The 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 2010 is disclosed in Note 27 to the Financial Statements on page 196.
- > A review and assessment of the Committee's performance which concluded that such performance was satisfactory.

In line with best practice, we 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, consider whether to undertake a formal tendering programme with audit firms of appropriate size and calibre. Following discussions at its meeting in January 2011, the Audit Committee unanimously recommended to the Board that a resolution for the re-appointment of KPMG Audit Plc as the Company's external auditor be proposed to shareholders at the AGM in April 2011. Based on its experience of working with external auditors, the Committee believes that the quality of the interaction with and level of service received from KPMG Audit Plc were key factors supporting this recommendation. The Committee was also satisfied that, notwithstanding the length of tenure of KPMG Audit Plc, KPMG Audit Plc met the independence criteria under the relevant statutory, regulatory and ethical standards applicable to auditors. Consistent with current market practice, KPMG Audit Plc's services to the Group are provided pursuant to terms of engagement which are reviewed by the 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 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 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 our disclosure controls and procedures required by Item 15(a) of Form 20-F at 31 December 2010. Based on their evaluation, the CEO and the CFO concluded that, as at that date, we maintain an effective system of disclosure controls and procedures.

There was no change in our 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, our internal control over financial reporting. The Audit Committee is currently scheduled to meet six times in 2011 and will meet at such other times as may be required.

The Audit Committee reviewed its terms of reference during January 2011 and recommended changes, which were approved by the Board in January 2011. The revised terms of reference are available on our website, astrazeneca.com.

#### Code of Conduct

Our 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 our 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 we seek to operate to the highest of these standards. The Code of Conduct is reviewed on a regular basis and updated where necessary to take account of changing legal and regulatory standards and obligations (eg the introduction of the UK Bribery Act 2010).

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 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 them to the Audit Committee, as appropriate.

During 2010, 368 reports of alleged compliance breaches or other ethical concerns were made via the telephone lines, the AZethics.com website or the Global Compliance e-mail or postal addresses described in the Code of Conduct. The number of reports through equivalent channels in 2009 was 289. We believe that the increase in the number of reports via these channels is due to our ongoing focus on compliance matters and work to raise awareness of the Code of Conduct and supporting policies through focused communication and training.

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.

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Overview

#### **Remuneration Committee**

The principal role of the Remuneration Committee is to consider and set, on behalf of the Board, the remuneration (including pension rights and compensation payments) of Executive Directors and other senior executives. It also considers and sets the remuneration of the Chairman, in conjunction with the Senior independent Non-Executive Director and in the absence of the Chairman. No Director is involved in deciding his or her own remuneration. More information is set out in the Directors' Remuneration Report from page 119.

#### **Nomination and Governance Committee**

The Nomination and Governance Committee's role is 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 our business. The Committee also advises the Board periodically on significant developments in corporate governance and the Company's compliance with the UK Corporate Governance Codes.

During 2010, the members of the Nomination and Governance Committee were Louis Schweitzer (Chairman of the Committee), Jane Henney, Michele Hooper and John Varley. 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 UK Corporate Governance Codes, the test of independence is not appropriate in relation to the Chairman after his appointment. The Company Secretary acts as secretary to the Committee.

The Nomination and Governance Committee met six times in 2010. The individual attendance record of its members is set out in the Board and Board Committee meeting attendance in 2010 table on page 111. During the year, it reviewed the knowledge, experience and balance of the Board overall and considered its likely future requirements given the strategic and business objectives of the Company. It recommended to the Board the appointment of two new Non-Executive Directors - Bruce Burlington and Shriti Vadera. For both these appointments, external board search firms were instructed to assist the Committee in identifying potential candidates and recruiting the new Board members. In addition, the Committee received reports about corporate governance developments and their potential impact on the Group. In particular, it reviewed the new UK Corporate Governance Code published in May 2010; no significant changes were required to our corporate governance framework as a result of the changes contained in the UK Corporate Governance Code.

The Nomination and Governance Committee reviewed its terms of reference during 2010 and recommended minor changes, which were approved by the Board in January 2011. The revised 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, competitiveness and integrity of the Group's R&D activities by way of: meetings and dialogue with our R&D leaders and other scientist employees; visits to our R&D sites throughout the world; and review and assessment of:

- > The approaches we adopt in respect of our chosen Therapy Areas
- > The scientific technology and R&D capabilities deployed
- > The decision making processes for R&D projects and programmes
- > The quality of our scientists.

The Science Committee also reviews, from time to time, important bioethical issues that we face, and assists in the formulation of, and agrees on behalf of the Board, appropriate policies in relation to such issues. It may also consider, from time to time, future trends in medical science and technology. The Committee does not review individual R&D projects.

During 2010, the members of the Science Committee, all of whom have a knowledge of, or an interest in, life sciences, were Nancy Rothwell (Chairman of the Committee), Jane Henney, Bruce Burlington (from his appointment as a Non-Executive Director in August), Marcus Wallenberg (from 28 April 2010) and Bo Angelin (until his retirement from the Board on 29 April 2010), all Non-Executive Directors. The President, Global R&D; the Executive Vice-President, Innovative Medicines; the Senior Vice-President, R&D, MedImmune; and the Executive Vice-President, Global Medicines Development attend meetings of the Committee. The Vice-President, Strategy, Portfolio & Performance, R&D also attends all meetings and acts as secretary to this Committee.

The Science Committee met twice in 2010, once by telephone and once at Gaithersburg, one of our US biologics sites. It reviewed its terms of reference during 2010 and recommended minor changes, which were approved by the Board in July. The revised terms of reference are available on our website, astrazeneca.com.

#### US corporate governance requirements

Our ADSs are traded on the NYSE and, accordingly, we are 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. We have 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. We have established a Disclosure Committee, further details of which can be found in the Disclosure Committee section on page 116.

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 136.

We are required to disclose any significant ways in which our corporate governance practices differ from those followed by US companies under the Listing Standards. In addition, we 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. We have reviewed the corporate governance practices required to be followed by US companies under the Listing Standards and our corporate governance practices are generally consistent with those standards.

### **Corporate Governance Report**

#### **Business organisation**

#### **Senior Executive Team**

The CEO has established and chairs the SET. The SET normally meets once a month to consider and decide major business issues, or as otherwise required by business needs. 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 addition to the CEO, the SET's members are: the CFO; the President, Global R&D; the Executive Vice-President, Global Commercial Operations; the General Counsel; the Executive Vice-President, Human Resources and Corporate Affairs; and the Executive Vice-President, Global Operations and Information Services. The Company Secretary acts as secretary to the SET.

#### Portfolio Investment Board (PIB)

The CEO has established and chairs the PIB, which is a senior-level, cross-functional governance body, which seeks to maximise the value of our internal and external R&D investments through robust, transparent and well-informed decisions that drive business performance and accountability.

Specifically, the PIB has responsibility for:

- > Reviewing the R&D portfolio by conducting an objective and transparent review of R&D performance, product launch profile and alignment with corporate strategy. The review is also an important step in reconfirming the R&D three-year budget.
- > Approving the business plans of the Innovative Medicines Units and the Global Medicines Development demand forecast – by confirming the allocation of resources across early- and late-stage elements of R&D as well as assessing licensing and acquisition opportunities.
- > Approving late-stage (internal and external) investment decisions.
- > Monitoring environmental events that could have a major
- transformational or disruptive impact on our business.

In addition to the CEO, the PIB's members are the CFO; the President, Global R&D; the Executive Vice-President, Global Commercial Operations; the Executive Vice-President, Innovative Medicines; the Senior Vice-President, R&D, MedImmune; the Executive Vice-President, Global Medicines Development; and the Vice-President, Strategic Partnering & Business Development. The PIB has a permanent secretary and typically meets at around the time of the monthly SET meetings, or as otherwise required by business needs.

#### **Disclosure Committee**

Our 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. The members of the Committee are: the CFO, who chairs the Committee; the President, Global R&D; 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 Committee meets regularly to assist and inform the decisions of the CEO concerning inside information and its disclosure. Periodically, it reviews our 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 our planned disclosures, such as our guarterly results announcements and scheduled investor relations events.

#### **Disclosure of information to auditors**

The Directors who held office at the date of approval of this Annual 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 or she ought to have taken as a Director to make himself or herself aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

#### **Compliance and Group Internal Audit (GIA)**

The role of the Global Compliance function is to manage and maintain the compliance programme infrastructure and 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 2010/2011 are closely aligned with the Group's strategic priorities and include strengthening our efforts for oversight at all levels of our business, including third parties, anti-bribery and anti-corruption efforts, and data privacy. During 2011, 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 2010, the Global Compliance function was restructured with a formal change to centralise the reporting of all globally-deployed compliance programme resources under the Global Compliance Officer who reports to the CEO. A new management structure, at the head of which is the Global Compliance leadership team, now incorporates all operational elements of the business. The remit of the team is to oversee and co-ordinate the 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 coordination of compliance auditing and monitoring; reviewing results; 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 anti-bribery and anti-corruption legislation as well as 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 Group 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 regarding 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.

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In addition to fulfilling its primary remit of assurance to the Audit Committee, GIA acts as a source of constructive advice and best practice, assisting senior management to improve governance, control, compliance and risk management.

#### **Other matters**

# Corporate governance statement under the UK Disclosure and Transparency Rules

The disclosures that fulfil the requirements of a corporate governance statement under the Disclosure and Transparency Rules can be found in this section and in other parts of this Annual Report as listed below, each of which is incorporated into this section by reference:

- > Significant holders of the Company's shares (contained in the Shareholder Information section from page 211).
- > Articles (contained in the Corporate Information section on page 216).
- > Amendments to the Company's Articles (contained in the Corporate Information section on page 216).

#### Subsidiaries and principal activities

The Company is the holding company for a group of subsidiaries whose principal activities are described in this Annual Report. Principal subsidiaries and their locations are given in the Principal Subsidiaries section in the Financial Statements on page 197.

# Branches and countries in which the Group conducts business

In accordance with the Companies Act 2006, we disclose below our subsidiary companies that have representative or scientific branches/offices outside the UK:

- > AstraZeneca UK Limited: Albania, Algeria, Angola, Armenia, Azerbaijan, Belarus, 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 2010

Our distribution policy comprises both a regular cash dividend and a share repurchase component, further details of which are set out in the Financial Review on page 87 and Notes 21 and 20 to the Financial Statements on page 167.

The Company's dividends for 2010 of \$2.55 (161.6 pence, SEK 17.11) per Ordinary Share amount to, in aggregate, a total dividend payment to shareholders of \$3,617 million. Two of our 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 2010 AGM authorising the Company to purchase its own shares. Pursuant to this resolution, the Company repurchased (and subsequently cancelled) 53,691,507 Ordinary Shares with a nominal value of \$0.25 each, at an aggregate cost of \$2,604 million, representing 3.8% of the total issued share capital of the Company. The Company will seek a renewal of its current permission from shareholders to purchase its own shares at the AGM on 28 April 2011. During our share repurchase programmes that operated between 1999 and 2010, a total of 430 million Ordinary Shares were repurchased, and subsequently cancelled, at an average price of 2,718 pence per share for a consideration, including expenses, of \$20,702 million.

#### Going concern accounting basis

Information on the business environment in which we operate, including the factors underpinning the industry's future growth prospects, are included in the section describing Our marketplace from page 10. Details of our product portfolio, our approach to product development and a summary of our development pipeline are included in the Business Review section from page 24. Additional information on our Therapy Areas is included in the Therapy Area Review from page 50. The table showing our development pipeline can be found from page 206.

The financial position of the Group, our cash flows, liquidity position and borrowing facilities are described in the Financial Review from page 78. In addition, Notes 15 and 23 to the Financial Statements from pages 158 and 168 respectively, include our objectives, policies and processes for managing our capital, our financial risk management objectives, details of our financial instruments and hedging activities and our exposures to credit, market and liquidity risk. Further details of our cash balances and borrowings are included in Notes 13 and 14 to the Financial Statements on pages 157 and 158 respectively.

We have considerable financial resources available. At 31 December 2010, we had \$15.25 billion in financial resources (cash balances of \$11.1 billion and committed undrawn bank facilities of \$4.25 billion, with only \$0.1 billion of debt due within one year). Our 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, we have a wide diversity of customers and suppliers across different geographic areas. As a consequence, the Directors believe that we are well placed to continue to manage our business risks successfully.

The Directors have a reasonable expectation that we have 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 2010, including details of the allotment of new shares under the Company's share plans, are given in Note 20 to the Financial Statements on page 167.

#### **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 represents at least 500 shares). Such holding must be obtained within two months of the date of the Director's appointment. At 31 December 2010, 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 132. 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 121 and 128 respectively.

# **Corporate Governance Report**

#### **Political donations**

Neither the Company nor its subsidiaries made any EU political donations or incurred any EU political expenditure in 2010 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 2011 AGM, similar to that passed at the 2010 AGM, to authorise the Company and its subsidiaries to:

- > make donations to political parties
- > make donations to political organisations other than political parties > incur political expenditure, up to an aggregate limit of \$250,000.

In 2010, the Group's US legal entities made contributions amounting in aggregate to \$1,999,150 (2009: \$733,687) to state political party committees and to campaign committees of various state candidates affiliated with the major parties in accordance with pre-established guidelines. The increase from 2009 to 2010 reflects the fact that many US states held legislative and executive elections in 2010, resulting in more state candidate and state political party activity. 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 we have contractual or other arrangements, who are deemed by the Directors to be essential to our business.

#### Use of financial instruments

Notes 15 and 23 to the Financial Statements, from pages 158 and 168 respectively, include further information on our use of financial instruments.

#### **Creditor payment policy**

It is not our policy formally to comply with the Confederation of British Industry's code of practice on the prompt payment of suppliers. It is, however, our policy to agree 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, to 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 62 days' average purchases (2009: 56 days). A considerable part of the trade creditors' balance continues to relate 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 57 days is obtained (2009: 47 days).

The Company has no external trade creditors.

#### **Annual General Meeting**

The Company's AGM will be held on 28 April 2011. 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 28 April 2011 for the re-appointment of KPMG Audit Plc as auditor of the Company. The external auditor has undertaken various non-audit work for us during 2010. More information about this work and the audit and non-audit fees that we have paid are set out in Note 27 to the Financial Statements on page 196. The external auditor is not engaged by us to carry out any non-audit work in respect of which it might, in the future, be required to express an audit opinion. As explained more fully in the Audit Committee section from page 113, 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 2010.

#### **Bureau Veritas**

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 our 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 2009 of €2.6 billion.

#### **Directors' Report**

The Directors' Report, which has been prepared in accordance with the requirements of the Companies Act 2006, comprises the following sections:

- > Our Strategy and Performance
- > Business Review
- > Corporate Governance
- > Development Pipeline
- > Shareholder Information
- > Corporate Information

and has been signed on behalf of the Board.

#### A C N Kemp

Company Secretary 27 January 2011



John Varley Non-Executive Director and Chairman of the Remuneration Committee

### In this introduction to the 2010 Directors' Remuneration Report I highlight a number of points to give context to the report that follows.

As we indicated in our 2009 annual report, the Remuneration Committee's main objectives during 2010 were to develop longterm compensation structures to support the strategic and financial progress of the Group, to invest in the development of human capital in AstraZeneca, and to focus on stewardship and shareholder value-creation over the long term. In particular, we stated our intention to reshape the Group's long-term incentive arrangements, maintaining (but not increasing) the overall value of the package, but recognising that AstraZeneca operates in a uniquely long-term industry. We sought thereby to strengthen the alignment between the time horizons over which our business investment decisions are taken and those to which part of our share incentive programmes relate. An important and informative part of this process was extensive consultation with institutional investors. We are grateful for their contribution to the development of the proposals. Our recommendations received strong support from shareholders at our AGM in April 2010 and the new AstraZeneca Investment Plan was approved.

Meanwhile, 2010 has been a year of considerable change for the senior leadership of AstraZeneca. Remuneration policy and practices play a key role in supporting the implementation of our strategy to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business. The Committee has endeavoured to strike an appropriate balance between levels of remuneration that reflect the need to attract and retain top talent in a highly competitive global market and policies that are aligned with best practice through risk adjustment, deferral, claw-back and reward for success. The Committee has applied careful oversight to internal moves and external hires to ensure that AstraZeneca attracts and retains world-class talent in its Senior Executive Team, particularly, in 2010, in light of the changes in our R&D organisation, across its R&D senior leadership. There have also been changes to the membership of the Committee itself during 2010. In April 2010, John Buchanan retired from the Committee when he stepped down from the Board. On behalf of the Committee I would like to thank John for his immensely valuable contribution to the Committee's operation and decisions during his tenure as a member. Following John's retirement, Rudy Markham has joined the Committee, bringing with him a wealth of relevant experience, including as a Non-Executive Director of the Financial Reporting Council. Rudy is also a member of the Audit Committee, and we thereby maintain an important link between the work and deliberations of the two Committees. As can be seen from the Committee members' biographies on page 106, each of AstraZeneca's Board Committees (including the Science Committee, which is chaired by Dame Nancy Rothwell) is represented in the membership of the Remuneration Committee. This is intentionally so, and ensures that critical issues concerning performance, productivity, risk and reputation continue to be at the forefront of the Committee's considerations.

The changes that were made to executive remuneration during the year (explained more fully below) reflect a clear desire in the business, which the Committee fully supported, to move towards a longer-term framework which will strengthen alignment with the inherently long-term nature of pharmaceutical drug development and thereby with the long-term interests of shareholders. The revised long-term incentive (LTI) structures have been designed, cognisant of shareholder views and expectations, to provide a clear focus for the business to outperform its industry peers over time, to deliver operational efficiency and engender a strong sense of stewardship that will deliver long-term sustainable shareholder value.

On behalf of the Remuneration Committee, I commend this Directors' Remuneration Report to you.

#### John Varley

Chairman of the Remuneration Committee

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 28 April 2011.

The following sections of this Report, up to and including the Non-Executive Directors section on page 128, were not subject to audit by KPMG Audit Plc.

#### **Remuneration Committee membership and meetings**

The members of the Committee are John Varley (Chairman), Rudy Markham, Louis Schweitzer and Nancy Rothwell. Rudy Markham became a member of the Committee on 29 April 2010. Until that date, upon which he retired from the Board, John Buchanan was a member of the Committee. Throughout 2010, all the members of the Committee were independent Non-Executive Directors – Louis Schweitzer was considered by the Board to be independent upon his appointment as Chairman. The independence of the Non-Executive Directors is discussed in more detail in the Corporate Governance Report from page 109. The Company Secretary acts as the secretary to the Committee.

The Committee met seven times in 2010. The individual attendance record of members of the Committee is set out in the Board and Board Committee meeting attendance in 2010 table on page 111.

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 and her successor, Katie Jackson-Turner, Vice-President, Global Compensation attended one or more Committee meetings in 2010 and provided advice and services that materially assisted the Committee.

The Committee retains Carol Arrowsmith of Deloitte LLP (Deloitte) who provided independent advice on various matters it considered in 2010. During the year, the Committee reviewed the voluntary code of conduct in relation to executive remuneration consulting in the UK, which is operated under the aegis of the Remuneration Consultants Group, in which Deloitte participates. During the year, Deloitte also provided taxation advice and other specific non-audit services to the Group. The Committee reviewed the potential for conflicts of interest and judged that there was none and that the independence of its adviser was not called into question.

# Committee terms of reference and main work during the year

#### **Committee terms of reference**

A copy of the Committee's terms of reference is available on our website, astrazeneca.com.

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, among 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 conducted a review of its terms of reference during 2010 and agreed to recommend to the Board a small number of changes, principally to reflect provisions in the new UK Corporate Governance Code. These were approved by the Board in January 2011 and the revised terms of reference are available on our website, astrazeneca.com.

#### Main work during the year

The Committee considered the following principal matters during 2010:

- > Completion of the strategic review of the remuneration and incentive framework for Executive Directors and other SET members. This included significant consultation with major shareholders and institutional investor organisations.
- > A review of the terms of senior executives' remuneration packages on appointment, promotion and termination, including the remuneration packages on the appointment of a number of senior leaders in R&D.
- > The assessment of Group and individual performance against performance targets to determine the level of executive bonuses for 2009 and to set executive bonus performance targets for 2010.
- > The approval of the rules of the new AstraZeneca Investment Plan (AZIP) prior to the AZIP being proposed to shareholders for approval at the 2010 AGM, and the approval of the rules of the new AstraZeneca Global Restricted Stock Plan (GRSP), which did not require shareholder approval.
- > The approval of the introduction of a new cash flow target for the AstraZeneca Performance Share Plan (PSP), to be used in conjunction with the existing TSR performance condition.
- > The approval of awards made under the Group's main LTI plans: the PSP; the AZIP; and the GRSP to SET members and other participants.

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- > The approval of restricted share awards to a limited number of senior executives under the AstraZeneca Restricted Share Plan (RSP).
- > A review of the use of claw-back provisions by the Company.
- > 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 levels of share ownership of Executive Directors and other SET members.
- > 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.
- > A review of the voluntary code of conduct operated under the aegis of the Remuneration Consultants Group in relation to executive remuneration consulting in the UK.
- > In conjunction with the Senior independent Non-Executive Director and not in the presence of the Chairman of the Board, a review of the basic fee paid to the Chairman of the Board for his services.
- > The preparation, review and approval (in January 2011) of this Report.

#### Key remuneration principles

The Committee considers 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 designed to help AstraZeneca create sustainable growth in shareholder value by the successful implementation of strategy and be developed in the context of shareholder views on best practice.
- > 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.

Following the 2010 AGM, the shareholding guidelines for Executive Directors and other SET members were increased. The shareholding requirement for the CEO was increased to 200% of base salary (from 100%) and the requirement for all other Executive Directors and SET members was increased to 125% of base salary (from 100%).

# Incentive programmes designed to deliver long-term shareholder value

The long-term share interests of Executive Directors and other SET members are provided through two complementary share plans, the PSP and the AZIP.

Under the PSP, a relative TSR performance condition applies in respect of one half of any award made and the other half of the award is subject to a cash flow performance measure that reflects operational management of the business in a way that is consistent with generating value for shareholders. A cash flow measure was introduced in 2010 because it encompasses 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. Together, the TSR and cash flow performance conditions focus reward under the PSP on outperformance of competitors.

The AZIP, approved by shareholders in 2010, operates with an eight-year time horizon where reward is conditional on sustainable shareholder returns and financial performance. The AZIP creates the opportunity for 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 is given to awards under the PSP. Awards under the PSP are positioned so that interests under this plan can deliver 75% of the overall expected value from long-term remuneration and the AZIP 25%. The Committee keeps under review the appropriateness of this weighting.

The combination of awards under these two plans enhances the alignment between the time horizons over which our business investment decisions are taken and those to which our long-term remuneration vehicles relate.

The AstraZeneca Share Option Plan (SOP) expired during 2010 and grants of share options no longer form part of our LTI arrangements.

#### **Components of remuneration**

During 2010, 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 Components of remuneration table below.

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 while at the same time giving them an opportunity to participate as shareholders in the creation of long-term economic value.

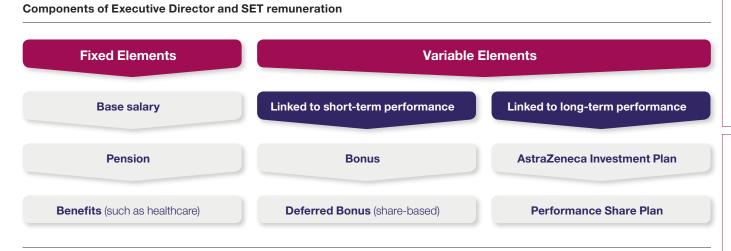
The Committee has continued to take into account the wider business environment and employment conditions across the Group. In particular, with the exception of the CFO whose base salary had remained unchanged since he joined the Group, no base pay increases were awarded in respect of the 2010 calendar year to Executive Directors or other SET members whose responsibilities were unchanged. In addition, award opportunities for SET members under the Group's LTI plan framework have been held at a consistent level since the adoption of the PSP in 2005.

For 2011, 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, taking note also of the guidance issued within the last 12 months from bodies representing institutional shareholders.

#### **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 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 of performance.		Differs by market, but the Group performance measures ensure that all eligible employees receive an element of reward based on the Group's overall financial performance.	All eligible employees
		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 Business objectives and key performance indicators section from page 16, and are monitored as part of the guarterly 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 (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)	Long-term equity incentive awards to provide individual executives and employees with total compensation opportunities that are competitive against local market	AstraZeneca Performance Share Plan.	SET members and other senior executives
	practice, for the achievement of operational excellence,	AstraZeneca Investment Plan.	SET members
	strong financial performance and actions that are closely aligned with the interests of shareholders. The	Share Option Plan (final awards made in 2009).	Senior management and SET members
	primary LTI plans in which SET members participate are the PSP and the AZIP.	Global Restricted Stock Plan.	Eligible employees globally
Other share plans	'All employee' share participation arrangements, including some that are tax-approved, for example in the UK.	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 CEO is expected to hold shares equivalent to 200% of base salary and the CFO and other SET members are expected to hold 125% of base salary in shares.	SET members
Overall approach	When assessing the overall value of a SET member's rer component of the SET member's total remuneration.	muneration the Committee considers, both separately and	in aggregate, each

<sup>1</sup> Further information on these plans is provided in Note 24 to the Financial Statements from page 173.



# Illustration of fixed and variable performance-related remuneration

Based on AstraZeneca's remuneration policy, the Components of remuneration – expected value 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 apart from David Brennan's pension and health insurance arrangements, which are described below, and are benchmarked against external UK comparators.

#### Base salary

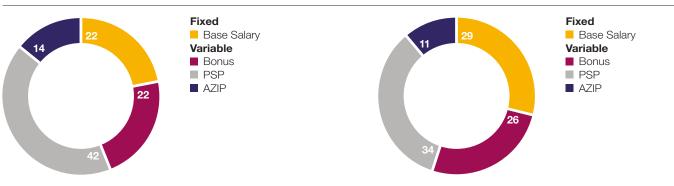
The base salary for Executive Directors and other SET members is determined by the Committee. Salary decisions reflect the experience and performance of the individuals to whom they apply, taking account of market competitiveness and the level of increases applicable to employees in the wider Group. There was no increase to the base salary of the CEO in either 2009 or 2010. The CFO's base salary was increased in 2010 for the first time since he joined the Group in 2007. Effective from 2011, the Committee awarded David Brennan and Simon Lowth base salary increases of 2.5%, illustrated in the Executive Directors' base salaries in 2010 and 2011 table below. This is in line with the adjustments being made to the base salaries of other employees within the Group in 2011.

#### Executive Directors' base salaries in 2010 and 2011

Chief Financial Officer (%)

Executive Director	Annual salary in 2010 £	Annual salary in 2011 £	Increase %
David Brennan	972,900	997,223	2.5
Simon Lowth	620,000	635,500	2.5

# Components of remuneration – expected value Chief Executive Officer (%)



#### Pension arrangements

The table in the Defined benefit arrangements section on page 130 gives details of the changes in the value of the Executive Directors' accrued pensions during 2010.

#### 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 nonqualified benefits which must be taken in lump sum form.

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 131.

In the event of a US participant becoming incapacitated, 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).

#### CFO's pension arrangements

Simon Lowth is eligible to join the AstraZeneca Group Self Invested Personal Pension (UK Defined Contribution Plan (UK DCP)) 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 2009 to 30 June 2010 and 1 July 2010 to 30 June 2011, he elected to take the cash allowance, as detailed in the Defined contribution arrangements section on page 131.

In the event of a senior employee in the UK DCP (including one who has taken an alternative cash allowance) becoming incapacitated, 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.

<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 under the US Tax Code.

#### Benefits

Consistent 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 performance-related 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, in making such a determination, 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.

#### 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 2009 Directors' Remuneration Report, the performance criteria for the determination of annual bonuses for Executive Directors and other SET members have been aligned more closely with the current objectives and measures that are used by the business. This approach continued to apply for 2010 and will do so for 2011. For 2011, the bonus ranges are unchanged from 2010. The bonus deferral requirements, described in more detail below, applied for 2010 and will be reviewed during 2011. Executive Directors' and other SET members' bonuses for 2010 were based on performance criteria linked to the following targets:

- > 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 Business objectives and key performance indicators section from page 16 and which are monitored as part of the quarterly business review (QBR) process against targets set by the Committee at the beginning of the year and, which among other things, take into account external expectations of performance;
- > 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 Business objectives and key performance indicators section 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 process. The outcome of this process is rigorously scrutinised by the Committee.

#### Bonus ranges for 2011

For 2011, the bonus ranges for each Executive Director are shown below and are the same as 2010.

Executive Director	Bonus range for 2011 %
David Brennan	0-180
Simon Lowth	0-150

#### Bonus outcomes for 2010

In assessing bonuses for 2010, the Committee took into account the strong EPS (excluding restructuring and synergy costs) and cash flow performance, which in both cases significantly exceeded target, 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 Business objectives and key performance indicators section from page 16, in relation to the following categories, which the Committee believes are consistent with delivering shareholder value:

- > Pipeline
- > Deliver the business
- > Business shape
- > People and values.

When assessing the performance of the business in these categories, the Committee noted that during 2010:

- > In relation to the pipeline and life-cycle management, Vimovo was approved in the US and the EU; Brilique was approved in the EU; Kombiglyze™ XR (Onglyza™/metformin combination) was approved in the US; additional indications were approved for other products; decisions were made in December to discontinue development of motavizumab and Certriad.
- > Although we suffered some pipeline disappointments, the new R&D leadership team has made significant progress in 2010 with the creation of a single R&D organisation.
- > The Commercial organisation has continued to drive strong sales performance in the face of an increasingly challenging environment.
- > Our Operations function has continued to deliver on efficiency.
- > The business broadly maintained a good level of employee engagement despite a period of significant organisational change.
- > The business response to the Corporate Integrity Agreement has been rigorous with significant work undertaken to continue to promote a culture of responsibility and accountability across the organisation.

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 2010 are shown in the table below.

#### Bonus outcomes for 2010

Short-term bonus (delivered as a combination of cash and shares, as shown in the Directors'

	emoluments in 2010 section from page 129			
Executive Director	£	% of salary		
David Brennan	1,583,025	162.71		
Simon Lowth	918,245	148.10		

<sup>1</sup> Bonuses for Executive Directors are not pensionable.

#### Bonus share deferral requirements

Consistent with best practice, and to encourage a long-term view and align SET members' interests with those of shareholders, 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 (together, Shares). 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. The Committee will review whether the proportion of bonus to be deferred should be increased in 2011. 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.

#### AstraZeneca Performance Share Plan

The PSP was approved by shareholders at the AGM in 2005 and provides for the grant of performance share awards (PSP Share Awards) over Shares. The operation of the PSP was reviewed in 2010 and a new cash flow performance condition, described in more detail below, was introduced.

#### Basis of participation

Participation in the PSP is highly selective and usually includes only senior employees on the basis of their performance.

Generally, PSP 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 2010, the main grant of PSP Share Awards was made on 26 March, (for SET members on 7 May) with other Share Awards approved by the Committee in relation to, for example, new appointments, promotions or assignments being granted on 27 August and 5 November. The value of Shares subject to a PSP 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 PSP Share Awards granted to Executive Directors are shown in the Performance Share Plan table on page 133.

#### Individual limit

In respect of any financial year of the Company, the maximum market value of Shares that may in theory be put under a PSP 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 conditions

Other than in exceptional circumstances, which are prescribed in the PSP rules, the vesting of PSP 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, PSP Share Awards will generally not vest until the third anniversary of the date of grant. If a participant ceases to be in relevant employment, the award will be time pro-rated and vest at the end of the performance period.

#### Performance period and vesting dates

In the case of all PSP 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 PSP Share Awards made in 2010, the performance period runs from 1 January 2010 to 31 December 2012. The vesting date is the third anniversary of the date of grant.

#### Performance targets

> 50% of the award is based on relative TSR against a selected

- peer group of global pharmaceutical companies, of which:
  25% of the maximum award vests for performance at the median of the peer group;
- 75% of the maximum award vests for upper quartile performance; and

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- 100% of the maximum award may vest at the Committee's discretion if the Company's TSR performance is substantially better than that of the upper quartile of the comparator group. For PSP 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.
- > 50% of the award vests subject to the achievement of the free cash flow target, which operates as a cumulative cash flow target over a three-year performance period.

The peer group for the TSR measure is: Abbott Laboratories, Inc., BMS, Eli Lilly & Company, GlaxoSmithKline plc, Johnson & Johnson, Merck, Novartis AG, Pfizer Inc., F. Hoffmann-La Roche Ltd and Sanofi-Aventis.

TSR measures share price growth, and dividends reinvested 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 PSP Share Award. Payouts against performance in relation to TSR for PSP Share Awards are expressed as a percentage of the maximum PSP Share Award currently payable, shown within a range of 0% to 100%. This presentation is shown in the table below.

The TSR vesting schedule is as follows:

TSR ranking of the Company	Vesting %
Below median	0
Median	25
Between median and upper quartile	Pro rata
Upper quartile	75
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 PSP 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 Group's underlying financial performance and has the discretion to prevent PSP Share Awards from vesting or only to allow them to partially vest where this appears to the Committee to be warranted.

The cash flow target will operate as a cumulative performance target over the same three-year performance period as the TSR measure. The measure for the cash flow target is net cash flow (before distributions) and the level of vesting will be based on a sliding scale between a threshold cash flow target of \$16 billion and an upper target of \$23 billion. Twenty five percent of the relevant portion of the award will vest for achievement of the threshold target, rising on a sliding scale to full vesting for achievement of the upper target as shown in the table below. Net cash flow is considered to be the most appropriate measure of cash flow performance because it relates to the residual cash available to finance additional investment in specific business needs, debt repayments and our distribution policy.

The cash flow measure 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 is 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 are disclosed to shareholders. There is no retesting of performance.

Adjusted cumulative cash flow	Vesting %
Less than \$16 billion	0
\$16 billion	25
Between \$16 billion and \$23 billion	Pro rata
\$23 billion and above	100

For PSP Share Awards granted up to and including 2007, the companies included in the peer group for the TSR measure 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, the Committee has decided the following in relation to outstanding unvested awards:

- > PSP 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.).
- > PSP Share Awards from 2008 onwards: 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.

#### Performance under the PSP in 2010

The TSR graphs on page 131 show, for each PSP 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 2010 and how the Company ranks against those other peer companies on this basis. At the end of 2010, the Company is on track to meet the cash flow target. We will continue to report on the performance of each PSP Share Award against the relevant performance target during the relevant vesting period.

#### AstraZeneca Investment Plan

The AZIP was approved by shareholders at the 2010 AGM and provides for the grant of share awards (AZIP Share Awards) over Shares.

#### Basis of participation

Participation in the AZIP is highly selective and usually includes only senior employees on the basis of their performance.

The first grant of AZIP Share Awards was made on 7 May, shortly after the approval of the AZIP by shareholders. In future years, AZIP Share Awards are likely to be made annually at the same time as the annual awards under other long-term incentive plans. The value of Shares subject to an AZIP 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 AZIP Share Awards granted to Executive Directors are shown in the AstraZeneca Investment Plan table on page 133.

#### Performance period and holding period

It is intended to operate the AZIP with a four-year performance period (Performance Period) and a four-year holding period (Holding Period). Under the rules of the AZIP, the Performance Period is the period of up to eight years (and not less than three years) from 1 January of the financial year in which the AZIP Share Award is made. The Holding Period starts at the end of the Performance Period and ends eight years from the first day of the financial year in which the AZIP Share Award was made.

#### Performance requirement for awards under the AZIP

The AZIP is aligned to AstraZeneca's targeted product development cycle, reflecting the long-term investment horizons that are a feature of the industry. The performance requirement attached to awards under the AZIP is 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.

At the end of the Performance Period, the extent to which the performance hurdle has been met will determine the number of Shares in respect of which the AZIP Share Award will vest at the end of the Holding Period.

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. The performance hurdle for Share Awards made in 2010 is that the annual dividend per share paid to holders of Ordinary Shares is increased from \$2.30 over the four year Performance Period (\$2.30 being the full year dividend for 2009) and that dividend cover (based on reported earnings before restructuring costs) does not fall below 1.5 times.

#### Performance under the AZIP in 2010

The full year dividend was \$2.55 for 2010 and dividend cover did not fall below the 1.5 times threshold. We will continue to report on the performance of each AZIP Share Award against the relevant performance hurdle during the relevant performance period.

#### Cessation of employment during the Performance Period

If a participant ceases to be in employment (and also, if relevant, an Executive Director) with the Group during the Performance Period, his/her AZIP Share Award will generally lapse, unless his cessation is because of death, ill-health, injury, disability, redundancy, retirement with the agreement of his/her employing company, or because of a sale or transfer out of the Group (each a Good Leaver Reason). In these circumstances, the maximum number of Shares comprised in an AZIP Share Award will, unless the Committee determines otherwise, be pro-rated to reflect the proportion of the period of employment between grant and cessation, relative to the four-year Performance Period. In circumstances where the Good Leaver Reason is death, ill-health, injury or disability (being compassionate circumstances), the performance hurdle will be assessed and the AZIP Share Award may vest following cessation of employment, unless the Committee determines otherwise. On cessation of employment for any other Good Leaver Reason, the pro-rated AZIP Share Award will remain subject to the performance hurdle, which will be assessed at the end of the Performance Period, unless the Committee determines that special circumstances apply, and the AZIP Share Award may then vest on the later of: (i) the end of the Performance Period; or (ii) 24 months after cessation of employment, unless the Committee determines otherwise.

#### Cessation of employment during the Holding Period

If a participant ceases to be in employment (and also, if relevant, an Executive Director) with the Group during the Holding Period, his/ her AZIP Share Award will generally lapse, unless his/her cessation is because of a Good Leaver Reason. In circumstances where the Good Leaver Reason is death, ill-health, injury or disability (being compassionate circumstances), the AZIP Share Award will vest in respect of all the Shares subject to the AZIP Share Award (as calculated at the end of the Performance Period) as soon as possible following cessation of employment. On cessation of employment for any other Good Leaver Reason, the AZIP Share Award will vest in respect of all the Shares subject to the AZIP Share Award (as calculated at the end of the Performance Period) on the earlier of: (i) the end of the period of 24 months from the date of cessation of employment; and (ii) the end of the Holding Period. The Committee does have discretion to determine otherwise if it believes the circumstances justify this.

#### Individual limit

In respect of any financial year of the Company, the maximum market value of Shares that may in theory be put under an AZIP Share Award in respect of an employee is 500% of that employee's base salary. The actual individual limits that apply under the AZIP, subject to this maximum, are set by the Committee from time to time. Share Awards made to Executive Directors in 2010 did not exceed 65% of base salary.

#### Claw-back of Shares

The Committee can claw back some or all of the Shares that are the subject of a participant's AZIP Share Award at any time during the Performance Period and the Holding Period if, in the opinion of the Committee (acting fairly and reasonably), any of the underlying performance of the Company, the occurrence of an event that causes or is very likely to cause reputational damage to the Company, or serious misconduct by the participant, warrants the claw-back. If this discretion is exercised, the AZIP Share Award will be deemed to have been granted over the reduced number of Shares.

#### 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 expired in May. The Company did not seek re-approval of the SOP by shareholders.

Details of outstanding Option Awards granted to Executive Directors are shown in the Share option plan table on page 134.

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.

#### Other incentive plans

#### Global Restricted Stock Plan

The GRSP was introduced in 2010 and provides for the grant of restricted stock awards (Stock Awards) over Shares. As the GRSP is operated for below SET-level employees only, no SET member participates in the GRSP. During 2010, two restricted stock plans (the AZ RSU Plan and the MedImmune RSU Plan described below) applicable to below SET-level employees were discontinued and replaced by the GRSP (on broadly similar terms to the existing plans, with no increase in overall award levels) for the purposes of simplifying the administration.

In 2010, Stock Awards were made under the GRSP on 26 March, with other Stock Awards approved by the Committee in relation to, for example, new appointments, promotions or assignments being granted on 27 August. Stock Awards granted under the GRSP do not involve the issue and allotment of new Ordinary Shares but rather rely on the market purchase of Shares that have already been issued. There is no increase in the overall quantum of awards applicable to target employees through the introduction of the GRSP.

#### Restricted Stock Unit Plans

The AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan (AZ RSU Plan) was introduced in 2007 and provided for the grant of restricted stock unit awards to selected employees (predominantly in the US). The MedImmune, Inc. 2008 Restricted Stock Unit Award Plan (MedImmune RSU Plan) was introduced in 2008 to make restricted stock unit awards to employees of MedImmune. The AZ RSU Plan and the MedImmune RSU Plan were 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. The AZ RSU Plan and the MedImmune RSU Plan were replaced in 2010 by 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 Ordinary Shares or Ordinary Shares transferred from treasury. The RSP was used a number of times in 2010 to make RS Awards to a limited number of key senior executives in specific situations considered by the Committee. 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.

#### 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 from page 173.

#### **Dilution under LTI Plans**

Only outstanding awards under the SOP are settled using newly issued Ordinary Shares. 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 Shares that have already been issued.

#### **Service contracts**

Details of the service contracts for each of the Executive Directors, including their notice periods, are set out opposite. Either the Company or the Executive Director may terminate the service contract on 12 months' notice. It is the Committee'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.

During 2010, with the approval of the Board, Simon Lowth was appointed as a Non-Executive Director of Standard Chartered PLC. In respect of such position, he retained the fees paid to him for his services which, during the period of his directorship from 1 May to 31 December, amounted to £66,667.

#### **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 awards or options. No pension contributions are made on their behalf.

During 2010, the annual fees paid to Non-Executive Directors were reviewed. The basic Board fee, the fee of the Chairman and of the Senior independent Non-Executive Director, and the fee for membership of the Audit Committee were increased. These increases took into account the need for the Company to continue to attract skilled and experienced Non-Executive Directors, having regard to comparable fees at other UK public listed companies of a similar size, and to recognise the significant responsibility and time commitment expected of Non-Executive Directors. The increases ensure that the Company is well positioned when seeking to recruit new Non-Executive Directors as part of routine refreshment of the Board and succession planning. The annual aggregate remuneration of the Non-Executive Directors remains well below the limit in the Articles approved by shareholders at the 2010 AGM. None of the Non-Executive Directors has participated or will participate in any decision made in relation to the determination of their own fees.

The Chairman's annual fee is £500,000, 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' section on page 216, 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 (£75,000) or, in the case of the Chairman, approximately equivalent to his annual fee (£500,000).

#### Audit

The Directors' emoluments in 2010 disclosed in the Directors' emoluments in 2010 section from page 129 and the details of the Directors' interests in Ordinary Shares disclosed in the Directors' interests in shares section from page 132, have been audited by KPMG Audit Plc.

#### Details of Executive Directors' service contracts at 31 December 2010

Executive Director <sup>1</sup>	Date of service contract	Unexpired term at 31 December 2010	Notice 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

Non-Executive Director <sup>1,2</sup>	Effective date of appointment
Bruce Burlington	1 August 2010
Jean-Philippe Courtois	18 February 2008
Jane Henney	24 September 2001
Michele Hooper	1 July 2003
Rudy Markham	12 September 2008
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**

	L
Basic Fee	75,000
Senior independent Non-Executive Director	30,000
Membership of the Audit Committee	20,000
Membership of the Remuneration Committee	15,000
Chairman of the Audit Committee or the Remuneration Committee <sup>1</sup>	20,000
Membership of the Science Committee	10,000
Chairman of the Science Committee <sup>1</sup>	7,000

<sup>1</sup> This fee is in addition to the fee for membership of the relevant Committee.

#### **Directors' emoluments in 2010**

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 2010 was £5,880,000 (\$9,088,000). 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

Name	Salary and fees £000	Bonus cash £000	Bonus Shares¹ £000	Taxable benefits £000	Other payments and allowances £000	Total 2010 £000	Total 2009 £000	Total 2008 £000
Louis Schweitzer	456	-	-	-	-	456	325	303
David Brennan	973 <sup>2</sup>	1,055	528	24	464 <sup>3</sup>	3,044	3,186	2,506
Simon Lowth	620	612	306	8	<b>96</b> <sup>4</sup>	1,642	1,426	1,304
Bruce Burlington⁵	33	-	-	-	-	33	-	-
Jean-Philippe Courtois	80	-	-	-	-	80	75	58
Jane Henney	90	-	-	-	-	90	85	76
Michele Hooper	120	-	-	-	-	120	100	90
Rudy Markham	90	-	-	-	-	90	75	23
Nancy Rothwell	96	-	-	-	-	96	92	80
John Varley	99	-	-	-	-	99	95	83
Marcus Wallenberg	71	-	-	-	-	71	60	53
Former Directors								
Bo Angelin <sup>6</sup>	23	-	-	-	-	23	70	63
John Buchanan <sup>6</sup>	36	-	-	-	-	36	110	96
Others	-	-	-	-	-	-	479	1,181
Total	2,787	1,667	834	32	560	5,880	6,178	5,916

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#### Directors' remuneration – US dollars

Name	Salary and fees \$000	Bonus cash \$000	Bonus Shares¹ \$000	Taxable benefits \$000	Other payments and allowances \$000	Total 2010 \$000	Total 2009 \$000	Total 2008 \$000
Louis Schweitzer	705	-	-	-	-	705	504	567
David Brennan	1,504 <sup>2</sup>	1,631	816	37	<b>717</b> <sup>3</sup>	4,705	4,937	4,692
Simon Lowth	958	946	473	12	<b>148</b> <sup>4</sup>	2,537	2,209	2,442
Bruce Burlington⁵	51	-	-	-	-	51	-	-
Jean-Philippe Courtois	124	-	-	-	-	124	116	109
Jane Henney	139	-	-	-	-	139	132	142
Michele Hooper	185	-	-	-	-	185	155	169
Rudy Markham	139	-	-	-	-	139	116	43
Nancy Rothwell	148	-	-	-	-	148	143	150
John Varley	153	-	-	-	-	153	147	155
Marcus Wallenberg	110	-	-	-	-	110	93	99
Former Directors								
Bo Angelin <sup>6</sup>	36	-	-	-	-	36	108	118
John Buchanan <sup>6</sup>	56	-	-	-	-	56	170	180
Others	-	-	-	-	-	-	743	2,211
Total	4,308	2,577	1,289	49	865	9,088	9,573	11,077

<sup>1</sup> These figures represent that portion of the 2010 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 125.

<sup>2</sup> This figure includes a sum of \$356,000/£230,000 in respect of member contributions to the AstraZeneca Executive Deferred Compensation Plan and 401(k) plan which were paid into the plan by means of a salary sacrifice (see the Defined contribution arrangements section on page 131 for further details).

<sup>3</sup> Relates to relocation allowances, a car allowance and cash payments in respect of dividends accrued on vesting of LTI share plan awards.

<sup>4</sup> Relates to remaining cash following selection of benefits within AstraZeneca's UK flexible benefits programme and a cash payment in respect of dividends accrued on vesting of an LTI share plan award.

<sup>5</sup> Part-year only as appointed as a Director with effect from 1 August 2010.

<sup>6</sup> Part-year only as ceased to be a Director on 29 April 2010.

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
2010	0.647
2009	0.645
2008	0.534

Details of share options 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 Director's interests in shares section from page 132.

No Director has a family relationship with any other Director.

#### Pensions

#### Defined benefit arrangements

Pension is payable to David Brennan 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 2010 set out above.

	Dav	vid Brennan
	£000	\$000
Defined benefit arrangements		
1. Accrued pension at 1 January 2010	918	1,419
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	69	107
4. Increase in accrued pension as a result of additional service	19	29
5. Accrued pension at 31 December 2010	1,006	1,555
6. Employee contributions during 2010	-	-
7. Transfer value of accrued pension at 31 December 2009	12,890	19,922
8. Transfer value of accrued pension at 31 December 2010 <sup>1</sup>	14,711	22,738
9. Change in transfer value during the period less employee contributions	1,822	2,816
10. Age at 31 December 2010	<b>57</b> <sup>4</sup> ⁄12	<b>57</b> <sup>4</sup> / <sub>12</sub>
11. Pensionable service (years) at 31 December 2010	35	35

<sup>1</sup> 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 value shown at 31 December 2010 has been adjusted to reflect a change in the lump sum factor at 31 December 2009.

#### **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. During 2010, total employer matching contributions of \$91,000 (£59,000) (2009: \$98,000 (£64,000)) were made to his 401(k) plan and EDCP. Member contributions of \$356,000 (£230,000) were paid through salary sacrifice into the plans. As described in the Pension arrangements section on page 124, Simon Lowth chose to receive a cash allowance in lieu of pension, which during 2010 amounted to £149,000 (\$230,000) (2009: £132,000 (\$205,000)).

#### **Transactions with Directors**

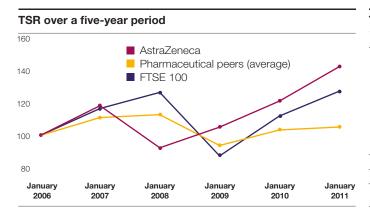
There were no material recorded transactions between the Company and the Directors during 2010 or 2009.

#### **Total shareholder return**

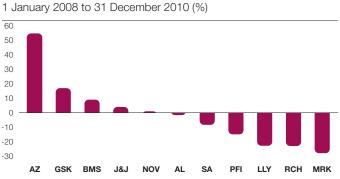
The Regulations require the inclusion of a graph showing TSR over a five-year period in respect of a holding of the Company's shares, plotted against TSR in respect of a hypothetical holding of shares of a similar kind and number by reference to which a broad equity market index is calculated. The Company is a member of the FTSE 100 Index and consequently, for the purposes of this graph, which is set out below, 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 graphs below.

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 from page 125). The graphs below 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 2010 and how the Company ranks against those other companies on this basis.

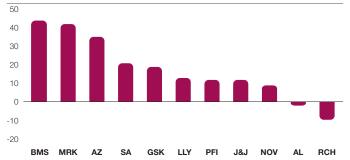
To alleviate any short-term volatility, the return index is averaged in the TSR calculations for each company over the three months prior to the start of the relevant performance period (as stipulated in the PSP) and, for the purposes of the graphs below, over the last three months of 2010.



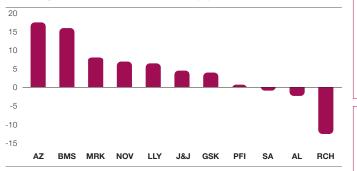
TSR – AstraZeneca compared with peer group







TSR - AstraZeneca compared with peer group 1 January 2010 to 31 December 2010 (%)



#### **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 2010 to 31 December 2010 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 PSP Share Awards, AZIP Share Awards and/or the Deferred Bonus Plan discussed in this Report, are not included in the table below but are shown in the Performance Share Plan, AstraZeneca Investment Plan and Deferred Bonus Plan tables on page 133. None of the Directors has a beneficial interest in the shares of any of the Company's subsidiaries. Between 31 December 2010 and 27 January 2011, there was no change in the interests in Ordinary Shares shown in the table below.

Name	Beneficial interest in Ordinary Shares at 1 January 2010 or (if later) appointment date	Change to beneficial interest	Beneficial interest in Ordinary Shares at 31 December 2010 or (if earlier) resignation date
Louis Schweitzer	5,356	11,259	16,615
David Brennan	128,375	58,607	186,982
Simon Lowth	850	8,496	9,346
Bo Angelin <sup>1</sup>	787	-	787
John Buchanan <sup>1</sup>	2,500	-	2,500
Bruce Burlington <sup>2</sup>	553	-	553
Jean-Philippe Courtois	2,635	-	2,635
Jane Henney	787	527	1,314
Michele Hooper	1,700	700	2,400
Rudy Markham	1,420	520	1,940
Nancy Rothwell	787	527	1,314
John Varley	500	794	1,294
Marcus Wallenberg <sup>3</sup>	67,264	(3,618)	63,646

<sup>1</sup> Part-year only as ceased to be a Director on 29 April 2010.

<sup>2</sup> Part-year only as appointed as a Director on 1 August 2010.
 <sup>3</sup> Ceased to have an interest in 3,618 shares held by a family member who ceased to be a Connected Person during 2010.

#### Unitised stock plans

David Brennan, in common with other participating executives in the US, has interests in the following plans which were awarded to him prior to him becoming CEO: 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 represent 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 2010	Net ADSs acquired during 2010	ADSs held at 31 December 2010
AstraZeneca Executive Deferral Plan	35,906	1,835	37,741
AstraZeneca Savings and Security Plan	8,103	420	8,523

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 from other shareholders.

#### **Performance Share Plan**

The interests of Directors at 31 December 2010 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:

			Price on			
	Number of shares	Award price (pence)	vesting date (pence)	Grant date <sup>1</sup>	Vesting date <sup>1</sup>	Performance period <sup>1</sup>
David Brennan	5110165	(perice)	uale (perice)	Grani uale	vesting date	r en ormanice penou
	107.051	0744		00.00.07	00.00.10	01 01 07 01 10 00
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
2009 Share Award	133,347	2280		27.03.09	27.03.12	01.01.09 - 31.12.11
Total at 1 January 2010	401,944					
Partial vesting of 2007 Share Award <sup>2</sup>	(83,499) <sup>3,5</sup>		2980			
Partial lapse of 2007 Share Award	(23,552)					
2010 Share Award	127,520	2861		07.05.10	07.05.13	01.01.10 - 31.12.12
Total at 31 December 2010	422,413					
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
2009 Share Award	54,276	2280		27.03.09	27.03.12	01.01.09 - 31.12.11
Total at 1 January 2010	128,278					
Partial vesting of 2007 Share Award <sup>2</sup>	(12,132) <sup>4,5</sup>		3016			
Partial lapse of 2007 Share Award	(3,422)					
2010 Share Award	52,009	2861		07.05.10	07.05.13	01.01.10 - 31.12.12
Total at 31 December 2010	164,733					

UK date convention applies

<sup>2</sup> Share Awards granted in 2007 vested in 2010 at 78% based on the outcome of the performance conditions and targets (which are set out in the AstraZeneca Performance Share Plan section from page 125).

Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 49,264 Ordinary Shares.
 Following certain mandatory tax deductions, Simon Lowth became beneficially interested in a net number of 5,944 Ordinary Shares.

Cash payments equivalent to dividends accruing over the vesting period are made at the date of vesting and are included in 'Other payments and allowances' in the Directors' remuneration tables from page 129.

#### AstraZeneca Investment Plan

The interests of Directors at 31 December 2010 in Shares that are the subject of Share Awards under the AZIP are not included in the table on the previous page but are shown below:

	Number of shares	Award price (pence)	Grant date <sup>1</sup>	Vesting date <sup>1</sup>	Performance period <sup>1</sup>
David Brennan					
2010 Share Award	21,253	2861	07.05.10	01.01.18	01.01.10 - 31.12.13
Total at 31 December 2010	21,253				
Simon Lowth					
2010 Share Award	8,668	2861	07.05.10	01.01.18	01.01.10 - 31.12.13
Total at 31 December 2010	8,668				

<sup>1</sup> UK date convention applies.

#### **Deferred Bonus Plan**

As described in the Bonus share deferral requirements section on page 125, 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 at 31 December 2010 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:

	Number of shares	Award price (pence)	Price on vesting date (pence)	Grant date <sup>1</sup>	Vesting date <sup>1</sup>
David Brennan					
2007 Award	12,014	2911		23.02.07	23.02.10
2008 Award	16,810	1999		25.02.08	25.02.11
2009 Award	17,992	2400		25.02.09	25.02.12
Total at 1 January 2010	46,816				
Vesting of 2007 Award	<b>(12,014)</b> <sup>2,3</sup>		2810		
2010 Award	20,718	2817.5		25.02.10	25.02.13
Total at 31 December 2010	55,520				
Simon Lowth					
2008 Award	1,340	1999		25.02.08	25.02.11
2009 Award	9,775	2400		25.02.09	25.02.12
Total at 1 January 2010	11,115				
2010 Award	9,760	2817.5		25.02.10	25.02.13
Total at 31 December 2010	20,875				

UK date convention applies.

<sup>2</sup> Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 7,088 Ordinary Shares.

<sup>3</sup> Cash payments equivalent to dividends accruing over the vesting period are made at the date of vesting and are included in 'Other payments and allowances' in the Directors' remuneration tables from page 129.

#### Share option plans

The interests of Directors who served during 2010, in options to subscribe for Ordinary Shares, granted under the SOP and, where indicated, the Zeneca Plan, are included in the following table. None of the Directors in the table below hold options under the AstraZeneca Savings-Related Share Option Plan. There were no grants of options made under any of the plans in 2010.

		Number of Ordinary Shares under option <sup>1</sup>	Exercise price per Ordinary Share <sup>2</sup>	Market price on date of exercise	First day exercisable <sup>3,4</sup>	Last day exercisable <sup>3,4</sup>
David Brennan	At 1 January 2010 – options over Ordinary Shares	592,975	2375p		24.03.09	26.03.19
	<ul> <li>market price above option price (Ordinary Shares)</li> </ul>	505,244	2271p		19.05.09	26.03.19
	<ul> <li>market price at or below option price (Ordinary Shares)</li> </ul>	87,731	2975p		24.03.09	23.03.16
	At 31 December 2010 – options over Ordinary Shares	592,975	2375p		24.03.09	26.03.19
	<ul> <li>market price above option price (Ordinary Shares)</li> </ul>	505,244	2271p		19.05.09	26.03.19
	<ul> <li>market price at or below option price (Ordinary Shares)</li> </ul>	87,731	2975p		24.03.09	23.03.16
	At 1 January 2010 – 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
	– market price at or below option price (ADSs)	144,991	\$48.58		29.03.04	27.03.12
	Exercised 2 March 2010	(32,727)5	\$44.00	\$44.35	16.03.03	26.03.19
	At 31 December 2010 – options over ADSs	322,519	\$45.35		29.03.04	23.03.15
	<ul> <li>market price above option price (ADSs)</li> </ul>	110,987	\$40.35		24.03.08	23.03.15
	– market price at or below option price (ADSs)	211,532	\$47.97		29.03.04	25.03.14
Simon Lowth	At 1 January 2010	153,934	2090p		16.11.10	26.03.19
	<ul> <li>market price above option price</li> </ul>	153,934	2090p		16.11.10	26.03.19
	- market price at or below option price	-	n/a		n/a	n/a
	Exercised 17 November 2010	(18,665)	2210p	3048 p	16.11.10	15.11.17
	At 31 December 2010	135,269	2074p		28.03.11	26.03.19
	– market price above option price	135,269	2074p		28.03.11	26.03.19
	<ul> <li>market price at or below option price</li> </ul>	-	n/a		n/a	n/a

<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 the SOP is set out in the AstraZeneca Share Option Plan section on page 127. 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>3</sup> First and last exercise dates of groups of options, within which period there may be shorter exercise periods.

<sup>4</sup> UK date convention applies.

<sup>5</sup> Option granted under the Zeneca Plan.

#### Gains by Directors on exercise of share options

The aggregate gains made by Directors on the exercise of share options during the year and the two previous years are set out below.

Year	Gains made by Directors on the exercise of share options \$	Gains made by the highest paid Director \$
2010	260,182.40	11,454.45
2009	-	-
2008	1,764.96	-

During 2010, the market price of Ordinary Shares or ADSs was as follows:

Stock Exchange	Ordinary Share/ADS market price at 31 December 2010	Range of the Ordinary Share/ ADS market price during 2010
London	2922p	2732p to 3385p
Stockholm	309.3 SEK	309.3 SEK to 382.2 SEK
New York	\$46.19	\$40.91 to \$53.50

#### On behalf of the Board

#### A C N Kemp

Company Secretary 27 January 2011

# How are the financial statements structured?

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# **Financial Statements**

# **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 27 January 2011

#### **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 2010 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 2010, 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 2010 and, as explained on page 137, 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 2010 (Sarbanes-Oxley Act Section 404). The Directors' statement on internal control over financial reporting is set out on page 136.

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 198.

# 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 2010 set out on pages 138 to 197. 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 and, in respect of the separate opinion in relation to IFRSs as issued by the International Accounting Standards Board (IASB), on terms agreed with the Company. 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, in respect of the separate opinion in relation to IFRSs as issued by the IASB, those matters that we have agreed to state to them in our 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 136, 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, and express an opinion on, 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/private.cfm.

#### **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 2010 and of its profit for the year then ended.
   > Have been properly properly according with ICPS and
- > 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 Group Accounting Policies section to the Group Financial Statements set out on pages 142 to 146, 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 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:

Linder the Companies Act 2006 we are required to report to visu

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 page 142, 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.
- > Certain elements of the report to shareholders by the Board on directors' remuneration.

#### **Other matters**

We have reported separately on the Parent Company Financial Statements of AstraZeneca PLC for the year ended 31 December 2010 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 15 Canada Square, London, E14 5GL

27 January 2011

# **Consolidated Statement of Comprehensive Income**

for the year ended 31 December

Gross profit         28,880         27,029         25,003           Distribution costs         (335)         (298)         (291)           Research and development         2         (5,318)         (4,409)         (5,172)           Besterich and development         2         (10,445)         (11,332)         (10,913)           Other operating income and expense         2         712         553         524           Operating profit         2         11,494         11,543         9,144           Finance expense         3         516         462         854           Finance expense         3         (1,033)         (1,198)         (1,317)           Profit before tax         10,977         10,807         8,681           Taxation         4         (2,896)         (3,263)         (2,551)           Profit for the period         8,081         7,544         6,130           Other comprehensive income:         26         388         (1,336)           Foreign exchange differences on borrowings forming net investment hedges         101         1         1           Nortisation         0.680         2.63         388         (1,336)           Foreign exchange differences on borrowings forming net inves		Notes	2010 \$m	2009 \$m	2008 \$m
Gross profit         26,880         27,029         25,003           Distribution costs         (339)         (299)         (291)           Research and development         2         (5,318)         (4,409)         (5,179)           Belling, general and administrative costs         2         (10,445)         (11,332)         (10,913)           Other operating income and expense         2         712         553         524           Operating profit         2         11,494         11,543         9,144           Finance income         3         516         422         854           Finance expense         3         (1,033)         (1,198)         (1,317)           Profit before tax         10,977         10,807         8,681           Toxation         4         (2,899)         (2,299)         (2,215)           Profit for the period         8,081         7,544         6,130           Other comprehensive income:         2         2         2           Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Armottisation of loss on cash flow hedge         1         1         1         1           Net avaitablo for sale gains taken	Revenue	1	33,269	32,804	31,601
Distribution costs         (335)         (298)         (291)           Research and development         2         (5,318)         (4,409)         (5,179)           Selling, general and administrative costs         2         (10,445)         (11,332)         (10,913)           Other operating income and expense         2         712         553         524           Operating profit         2         11,494         11,543         9,144           Finance expense         3         516         462         854           Finance expense         3         (1,033)         (1,093)         (1,017)           Profit before tax         10,977         10,807         8,681         7,544         6,130           Other comprehensive income:	Cost of sales		(6,389)	(5,775)	(6,598)
Research and development         2         (5,318)         (4,409)         (5,179)           Selling, general and administrative costs         2         (10,445)         (11,332)         (10,913)           Other operating income and expense         2         712         553         524           Operating profit         2         11,494         11,543         9,144           Finance income         3         516         462         854           Finance expense         3         (1,033)         (1,196)         (1,317)           Profit before tax         10,977         (1,860)         (2,255)           Profit before tax         8,081         7,544         6,130           Other comprehensive income:	Gross profit		26,880	27,029	25,003
Selling, general and administrative costs         2         (10,445)         (11,332)         (10,913)           Other opperating income and expense         2         712         553         524           Operating profit         2         11,494         11,543         9,144           Finance income         3         516         462         854           Finance income         3         (1,033)         (1,198)         (1,317)           Profit before tax         10,977         10,807         8,681         7,544           Taxation         4         (2,896)         (3,263)         (2,251)           Profit for the period         8,061         7,544         6,130           Other comprehensive income:	Distribution costs		(335)	(298)	(291)
Output         Question         Question <thquestion< th="">         Question         <t< td=""><td>Research and development</td><td>2</td><td>(5,318)</td><td>(4,409)</td><td>(5,179)</td></t<></thquestion<>	Research and development	2	(5,318)	(4,409)	(5,179)
Operating profit         2         11,494         11,543         9,144           Finance income         3         516         462         854           Finance expense         3         (1,033)         (1,198)         (1,317)           Profit before tax         10,977         10.807         8,681         7,544         6,130           Other comprehensive income:         8,081         7,544         6,130         0         26         388         (1,369)         291           Foreign exchange arising on consolidation         26         388         (1,369)         291         4         2         2         2         4         2         2         2         4         2         2         2         4         2         2         2         4         2         2         2         4         2         2         2         4         2         2         2         3         1	Selling, general and administrative costs	2	(10,445)	(11,332)	(10,913)
Finance Income         3         516         462         854           Finance expense         3         (1,033)         (1,198)         (1,317)           Profit before tax         10,977         10,807         8,681           Taxation         4         (2,896)         (3,263)         (2,551)           Profit for the period         8,081         .7,544         6,130           Other comprehensive income:         26         388         (1,336)           Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Amortisation of loss on cash flow hedge         1         1         1         1           Net available for sale gains taken to equity         4         2         2           Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         25         (54)         (1,906)           Owners of the Parent         8,053         7,521         6,101           Non-controlling inte	Other operating income and expense	2	712	553	524
Finance expense         3         (1,033)         (1,198)         (1,317)           Profit before tax         10,977         10,807         8,681           Taxation         4         (2,896)         (3,263)         (2,551)           Profit for the period         8,081         7,544         6,130           Other comprehensive income:         5         8,081         7,544         6,130           Foreign exchange arising on consolidation         26         388         (1,336)           Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Amortisation of loss on cash flow hedge         1         1         1         1           Net available for sale gains taken to equity         4         2         2         2           Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         26         (1,906)           Other comprehensive income for the pe	Operating profit	2	11,494	11,543	9,144
Profit before tax         10,977         10,807         8,681           Taxation         4         (2,896)         (3,263)         (2,551)           Profit for the period         8,081         7,544         6,130           Other comprehensive income:         5         5,651         8,081         7,544         6,130           Foreign exchange arising on consolidation         26         388         (1,336)         291           Amortisation of loss on cash flow hedge         1         1         1         1           Net available for sale gains taken to equity         4         2         2         2           Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,063         7,521         6,101           Non-controlling interests         28         23         29           Owners of the Parent         8,053         7,521         6,101           Non-controlling interests         28         23         48	Finance income	3	516	462	854
Taxation         4         (2,896)         (3,263)         (2,551)           Profit for the period         8,081         7,544         6,130           Other comprehensive income:	Finance expense	3	(1,033)	(1,198)	(1,317)
Profit for the period         8,081         7,544         6,130           Other comprehensive income:         26         388         (1,336)           Foreign exchange arising on consolidation         26         388         (1,336)           Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Amortisation of loss on cash flow hedge         1         1         1         1         1           Attavarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         0 <td>Profit before tax</td> <td></td> <td>10,977</td> <td>10,807</td> <td>8,681</td>	Profit before tax		10,977	10,807	8,681
Other comprehensive income:         26         388         (1,336)           Foreign exchange arising on consolidation         26         388         (1,336)           Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Amortisation of loss on cash flow hedge         1         1         1         1           Net available for sale gains taken to equity         4         2         2           Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         0         0         7,490         4,224           Owners of the Parent         8,053         7,521         6,101           Non-controlling interests         28         23         29           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Bas	Taxation	4	(2,896)	(3,263)	(2,551)
Foreign exchange arising on consolidation         26         388         (1,336)           Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Amortisation of loss on cash flow hedge         1         1         1         1           Net available for sale gains taken to equity         4         2         2           Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,22           Profit attributable to:         28         23         29           Owners of the Parent         8,053         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         28         23         29           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per	Profit for the period		8,081	7,544	6,130
Foreign exchange differences on borrowings forming net investment hedges         101         (68)         291           Amortisation of loss on cash flow hedge         1	Other comprehensive income:				
Amortisation of loss on cash flow hedge       1       1       1       1         Net available for sale gains taken to equity       4       2       2         Actuarial loss for the period       18       (46)       (569)       (1,232)         Income tax relating to components of other comprehensive income       4       (61)       192       368         Other comprehensive income for the period, net of tax       25       (54)       (1,906)         Total comprehensive income for the period       8,106       7,490       4,224         Profit attributable to:       0       0       4       23       28         Owners of the Parent       8,053       7,521       6,101         Non-controlling interests       28       23       29         Total comprehensive income attributable to:       0       28       23       29         Owners of the Parent       8,058       7,467       4,176         Non-controlling interests       48       23       48         Basic carnings per \$0.25 Ordinary Share       5       \$5.60       \$5.19       \$4.20         Diluted earnings per \$0.25 Ordinary Share       5       \$5.57       \$5.19       \$4.20         Weighted average number of Ordinary Shares in issue (millions)	Foreign exchange arising on consolidation		26	388	(1,336)
Net available for sale gains taken to equity         4         2         2           Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         0         0         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         0         0         2         2           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         28         23         29           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20	Foreign exchange differences on borrowings forming net investment hedges		101	(68)	291
Actuarial loss for the period         18         (46)         (569)         (1,232)           Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         0	Amortisation of loss on cash flow hedge		1	1	1
Income tax relating to components of other comprehensive income         4         (61)         192         368           Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         8,053         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         0         9,053         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         0         9,058         7,467         4,176           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5,60         \$5,19         \$4.20           Diluted earnings per \$0.25 Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Net available for sale gains taken to equity		4	2	2
Other comprehensive income for the period, net of tax         25         (54)         (1,906)           Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         0	Actuarial loss for the period	18	(46)	(569)	(1,232)
Total comprehensive income for the period         8,106         7,490         4,224           Profit attributable to:         8,053         7,521         6,101           Owners of the Parent         8,053         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         28         23         29           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Income tax relating to components of other comprehensive income	4	(61)	192	368
Profit attributable to:         8,053         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         0wners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Downers of the Parent         5         \$5.60         \$5.19         \$4.20           Non-controlling interests         5         \$5.57         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20           Weighted average number of Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Other comprehensive income for the period, net of tax		25	(54)	(1,906)
Owners of the Parent         8,053         7,521         6,101           Non-controlling interests         28         23         29           Total comprehensive income attributable to:         28         23         29           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Total comprehensive income for the period		8,106	7,490	4,224
Non-controlling interests         28         23         29           Total comprehensive income attributable to:              4,176           Owners of the Parent         8,058         7,467         4,176            48         23         48            48         23         48	Profit attributable to:				
Total comprehensive income attributable to:           Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Owners of the Parent		8,053	7,521	6,101
Owners of the Parent         8,058         7,467         4,176           Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20           Weighted average number of Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Non-controlling interests		28	23	29
Non-controlling interests         48         23         48           Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20           Weighted average number of Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Total comprehensive income attributable to:				
Basic earnings per \$0.25 Ordinary Share         5         \$5.60         \$5.19         \$4.20           Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20           Weighted average number of Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Owners of the Parent		8,058	7,467	4,176
Diluted earnings per \$0.25 Ordinary Share         5         \$5.57         \$5.19         \$4.20           Weighted average number of Ordinary Shares in issue (millions)         5         1,438         1,448         1,453           Diluted weighted average number of Ordinary Shares in issue (millions)         5         1,446         1,450         1,453	Non-controlling interests		48	23	48
Weighted average number of Ordinary Shares in issue (millions)51,4381,4481,453Diluted weighted average number of Ordinary Shares in issue (millions)51,4461,4501,453		5	\$5.60	\$5.19	\$4.20
Diluted weighted average number of Ordinary Shares in issue (millions)51,4461,4501,453	Diluted earnings per \$0.25 Ordinary Share	5	\$5.57	\$5.19	\$4.20
	Weighted average number of Ordinary Shares in issue (millions)	5	1,438	1,448	1,453
Dividends declared and paid in the period         21         3,494         3,026         2,767	Diluted weighted average number of Ordinary Shares in issue (millions)	5	1,446	1,450	1,453
	Dividends declared and paid in the period	21	3,494	3,026	2,767

All activities were in respect of continuing operations.

\$m means millions of US dollars.

# **Consolidated Statement of Financial Position**

at 31 December

	Notes	2010 \$m	2009 \$m	2008 \$m
Assets				
Non-current assets				ļ
Property, plant and equipment	7	6,957	7,307	7,043
Goodwill	8	9,871	9,889	9,874
Intangible assets	9	12,158	12,226	12,323
Derivative financial instruments	15	324	262	449
Other investments	10	211	184	156
Deferred tax assets	4	1,475	1,292	1,236
		30,996	31,160	31,081
Current assets	11	1,682	1,750	1,636
Trade and other receivables	12	7,847	7,709	7,261
Other investments	12	1.482	1,484	105
Derivative financial instruments	10	1,482	1,484	
Income tax receivable		3,043	24	2,581
Cash and cash equivalents	13	3,043	2,875	4,286
Cash and cash equivalents	10	25,131	23,760	4,286
Total assets		56,127	54,920	46,950
		50,121	04,020	40,800
Liabilities Current liabilities				
Interest-bearing loans and borrowings	14	(125)	(1,926)	(993)
Trade and other payables	16	(8,661)	(8,687)	(7,178)
Derivative financial instruments	15	(8)	(90)	(95)
Provisions	17	(1,095)	(1,209)	(600)
Income tax payable		(6,898)	(5,728)	(4,549)
		(16,787)	(17,640)	(13,415)
Non-current liabilities		, -		
Interest-bearing loans and borrowings	14	(9,097)	(9,137)	(10,855)
Derivative financial instruments	15	-	-	(71)
Deferred tax liabilities	4	(3,145)	(3,247)	(3,126)
Retirement benefit obligations	18	(2,472)	(3,354)	(2,732)
Provisions	17	(843)	(477)	(542)
Other payables	16	(373)	(244)	(149)
		(15,930)	(16,459)	(17,475)
Total liabilities		(32,717)	(34,099)	(30,890)
Net assets		23,410	20,821	16,060
Equity Capital and reserves attributable to equity holders of the Company				l
Share capital	20	352	363	362
Share premium account		2,672	2,180	2,046
Capital redemption reserve		107	2,180	2,040
Merger reserve		433	433	433
Other reserves	19	1,377	1,392	1,405
Retained earnings	19	18,272	16,198	11,572
netalilea camings		23,213	20,660	15,912
Non-controlling interests		197	161	148
Total equity		23,410	20,821	16,060
Total equity		20,110	20,021	10,000

The Financial Statements on pages 138 to 197 were approved by the Board on 27 January 2011 and were signed on its behalf by

David R	Brennan
Director	

Simon Lowth Director

Company's registered number 2723534

**Business Review** 

Overview

# **Consolidated Statement of Changes in Equity** for the year ended 31 December

	Share capital \$m	Share premium account \$m	Capital redemption reserve \$m	Merger reserve \$m	Other reserves \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m
At 1 January 2008	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
Repurchase 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 interests	-	-	-	-	-	-	-	(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 interests	-	-	-	-	-	-	-	(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
Profit for the period	-	-	-	-	-	8,053	8,053	28	8,081
Other comprehensive income	-	-	-	-	-	5	5	20	25
Transfer to other reserves <sup>1</sup>	-	-	-	-	(15)	15	-	-	-
Transactions with owners Dividends	_	_	_	_	_	(3,494)	(3,494)	_	(3,494)
Issue of Ordinary Shares	2	492	-	-	-	-	494	-	494
Repurchase of Ordinary Shares	(13)	-	13	-	-	(2,604)	(2,604)	-	(2,604)
Share-based payments	-	-	-	-	-	99	99	-	99
Transfer from non-controlling interests to payables	-	-	-	-	-	-	-	(11)	(11)
Dividend paid by subsidiary to non-controlling interests	-	-	-	-	-	-	-	(1)	(1)
Net movement	(11)	492	13	-	(15)	2,074	2,553	36	2,589
At 31 December 2010	352	2,672	107	433	1,377	18,272	23,213	197	23,410

<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	2010 \$m	2009 \$m	2008 \$m
Cash flows from operating activities			
Profit before tax	10,977	10,807	8,681
Finance income and expense 3	517	736	463
Depreciation, amortisation and impairment	2,741	2,087	2,620
Decrease/(increase) in trade and other receivables	10	(256)	(1,032)
Decrease in inventories	88	6	185
(Decrease)/increase in trade and other payables and provisions	(16)	1,579	637
Other non-cash movements	(463)	(200)	87
Cash generated from operations	13,854	14,759	11,641
Interest paid	(641)	(639)	(690)
Tax paid	(2,533)	(2,381)	(2,209)
Net cash inflow from operating activities	10,680	11,739	8,742
Cash flows from investing activities			
Acquisitions of business operations 22	(348)	-	_
Movement in short-term investments and fixed deposits	(239)	(1,371)	1
Purchase of property, plant and equipment	(791)	(962)	(1,095)
Disposal of property, plant and equipment	83	138	38
Purchase of intangible assets	(1,390)	(624)	(2,944)
Disposal of intangible assets	210	269	-
Purchase of non-current asset investments	(34)	(31)	(40)
Disposal of non-current asset investments	5	3	32
Interest received	174	113	149
Payments made by subsidiaries to non-controlling interests	(10)	(11)	(37)
Net cash outflow from investing activities	(2,340)	(2,476)	(3,896)
Net cash inflow before financing activities	8,340	9,263	4,846
Cash flows from financing activities			
Proceeds from issue of share capital	494	135	159
Repurchase of shares	(2,604)	-	(610)
Issue of loans	-	-	787
Repayment of loans	(1,741)	(650)	_
Dividends paid	(3,361)	(2,977)	(2,739)
Movement in short-term borrowings	(8)	(137)	(3,959)
Net cash outflow from financing activities	(7,220)	(3,629)	(6,362)
Net increase/(decrease) in cash and cash equivalents in the period	1,120	5,634	(1,516)
Cash and cash equivalents at the beginning of the period	9,828	4,123	5,727
Exchange rate effects	33	71	(88)
Cash and cash equivalents at the end of the period13	10,981	9,828	4,123

# **Group 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 EU (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.

During the year the Company adopted the revised IFRS 3 'Business Combinations' (issued in January 2008). The revised IFRS 3 included the following changes relevant to the Group's operations:

- > Contingent consideration is measured at fair value, with subsequent changes to the fair value being recognised in profit.
- > Transaction costs, other than share and debt issue costs, are expensed as incurred.
- > Any pre-existing interest in the acquiree is measured at fair value with the gain or loss recognised in profit.
- > Any non-controlling (minority) interest is 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 was effective for AstraZeneca business combinations on or after 1 January 2010 and has been applied prospectively from that date. Our acquisition of Novexel S.A. was accounted for under the revised standard. Further details of this acquisition are included in Note 22 of the Financial Statements. The adoption of this revised standard has not had a significant effect on the Group's profit for the period, net assets or cash flows.

The amendments to IAS 27 'Consolidated and Separate Financial Statements (2008)', IFRS 5 'Non-current Assets Held for Sale and Discontinued Operations', IAS 39 'Financial Instruments: Recognition and Measurement – Eligible Hedged Items', IFRIC 9 and IAS 39 'Embedded Derivatives', IFRS 2 'Group Cash-settled Share-based Payment Transactions' and the Improvements to IFRS (issued April 2009) have all been adopted in the year.

The adoptions of the amendments and improvements did not have a significant effect on the Group's profit for the period, net assets or cash flows.

IFRIC 17 'Distribution of Non-Cash Assets to Owners' and IFRIC 18 'Transfer of Assets from Customers' have also been adopted by the Company, neither of which had a significant effect on the Group's profit for the period, net assets or cash flows.

The Company has elected to prepare the Company Financial Statements in accordance with UK Accounting Standards. These are presented on pages 199 to 203 and the accounting policies in respect of Company information are set out on page 200.

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 Consolidated 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 flows, liquidity position and borrowing facilities are described in the Financial Review from page 78. In addition, Note 23 to the Financial Statements includes 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 2010, the Group has \$15.25bn in financial resources (cash balances of \$11.1bn and committed bank facilities of \$4.25bn, with only \$0.1bn 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 and the determination of operating segments while 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 judgements and estimates need exercising, the most significant of which are revenue recognition, research and development (including impairment reviews of associated intangible assets), business combinations and goodwill, litigation and environmental liabilities, employee benefits, taxation and operating segments.

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, 15, 18, 22 and 25 in the Financial Statements. Financial risk management policies are detailed in Note 23.

# **Business Review**

Overview

#### Revenue

Revenues comprise sales and income under co-promotion and co-development agreements.

Income under co-promotion and co-development 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 straight-line basis over their useful economic lives from product launch. At 31 December 2010, no amounts have met recognition criteria.

Payments to in-licence products and compounds from external third parties for new research and development projects (in-process research and development), generally taking the form of up-front payments and milestones, are capitalised. Where payments made to third parties represent future research and development activities, an evaluation is made as to the nature of the payments. Such payments are expensed if they represent compensation for subcontracted research and development services not resulting in a transfer of intellectual property. By contrast, payments are capitalised if they represent compensation for the transfer of intellectual property developed at the risk of the third party. Since acquired products and compounds will only generate sales and cash inflows following launch, our policy is to minimise the period between final approval and launch if it is within AstraZeneca's control to do so. Assets capitalised 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 the fair value of the consideration 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 while 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 'Share-based 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 reflect 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
- > Bank and other 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, plus 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 remeasured to fair value at each reporting date. 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.

Overview

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, or in the rare circumstances where the amount of the legal liability cannot be estimated reliably, 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 values 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 flows, adjusted for the risks specific to each asset, are discounted to their present value using a discount rate that reflects 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 inflows from continuing use that are largely independent of the cash flows of other assets. Impairment losses are recognised in profit.

#### **Operating segments**

In 2009, the Company 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 decision making is at SET level as a whole. Where necessary these are implemented through cross-functional sub-committees that consider the Groupwide 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 Portfolio Investment Board to facilitate a Groupwide single combined discovery and development strategy. The Group's 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.

# 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

IFRS 9 'Financial Instruments' was issued in November 2009. It is applicable to financial assets and financial liabilities. For financial assets it requires classification and measurement in either the amortised cost or the fair value category. For a company's own debt held at fair value, the standard requires the movement in the fair value as a result of changes in the company's own credit risk to be included in other comprehensive income. It is effective for accounting periods beginning on or after 1 January 2013. The standard has not yet been endorsed by the EU. The adoption of IFRS 9 is not expected to have a significant impact upon the Group's net results or net assets.

Improvements to IFRS (issued in May 2010) is yet to be endorsed by the EU and contains amendments to several individual accounting standards which are effective for accounting periods beginning on or after 1 July 2010 or 1 January 2011. None of the amendments are expected to have a significant impact upon the Group's net results, net assets or disclosures.

IAS 24 'Related Party Disclosures' was revised by the IASB in 2009 and is effective for accounting periods beginning on or after 1 January 2011. The changes introduced relate mainly to disclosure requirements for government-related entities, and the definition of a related party, and are not expected to have a significant impact on the disclosures of AstraZeneca. The revised standard was endorsed by the EU during 2010.

The amendments to IAS 32 'Classification of Rights Issues' (endorsed by the EU in 2009) and IFRS 7 'Disclosures – Transfer of Financial Assets' and IAS 12 'Deferred Tax: Recovery of Underlying Assets' (not yet endorsed by the EU) are effective for accounting periods beginning on or after 1 February 2010, 1 July 2011 and 1 January 2012 respectively. They are not expected to have a significant impact upon the Group's net results, net assets or disclosures.

The following IFRIC amendments and interpretations have been issued but are not yet adopted by AstraZeneca:

- > Amendments to IFRIC 13 'Customer Loyalty Programmes' Fair value of award credit
- > Amendments to IFRIC 14 'Prepayments of a Minimum Funding Requirement'
- > IFRIC 19 'Extinguishing Financial Liabilities with Equity Instruments'.

The amendments and interpretations are effective for accounting periods commencing on or after 1 January 2011, 1 January 2011 and 1 July 2010 respectively. None of the amendments or interpretations are 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 Group Financial Statements

# **1 Product revenue information**

	2010 \$m	2009 \$m	2008 \$m
Contraintentingly	ŞIII	φIII	ΦΠ
Gastrointestinal: Nexium	4,969	4,959	5,200
Losec/Prilosec	986	946	1,055
Others	133	106	89
Total Gastrointestinal	6,088	6,011	6,344
Cardiovascular:	0,000	0,011	0,011
Cardiovascular: Crestor	5,691	4,502	3,597
Atacand	1,483	1,436	1,471
Seloken/Toprol-XL	1,485	1,430	807
Plendil	255	241	268
Zestril	157	184	200
Onglyza™	69	104	
	538	559	584
Others Total Cardiovascular	9,403	8,376	
Total Cardiovascular	3,403	0,370	6,963
Respiratory & Inflammation:	0.746	0.004	0.004
Symbicort Deteriorat	2,746	2,294	2,004
Pulmicort	872	1,310	1,495
Rhinocort	227	264	322
Oxis	63	63	71
Others	191	201	236
Total Respiratory & Inflammation	4,099	4,132	4,128
Oncology:			
Arimidex	1,512	1,921	1,857
Zoladex	1,115	1,086	1,138
Casodex	579	844	1,258
Iressa	393	297	265
Faslodex	345	262	249
Nolvadex	89	88	85
Abraxane™	-	-	64
Ethyol	8	15	28
Others	4	5	10
Total Oncology	4,045	4,518	4,954
Neuroscience:			
Seroquel	5,302	4,866	4,452
Local anaesthetics	605	599	605
Zomig	428	434	448
Diprivan	322	290	278
Others	47	48	54
Total Neuroscience	6,704	6,237	5,837
Infection and Other:	· · ·		<u>_</u>
Synagis	1,038	1,082	1,230
Merrem	817	872	897
FluMist	174	145	104
Non Seasonal Flu	39	389	-
Other Products	108	143	220
Total Infection and Other	2,176	2,631	2,451
	2,110	2,001	2,401
	505	FOC	500
Astra Tech	535	506	529
Aptium Oncology	219	393	395
Total	33,269	32,804	31,601

Overview

# **2 Operating profit**

Operating profit includes the following items:

#### **Research and development**

Research and development includes a \$445m impairment of intangible assets related specifically to motavizumab (see Note 9).

#### Selling, general and administrative costs

Selling, general and administrative expenses includes a provision of \$592m with respect to *Seroquel* legal matters. The current status of these matters is described in Note 25. These provisions constitute our best estimate at this time of losses expected for these matters.

Also included within selling, general and administrative costs in 2010 are gains of \$791m arising from changes made to benefits under certain of the Group's post-retirement benefit plans, chiefly the Group's UK pension plan. Further details of this gain are included in Note 18.

In 2009, AstraZeneca was 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 Group made provisions in aggregate of \$636m during 2009. \$524m of this was made in respect of the US Attorney's Office investigation into sales and marketing practices involving *Seroquel* and \$112m related to average wholesale price litigation.

# Other operating income and expense

	2010 \$m	2009 \$m	2008 \$m
Royalties			
Income	522	255	288
Amortisation	(59)	(79)	(84)
Impairment	(123)	(150)	(91)
Net gain on disposal of property, plant and equipment	66	8	6
Gains on disposal of product rights	-	170	-
Net (loss)/gain on disposal of other intangible assets	(1)	1	(17)
Gains on divestments of non-core products	-	216	118
Impairment of intangible assets relating to future licensing and contractual income	-	(115)	-
Other income	307	265	304
Other expense	-	(18)	-
Other operating income and expense	712	553	524

Royalty amortisation relates to income streams acquired with MedImmune.

#### **Restructuring costs**

During 2010, the Group continued the restructuring programmes approved by the SET and announced in previous years. 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 17.

	2010	2009	2008
	\$m	\$m	\$m
Cost of sales	144	188	405
Research and development	654	68	166
Selling, general and administrative costs	404	403	310
Total charge	1,202	659	881
	2010	2009	2008
	\$m	\$m	\$m
Severance costs	505	262	499
Accelerated depreciation and impairment	299	148	219
Other	398	249	163
Total charge	1,202	659	881

# 3 Finance income and expense

	2010 \$m	2009 \$m	2008 \$m
Finance income			
Returns on fixed deposits and equity securities	9	20	15
Returns on short-term deposits	33	22	127
Expected return on post-employment defined benefit plan assets	451	388	584
Fair value gains on debt, interest rate swaps and investments	23	1	128
Net exchange gains	_	31	-
Total	516	462	854

#### 3 Finance income and expense continued

	2010 \$m	2009 \$m	2008 \$m
Finance expense			
Interest on debt and commercial paper	(450)	(542)	(664)
Interest on overdrafts and other financing costs	(29)	(18)	(50)
Interest on post-employment defined benefit plan liabilities	(543)	(493)	(589)
Fair value charges on debt, interest rate swaps and investments	-	(145)	(2)
Net exchange losses	(11)	-	(12)
Total	(1,033)	(1,198)	(1,317)
Net finance expense	(517)	(736)	(463)

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 'Financial Instruments: Recognition and Measurement' (see Note 15), is a loss of \$11m (2009: gain of \$31m; 2008: loss of \$12m).

#### 4 Taxation

Taxation recognised in the profit for the period in the consolidated statement of comprehensive income is as follows:

	2010 \$m	2009 \$m	2008 \$m
Current tax expense			
Current year	3,065	2,854	2,946
djustment for prior years	370	251	130
	3,435	3,105	3,076
Deferred tax expense			
Origination and reversal of temporary differences	(369)	98	(486)
Adjustment to prior years	(170)	60	(39)
	(539)	158	(525)
Taxation recognised in the profit for the period	2,896	3,263	2,551

Taxation relating to components of other comprehensive income is as follows:

	2010 \$m	2009 \$m	2008 \$m
Current and deferred tax			
Foreign exchange arising on consolidation	(29)	16	20
Actuarial loss for the period	(18)	158	340
Share-based payments	9	17	9
Deferred tax impact of reduction in UK tax rate	(23)	_	
Other	-	1	(1)
Taxation relating to components of other comprehensive income	(61)	192	368

Taxation has been provided at current rates on the profits earned for the periods covered by the Group Financial Statements. The 2010 prior period current tax adjustment relates mainly to an increase in provisions for tax contingencies and double tax relief partially offset by a benefit of \$342m arising from a number of tax settlements (including the UK matters described in Note 25) and tax accrual to tax return adjustments. The 2009 and 2008 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 2010 prior period deferred tax adjustment relates mainly to tax accrual to tax return adjustments and a reclassification from deferred tax to current tax of amounts provided in relation to tax contingencies for prior periods. The 2009 and 2008 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 business of these companies. Unremitted earnings may be liable to overseas taxes and/or UK taxation (after allowing for double tax 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 \$16,768m at 31 December 2010 (2009: \$14,846m; 2008: \$8,449m).

#### 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, tax rates imposed and tax regime reforms. It is the UK Government's intention to enact legislation which will reduce the main rate of UK corporation tax to 24% by 2014. In November 2010, the UK Government also released a consultation document providing details on a proposed programme of corporate tax reforms including the introduction of a patent box regime. Details of material tax exposures and items currently under audit and negotiation are set out 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.

	2010 \$m	2009 \$m	2008 \$m
Profit before tax	10,977	10,807	8,681
Notional taxation charge at UK corporation tax rate of 28% (28% for 2009, 28.5% for 2008)	3,074	3,026	2,474
Differences in effective overseas tax rates	(333)	(212)	(8)
Deferred tax credit relating to reduction in Swedish, UK and other tax rates <sup>1,2</sup>	(21)	-	(70)
Unrecognised deferred tax asset	-	2	(7)
Items not deductible for tax purposes	12	156	119
Items not chargeable for tax purposes	(36)	(20)	(48)
Adjustments in respect of prior periods	200	311	91
Total tax charge for the year	2,896	3,263	2,551

<sup>1</sup> The 2010 item relates to the reduction in the UK statutory corporation tax rate from 28% to 27% effective from 1 April 2011.
<sup>2</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.

## Deferred tax

Deferred tax assets and liabilities and the movements during the year, before offset of balances within countries, are as follows:

			Pension	Inter-				_	osses and		
	Property, plant and equipment \$m	Intangible assets \$m	and post- retirement benefits \$m	company inventory transfers \$m	Untaxed reserves <sup>1</sup> \$m	Accrued expenses \$m	Share schemes \$m	Deferred capital gains \$m	tax credits carried forward \$m	Other \$m	Total \$m
Deferred tax assets at 1 January 2008	66	59	531	907	-	611	62	-	330	71	2,637
Deferred tax liabilities at 1 January 2008	(693)	(3,653)	(3)	(21)	(1,171)	(13)	-	(88)	-	(70)	(5,712)
Net deferred tax balance at 1 January 2008	(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)
Taxation expense	131	465	(178)	3	24	66	(5)	2	50	(19)	539
Other comprehensive income	-	-	(46)	-	-	-	4	-	-	1	(41)
Acquisition of subsidiary undertaking <sup>2</sup>	-	(143)	-	-	-	-	-	-	-	2	(141)
Exchange	(6)	5	(9)	15	(81)	12	(1)	3	(10)	-	(72)
Net deferred tax balance at 31 December 2010	(83)	(2,566)	679	970	(1,531)	548	127	(66)	271	(19)	(1,670)
Deferred tax assets at 31 December 2010	357	54	686	988	-	558	127	-	271	25	3,066
Deferred tax liabilities at 31 December 2010	(440)	(2,620)	(7)	(18)	(1,531)	(10)	_	(66)	-	(44)	(4,736)
Net deferred tax balance at 31 December 2010	(83)	(2,566)	679	970	(1,531)	548	127	(66)	271	(19)	(1,670)

Analysed in the statement of financial position, after offset of balances within countries, as:	2010 \$m	2009 \$m	2008 \$m
Deferred tax assets	1,475	1,292	1,236
Deferred tax liabilities	(3,145)	(3,247)	(3,126)
Net deferred tax balance	(1,670)	(1,955)	(1,890)

<sup>1</sup> Untaxed reserves relate to taxable profits where the tax liability is deferred to later periods.

<sup>2</sup> The deferred tax liability of \$143m relates to the acquisition of Novexel S.A.

# Unrecognised deferred tax assets

Deferred tax assets of \$128m have not been recognised in respect of deductible temporary differences (2009: \$104m; 2008: \$80m) 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			
	2010	2009	2008
Profit for the financial year attributable to equity holders (\$m)	8,053	7,521	6,101
Basic earnings per Ordinary Share	\$5.60	\$5.19	\$4.20
Diluted earnings per Ordinary Share	\$5.57	\$5.19	\$4.20
Weighted average number of Ordinary Shares in issue for basic earnings (millions)	1,438	1,448	1,453
Dilutive impact of share options outstanding (millions)	8	2	-
Diluted weighted average number of Ordinary Shares in issue (millions)	1.446	1.450	1.453

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 SET is AstraZeneca's chief operating decision making body (as defined by IFRS 8). All significant operating decisions are taken by the 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 Portfolio Investment Board 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.

			Revenue
	2010	2009	2008
	\$m	\$m	\$m
UK External	1,952	1,809	1,910
Intra-Group	9,957	9,056	8,460
Inta-Gloup	11,909	10,865	10,370
	11,909	10,000	10,370
Continental Europe Belgium	331	353	380
France	1,929	1,880	1,945
Germany	1,151	1,197	1,345
Italy	1,000	1,012	1,145
Spain	762	742	832
Sweden	1,157	1,070	1,135
Others	2,440	2,622	2,696
Intra-Group	5,144	4,944	3,895
Inda-Gloup	13,914	13,820	13,253
The Americas	10,011	10,020	10,200
Canada	1,492	1,188	1,269
US	14,010	14,994	13,657
Others	1,387	1,113	1,155
Intra-Group	2,341	1,962	1,169
	19,230	19,257	17,250
Asia, Africa & Australasia			
Australia	981	790	763
Japan	2,458	2,214	1,861
China	1,047	811	627
Others	1,172	1,009	1,001
Intra-Group	67	80	78
	5,725	4,904	4,330
Continuing operations	50,778	48,846	45,203
Intra-Group eliminations	(17,509)	(16,042)	(13,602)
	33,269	32,804	31,601

Export sales from the UK totalled \$10,944m for the year ended 31 December 2010 (2009: \$9,864m; 2008: \$9,439m). Intra-Group pricing is determined on an arm's length basis.

#### 6 Segment information continued

o Segment mormation continued		Operating profit			Profit before ta		
Profit from	2010 \$m	2009 \$m	2008 \$m	2010 \$m	2009 \$m	2008 \$m	
UK	3,258	3,124	2,907	3,098	2,813	2,612	
Continental Europe	4,591	4,809	3,136	4,581	4,821	3,233	
The Americas	3,278	3,265	2,705	2,932	2,832	2,440	
Asia, Africa & Australasia	367	345	396	366	341	396	
Continuing operations	11,494	11,543	9,144	10,977	10,807	8,681	

		Non-current assets <sup>1</sup>				Total assets
	2010 \$m	2009 \$m	2008 \$m	2010 \$m	2009 \$m	2008 \$m
UK	3,397	3,810	3,524	17,171	17,092	9,870
Continental Europe	4,470	3,966	3,674	7,596	6,706	6,275
The Americas	20,808	21,354	21,762	28,175	28,397	28,290
Asia, Africa & Australasia	522	476	436	3,185	2,725	2,515
Continuing operations	29,197	29,606	29,396	56,127	54,920	46,950

		As	sets acquired <sup>2</sup>		Net op	perating assets <sup>3</sup>
	2010 \$m	2009 \$m	2008 \$m	2010 \$m	2009 \$m	2008 \$m
UK	314	537	440	3,273	4,473	4,234
Continental Europe	1,053	643	295	4,827	4,094	3,683
The Americas	1,125	711	3,252	18,795	19,186	21,033
Asia, Africa & Australasia	107	79	67	2,021	1,707	1,732
Continuing operations	2,599	1,970	4,054	28,916	29,460	30,682

<sup>1</sup> 'Non-current assets' exclude deferred tax assets and derivative financial instruments.

<sup>2</sup> Included in 'assets acquired' are those assets that are expected to be used during more than one period (property, plant and equipment, goodwill and intangible assets).

<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 ar	nd equipment
	2010 \$m	2009 \$m	2008 \$m
UK	1,628	1,901	1,750
Sweden	1,647	1,700	1,722
US	2,381	2,386	2,200

#### **Geographic markets**

**Continuing operations** 

Rest of the world

The table below shows revenue in each geographic market in which customers are located.

	2010 \$m	2009 \$m	2008 \$m
UK	1,033	1,057	994
Continental Europe	9,315	9,286	9,937
The Americas	16,629	17,096	15,945
Asia, Africa & Australasia	6,292	5,365	4,725
Continuing operations	33,269	32,804	31,601

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 (2009: two; 2008: two). The values of these transactions recorded as revenue were \$4,164m and \$4,129m (2009: \$4,319m and \$4,228m; 2008: \$3,936m and \$3,900m).

1,301

6,957

1,320

7,307

1,371

7,043

#### 7 Property, plant and equipment

	Land and	Plant and	Assets in course	Total property, plant and
	buildings	equipment	of construction	equipment
	\$m	\$m	\$m	\$m
Cost				
At 1 January 2008	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
Capital expenditure	13	225	570	808
Transfer of assets into use	342	668	(1,010)	-
Disposals and other movements	(40)	(449)	(4)	(493)
Exchange adjustments	48	46	6	100
At 31 December 2010	5,699	9,293	591	15,583
Depreciation				
At 1 January 2008	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		011		
	44	6	-	50
Disposals and other movements	44 (343)	-	- (4)	50 (1,206)
Disposals and other movements Exchange adjustments		6		
	(343)	6 (859)	(4)	(1,206)
Exchange adjustments	(343) 117	6 (859) 434	(4) 2	(1,206) 553
Exchange adjustments At 31 December 2009	(343) 117 1,967	6 (859) 434 5,899	(4) 2 (5)	(1,206) 553 7,861
Exchange adjustments At 31 December 2009 Charge for year	(343) 117 1,967 <b>302</b>	6 (859) 434 5,899 <b>774</b>	(4) 2 (5) -	(1,206) 553 7,861 <b>1,076</b>
Exchange adjustments At 31 December 2009 Charge for year Impairment	(343) 117 1,967 <b>302</b> <b>2</b>	6 (859) 434 5,899 <b>774</b> 20	(4) 2 (5) -	(1,206) 553 7,861 <b>1,076</b> <b>22</b>
Exchange adjustments At 31 December 2009 Charge for year Impairment Disposals and other movements	(343) 117 1,967 <b>302</b> 2 (29)	6 (859) 434 5,899 774 20 (396)	(4) 2 (5) - - 5	(1,206) 553 7,861 1,076 22 (420)
Exchange adjustments At 31 December 2009 Charge for year Impairment Disposals and other movements Exchange adjustments At 31 December 2010	(343) 117 1,967 <b>302</b> 2 (29) 32	6 (859) 434 5,899 774 20 (396) 55	(4) 2 (5) - - 5 -	(1,206) 553 7,861 <b>1,076</b> <b>22</b> (420) 87
Exchange adjustments At 31 December 2009 Charge for year Impairment Disposals and other movements Exchange adjustments	(343) 117 1,967 <b>302</b> 2 (29) 32	6 (859) 434 5,899 774 20 (396) 55	(4) 2 (5) - - 5 -	(1,206) 553 7,861 1,076 22 (420) 87
Exchange adjustments          At 31 December 2009         Charge for year         Impairment         Disposals and other movements         Exchange adjustments         At 31 December 2010         Net book value	(343) 117 1,967 302 2 (29) 32 2,274	6 (859) 434 5,899 774 20 (396) 55 6,352	(4) 2 (5) - - 5 - -	(1,206) 553 7,861 1,076 22 (420) 87 8,626

Impairment charges in 2010 were due to the termination of the *Certriad* co-promotion with Abbott and various productivity initiatives. These costs were recognised in cost of sales and research and development respectively.

Impairment charges in 2009 were 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.

	2010 \$m	2009 \$m	2008 \$m
The net book value of land and buildings comprised:			
Freeholds	3,425	3,369	3,287

## 8 Goodwill

	2010 \$m	2009 \$m	2008 \$m
Cost			
At 1 January	10,228	10,211	10,225
Additions through business combinations	-	-	-
Exchange adjustments	(22)	17	(14)
At 31 December	10,206	10,228	10,211
Amortisation and impairment losses			
At 1 January	339	337	341
Exchange adjustments	(4)	2	(4)
At 31 December	335	339	337
Net book value at 31 December	9,871	9,889	9,874

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 (7.0% for 2010; 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 10% (11% for 2009; 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 2010 (and 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	Product,		Software	
	marketing and	Other	development	<b>T</b>
	distribution rights \$m	intangibles \$m	costs \$m	Total \$m
Cost	· · · · · · · · · · · · · · · · · · ·			
At 1 January 2008	11,549	2,385	976	14,910
Additions – separately acquired	2,743	20	178	2,941
Disposals	-	(33)	(30)	(63)
Exchange and other 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 and other adjustments	267	84	28	379
At 31 December 2009	14,353	2,304	1,212	17,869
Additions through business combinations	548	-	-	548
Additions – separately acquired	1,017	20	206	1,243
Disposals	(239)	(2)	-	(241)
Exchange and other adjustments	125	13	(19)	119
At 31 December 2010	15,804	2,335	1,399	19,538
Amortisation and impairment losses				
At 1 January 2008	2,373	528	542	3,443
Amortisation for year	529	182	96	807
Impairment	516	91	24	631
Disposals	_	(9)	(10)	(19)
Exchange and other adjustments	(357)	(104)	(36)	(497)
At 31 December 2008	3,061	688	616	4,365
Amortisation for year	481	162	86	729
Impairment	93	273	49	415
Disposals	(67)	-	-	(67)
Exchange and other adjustments	159	25	17	201
At 31 December 2009	3,727	1,148	768	5,643
Amortisation for year	573	121	116	810
Impairment	699	131	3	833
Disposals	-	(1)	-	(1)
Exchange and other adjustments	89	26	(20)	95
At 31 December 2010	5,088	1,425	867	7,380
Net book value				
At 31 December 2008	10,461	1,487	375	12,323
At 31 December 2009	10,626	1,156	444	12,226
At 31 December 2010	10,716	910	532	12,158

Other intangibles consist mainly of licensing and rights to contractual income streams.

Amortisation charges are recognised in profit as follows:

	Product, marketing and distribution rights	Other	Software development costs	Total
	Š\$m	Šm	\$m	\$m
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
Year ended 31 December 2010				
Cost of sales	60	-	-	60
Selling, general and administrative costs	513	22	116	651
Other operating income and expense	-	99	-	99
	573	121	116	810

Overview

#### 9 Intangible assets continued

Impairment charges are recognised in profit as follows:

	Product, marketing and distribution rights \$m	Other intangibles \$m	Software development costs \$m	Total \$m
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
Year ended 31 December 2010				
Cost of sales	128	-	-	128
Research and development	571	-	-	571
Selling, general and administrative costs	-	3	3	6
Other operating income and expense	-	128	-	128
	699	131	3	833

#### Amortisation and impairment charges

The 2010 impairment of product, marketing and distribution rights results from the withdrawal of the biological license application pending at the FDA for motavizumab (\$445m) and the termination of the lesogaberan development (\$128m) and other development projects in the year. The 2010 impairment of other intangibles chiefly results from a reassessment of the future royalties expected to be received relating to the HPV cervical cancer vaccine.

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 of a generic competitor, marketing and observed relating to the HPV cervical cancer vaccine. These impairment of product, marketing and distribution rights results from the termination of projects in development during the year.

The write downs in value of intangible assets, other than those arising from termination of research and development activities, were 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 (7.0% for 2010; 7.6% for 2009; 7.6% for 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% (2009: 14%; 2008: 14%).

# 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	186	3 and 7 years
Advance payment <sup>1</sup>	Product, marketing and distribution rights	490	8 years
Partial retirement <sup>1</sup>	Product, marketing and distribution rights	735	4-17 years
First Option <sup>1</sup>	Product, marketing and distribution rights	1,651	1-13 years
Non-refundable deposit <sup>1</sup>	Product, marketing and distribution rights	474	Not amortised
Intangible assets arising from the acquisition of CAT <sup>2</sup>	Product, marketing and distribution rights	363	5 and 10 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	Product, marketing and distribution rights	4,174	15 years
Intangible assets arising from the acquisition of MedImmune	Licensing and contractual income	522	1-9 years
Intangible assets arising from the acquisition of MedImmune	Product, marketing and distribution rights	603	21 years
Intangible assets arising from the collaboration with BMS <sup>3</sup>	Product, marketing and distribution rights	419	12-13 years
Intangible assets arising from the acquisition of Novexel <sup>2</sup>	Product, marketing and distribution rights	302	Not amortised
Intangible assets arising from the collaboration with Pozen <sup>4</sup>	Product, marketing and distribution rights	213	13 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> These assets arise from the collaboration agreement with BMS for Onglyza<sup>™</sup> and dapagliflozin.
<sup>4</sup> These assets arise from the collaboration agreement with Pozen for Vimovo.

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#### **10 Other investments**

	2010 \$m	2009 \$m	2008 \$m
Non-current investments			
Equity securities available for sale	211	184	156
	211	184	156
Current investments			
Equity securities and bonds available for sale	355	-	-
Equity securities held for trading	20	18	51
Fixed deposits	1,107	1,466	54
	1,482	1,484	105

The equity securities and bonds available for sale in current investments of \$355m are held in an escrow account. Further details of this escrow account are included in Note 18.

Fixed deposits relate to investments in US Treasury bills and commercial paper with a maturity of greater than 90 days at inception.

Impairment charges of \$2m in respect of available for sale securities are included in other operating income and expense in profit (2009: \$18m; 2008: \$25m).

## **11 Inventories**

	2010 \$m	2009 \$m	2008 \$m
Raw materials and consumables	539	445	409
Inventories in process	665	726	631
Finished goods and goods for resale	478	579	596
	1,682	1,750	1,636

Inventory write-offs in the year amounted to \$69m (2009: \$83m; 2008: \$51m).

#### 12 Trade and other receivables

	2010 \$m	2009 \$m	2008 \$m
Amounts due within one vear			<u>+</u>
Trade receivables	6,328	5,863	5,657
Less: Amounts provided for doubtful debts (Note 23)	(81)	(81)	(99)
	6,247	5,782	5,558
Other receivables	607	1,170	978
Prepayments and accrued income	733	580	552
	7,587	7,532	7,088
Amounts due after more than one year			
Other receivables	64	27	44
Prepayments and accrued income	196	150	129
	260	177	173
Trade and other receivables	7,847	7,709	7,261
		· · · · · · · · · · · · · · · · · · ·	·

# 13 Cash and cash equivalents

	2010 \$m	2009 \$m	2008 \$m
Cash at bank and in hand	1,750	1,077	1,039
Short-term deposits	9,318	8,841	3,247
Cash and cash equivalents	11,068	9,918	4,286
Unsecured bank overdrafts	(87)	(90)	(163)
Cash and cash equivalents in the cash flow statement	10,981	9,828	4,123

The Group's insurance subsidiaries hold cash and cash equivalents totalling \$415m (2009: \$173m; 2008: \$400m), of which \$370m (2009: \$49m; 2008: \$278m) 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 dates	2010 \$m	2009 \$m	2008 \$m
	On demand	87	90	163
US dollars	2009	-	-	650
Euros	2010	-	1,073	-
Euros	2010	-	717	-
	Within one year	38	46	180
		125	1,926	993
Euros	2010	-	-	1,053
Euros	2010	-	-	702
US dollars	2012	1,800	1,805	1,823
US dollars	2014	837	821	789
Euros	2015	993	1,072	1,051
US dollars	2017	1,855	1,818	1,896
US dollars	2023	359	346	324
Pounds sterling	2031	535	558	501
US dollars	2037	2,718	2,717	2,716
		9,097	9,137	10,855
	Euros Euros Euros Euros US dollars US dollars Euros US dollars US dollars US dollars Pounds sterling	datesOn demandUS dollars2009Euros2010Euros2010Within one yearEuros2010US dollars2010US dollars2012US dollars2014Euros2015US dollars2017US dollars2023Pounds sterling2031	dates         \$m           On demand         87           US dollars         2009         -           Euros         2010         -           Euros         2010         -           Within one year         38           Euros         2010         -           US dollars         2010         -           Euros         2010         -           Euros         2010         -           Euros         2010         -           US dollars         2010         -           US dollars         2010         -           US dollars         2010         -           US dollars         2011         1,800           US dollars         2012         1,800           US dollars         2014         837           US dollars         2017         1,855           US dollars         2017         1,855           US dollars         2023         359           Pounds sterling         2031         535           US dollars         2037         2,718	dates         \$m           On demand         87         90           US dollars         2009         -         -           Euros         2010         -         1,073           Euros         2010         -         717           Within one year         38         46           125         1,926         -           Euros         2010         -         -           US dollars         2010         -         -           US dollars         2012         1,800         1,805           US dollars         2012         1,800         1,805           US dollars         2015         993         1,072           US dollars         2017         1,855         1,818           US dollars         2023         359         346           Pounds sterling         2031         535         558           US dollars         2037         2,718         2,717

All loans and borrowings above are unsecured.

# **15 Financial instruments**

# **Derivative financial instruments**

Set out below is a summary of the derivative financial instruments included in the consolidated statement of financial position at 31 December 2010, 31 December 2009 and 31 December 2008.

	Non-current assets \$m	Current assets \$m	Current liabilities \$m	Non-current liabilities \$m	Total \$m
Designated in a fair value hedge	164	_	-	-	164
Related to instruments designated at fair value through profit or loss	160	-	-	-	160
Other derivatives	-	9	(8)	-	1
31 December 2010	324	9	(8)	-	325
	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 \$m	Current assets \$m	Current liabilities \$m	Non-current liabilities \$m	Total \$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

# 15 Financial instruments continued

#### 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 2010, 31 December 2009 and 31 December 2008. None of the financial assets or financial liabilities have been reclassified during the year.

	Instruments in a hedge relationship <sup>1</sup> \$m	Instruments designated at fair value <sup>2</sup> \$m	Other financial instruments at fair value <sup>3</sup> \$m	Available for sale \$m	Held for trading \$m	Amortised cost \$m	Total carrying value \$m	Fair value \$m
2010								
Cash and cash equivalents	-	-	-	-	-	11,068	11,068	11,068
Overdrafts	-	-	-	-	-	(87)	(87)	(87)
Loans due within one year	-	-	-	-	-	(38)	(38)	(38)
Loans due after more than one year	(1,659)	(1,196)	-	-	-	(6,242)	(9,097)	(10,022)
Derivative financial instruments	164	160	1	-	-	-	325	325
Other investments	-	-	-	566	20	1,107	1,693	1,693
Other financial assets	-	-	25	-	-	6,893	6,918	6,918
Other financial liabilities	-	-	(50)	-	_	(8,963)	(9,013)	(9,013)
2009								
Cash and cash equivalents	-	-	-	-	-	9,918	9,918	9,918
Overdrafts	-	-	-	-	-	(90	(9Ø)	(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)

<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> Includes derivatives not designated in hedge relationships or related to financial instruments designated at fair value through profit or loss, and contingent consideration arising on business combinations (Note 22).

Other financial assets represent trade and other receivables (Note 12) excluding prepayments and accrued income. Other financial liabilities represent trade and other payables (Note 16) excluding deferred income.

Credit risk increased the fair value of the bonds designated as fair value through profit or loss by \$5m for the year and increased the fair value by \$40m since designation. Changes in credit risk had no material effect on any other financial assets and liabilities recognised at fair value in the Group's 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 amount payable at maturity on bonds designated at fair value through profit or loss is \$1,037m.

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 consolidated 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) and forward foreign exchange 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.
- > Other investments held on the consolidated statement of financial position at fair value. These include equity securities held on the consolidated statement of financial position as other investments (Note 10). The fair value of listed investments is based on year end quoted market prices. Unlisted investments are held at cost which approximates to fair value.
- > Other financial assets and other financial liabilities with the exception of contingent consideration which is held at fair value (see Note 22), other financial assets and liabilities are held on the consolidated statement of financial position at amortised costs with carrying value being a reasonable approximation of fair value.

#### 15 Financial instruments continued

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:

	2010	2009	2008
Derivatives	0.7% to 4.0%	2.0% to 4.6%	3.8% to 4.6%
Loans and borrowings	0.7% to 4.0%	2.0% to 4.6%	3.8% to 4.6%

#### 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 2010				
Equity securities and bonds available for sale	399	-	167	566
Equity securities held for trading	20	-	-	20
Derivative assets	-	333	_	333
Other financial assets	-	_	25	25
Assets	419	333	192	944
Borrowing designated at fair value through profit or loss	(1,196)	_	_	(1,196)
Derivative liabilities	-	(8)	-	(8)
Other financial liabilities	-	_	(50)	(50)
Liabilities	(1,196)	(8)	(50)	(1,254)
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. These unlisted investments are held at cost, adjusted as necessary for impairments, which approximates to fair value. Hence, carrying value is adjusted only for additions, sales and permanent impairment and for no other movement. Consequently, in the current year, no change has been made to the fair value of individual investments. Level 3 other financial assets and liabilities arose on the acquisition of Novexel and the subsequent transaction with Forest as detailed in Note 22.

#### Net gains and losses on financial assets and financial liabilities

	2010 \$m	2009 \$m	2008 \$m
Included in operating profit	÷	2	
Gains/(losses) on forward foreign exchange contracts	29	114	(399)
(Losses)/gains on receivables and payables	(80)	(141)	391
Losses on available for sale current investments	(2)	(18)	(25)
	(53)	(45)	(33)
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	(5)	(169)	87
Interest and changes in carrying values of debt designated as hedged items, net of derivatives	(18)	(35)	(64)
Interest and fair value changes on fixed and short-term deposits and equity securities	61	43	140
Interest on debt, overdrafts and commercial paper held at amortised cost	(452)	(501)	(609)
Exchange (losses)/gains on financial assets and liabilities	(11)	31	(12)
	(425)	(631)	(458)
Included in other comprehensive income			
Foreign exchange differences on borrowings forming net investment hedges	101	(68)	291
Amortisation of loss on cash flow hedge through profit	1	1	1
Available for sale (losses)/gains taken to equity	4	2	2
	106	(65)	294

#### 15 Financial instruments continued

\$29m fair value gains (2009: \$95m fair value losses) on interest rate fair value hedging instruments and \$29m fair value losses (2009: \$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 Group Accounting Policies.

\$33m fair value gains (2009: \$94m fair value losses) on derivatives related to debt instruments designated at fair value through profit or loss and \$28m fair value losses (2009: \$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 Group Accounting Policies section from page 142. The amortisation of loss on cash flow hedge through profit included in other comprehensive income relates to a loss on a cash flow hedge of a prospective debt issue which was taken directly to reserves in 2007 and 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 (2009: \$nil; 2008: \$nil). The accounting treatment for net investment hedges is disclosed in the Group Accounting Policies section from page 142.

#### **16 Trade and other payables**

	2010 \$m	2009 \$m	2008 \$m
Current liabilities		·`	
Trade payables	2,257	2,316	1,940
Value added and payroll taxes and social security	323	342	371
Rebates and chargebacks	2,839	2,618	1,963
Other payables	945	1,038	1,026
Accruals	2,297	2,373	1,878
	8,661	8,687	7,178
Non-current liabilities			
Other payables	373	244	149

Included in other payables are amounts totalling \$259m (2009: \$259m; 2008: \$227m) to meet insurance obligations of the Group's insurance subsidiaries. These amounts are net of intra-group set-off.

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#### 17 Provisions for liabilities and charges

			Employee		Other	
	Severance	Environmental	benefits	Legal	provisions	Total
	\$m	\$m	\$m	\$m	\$m	\$m
At 1 January 2008	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
Charge for year	497	48	11	617	188	1,361
Cash paid	(335)	(43)	-	(709)	(22)	(1,109)
Reversals	(26)	-	-	(1)	(22)	(49)
Exchange and other movements	12	2	2	17	7	49
At 31 December 2010	659	119	127	562	471	1,938
				2010 \$m	2009 \$m	2008 \$m
Due within one year	-			1,095	1,209	600
Due after more than one year				843	477	542
	-			1,938	1,686	1,142

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.

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.

# 18 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 AstraZeneca's 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 AstraZeneca and appropriate fiduciaries specifically with reference to AstraZeneca's credit rating, market capitalisation, cash flows and the solvency of the relevant pension scheme.

#### **Financing Principles**

96.5% of the Group's defined benefit obligations at 31 December 2010 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 while 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. The Group believes in taking some rewarded risks with the investments underlying the funding, subject to a medium to long-term plan to reduce those risks if opportunities arise.
- > 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 shortterm 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.

AstraZeneca 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, liability valuations 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, AstraZeneca 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 AstraZeneca and Trustee agreeing on 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 (\$65m) 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 in the region of £42m per annum to the escrow and £132m per annum to the fund. This includes the contributions required to meet the benefits accruing in the region of £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. At 31 December 2010, £230m (\$355m) escrow fund assets are included within other investments (see Note 10).

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% per annum, salary increases at 3.5% per annum, pension increases at 3.5% per annum and investment returns at 7.1% per annum (pre-retirement) and 5.96% per annum (post-retirement).

During the first half of 2010, AstraZeneca consulted with its UK employees' representatives on proposals to freeze pensionable pay at 30 June 2010 levels for defined benefit members of the UK pension fund. The defined benefit fund remains open to existing members and employees who choose to leave the defined benefit fund will retain a deferred pension in addition to being offered membership in a new Group Self Invested Personal Pension Plan.

The amendment to the UK defined benefit fund to freeze pensionable pay at 30 June 2010 levels represents an accounting curtailment of certain pension obligations. The majority of members opted to remain in the defined benefit fund and continue benefit accrual with frozen pensionable pay. In accordance with IAS 19, the scheme obligations were revalued by the scheme actuaries immediately prior to the change and assumptions reviewed at that date. The resulting credit of \$693m has been recognised in comprehensive income during the year.

In July 2010, the UK government announced changes to the inflation index used for statutory pension increases (both for pensions in payment and pensions in deferment) to apply to private sector pension schemes. This has resulted in a small actuarial gain during the period in respect of the AstraZeneca Pension Fund.

# 18 Post-retirement benefits continued

#### Rest of Group

The IAS 19 positions as at 31 December 2010 are shown below for each of the other countries with significant defined benefit plans. These plans account for 90% of the Group's defined benefit obligations outside of the UK. 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 2010, when plan obligations were \$1,757m and plan assets were \$1,525m. 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 2010, when plan obligations were estimated to amount to \$1,338m and plan assets were \$809m.
- > The German defined benefits programme was actuarially revalued at 31 December 2010, when plan obligations amounted to \$241m and plan assets were \$25m.

On current bases, it is expected that contributions (excluding those in respect of past service cost) during the year ended 31 December 2011 to the four main countries will be \$342m.

#### 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 2010, some 3,973 retired employees and covered dependants currently benefit from these provisions and some 11,267 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 2010 was \$18m (2009: \$19m; 2008: \$21m). Plan assets were \$272m and plan obligations were \$310m at 31 December 2010. 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 2010. 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:

		2010		2009	
	UK	Rest of Group	UK	Rest of Group	
Inflation assumption	3.6%	2.3%	3.5%	2.3%	
Rate of increase in salaries	1_	3.4%	4.5%	3.4%	
Rate of increase in pensions in payment	3.5%	0.9%	3.5%	0.9%	
Discount rate	5.5%	4.9%	5.5%	5.0%	
Long-term rate of return expected at 31 December					
Equities	8.0%	7.9%	8.0%	8.1%	
Bonds	5.1%	5.0%	5.5%	5.2%	
Others	6.1%	4.7%	6.5%	4.8%	
Rate of increase in medical costs (initial rate)	10.0%	10.0%	10.0%	10.0%	

<sup>1</sup> Pensionable pay frozen at 30 June 2010 levels following UK fund changes.

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 2010 and members expected to retire in 2030.

Country	Life expecta	Life expectancy assumption for a male member retiring at age 65			
	2010	2030	2009	2029	
UK	22.7	24.6	23.8	25.8	
US	19.8	21.3	19.6	21.1	
Sweden	20.4	22.4	20.4	22.4	
Germany	17.9	20.7	17.7	20.5	

# 18 Post-retirement benefits continued

# Post-retirement scheme deficit

The assets and obligations of the defined benefit schemes operated by the Group at 31 December 2010, as calculated in accordance with IAS 19 'Employee Benefits' 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.

			2010			2009
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Scheme assets						
Equities	2,437	1,153	3,590	2,309	1,241	3,550
Bonds	2,660	1,124	3,784	2,279	903	3,182
Others	52	341	393	265	258	523
Total fair value of scheme assets	5,149	2,618	7,767	4,853	2,402	7,255
Present value of scheme obligations	(6,554)	(3,691)	(10,245)	(7,055)	(3,591)	(10,646)
Past service cost not yet recognised	-	6	6	-	37	37
Deficit in the scheme as recognised						
in the statement of financial position	(1,405)	(1,067)	(2,472)	(2,202)	(1,152)	(3,354)

## Fair value of scheme assets

			2010			2009
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
At beginning of year	4,853	2,402	7,255	3,835	2,013	5,848
Expected return on scheme assets	305	146	451	261	127	388
Expenses	(7)	-	(7)	(6)	-	(6)
Actuarial gains/(losses)	244	(4)	240	293	180	473
Exchange	(204)	(4)	(208)	430	17	447
Employer contributions	224	245	469	304	262	566
Participant contributions	28	3	31	31	3	34
Benefits paid	(294)	(170)	(464)	(295)	(200)	(495)
Scheme assets fair value at end of year	5,149	2,618	7,767	4,853	2,402	7,255

The actual return on the plan assets was a gain of \$691m (2009: gain of \$861m).

# Movement in post-retirement scheme obligations

			2010			2009
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Present value of obligation in scheme at beginning of year	(7,055)	(3,591)	(10,646)	(5,029)	(3,591)	(8,620)
Current service cost	(97)	(114)	(211)	(96)	(126)	(222)
Past service (cost)/credit	(39)	106	67	(53)	(21)	(74)
Participant contributions	(28)	(3)	(31)	(31)	(3)	(34)
Benefits paid	294	170	464	295	200	495
Other finance expense	(371)	(172)	(543)	(330)	(163)	(493)
Expenses	7	-	7	6	-	6
Actuarial (loss)/gain	(221)	(65)	(286)	(1,218)	176	(1,042)
Settlements and curtailments	693	6	699	-	-	-
Exchange	263	(28)	235	(599)	(63)	(662)
Present value of obligations in scheme at end of year	(6,554)	(3,691)	(10,245)	(7,055)	(3,591)	(10,646)

The obligation arises from the following plans:

		2010		2009	
	UK \$m	Rest of Group \$m	UK \$m	Rest of Group \$m	
Funded	(6,526)	(3,232)	(7,026)	(3,159)	
Unfunded	(28)	(459)	(29)	(432)	
Total	(6,554)	(3,691)	(7,055)	(3,591)	

#### 18 Post-retirement benefits continued

# **Consolidated 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 2010, are set out below:

			2010			2009
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Operating profit						
Current service cost	(97)	(114)	(211)	(96)	(126)	(222)
Past service (cost)/credit	(39)	75	36	(53)	(24)	(77)
Settlements and curtailments	693	6	699	_	-	-
Total charge to operating profit	557	(33)	524	(149)	(150)	(299)
Finance expense						
Expected return on post-retirement scheme assets	305	146	451	261	127	388
Interest on post-retirement scheme obligations	(371)	(172)	(543)	(330)	(163)	(493)
Net return	(66)	(26)	(92)	(69)	(36)	(105)
Charge before taxation	491	(59)	432	(218)	(186)	(404)
Other comprehensive income						
Difference between the actual return and the expected return on the post-retirement scheme assets	244	(4)	240	293	180	473
Experience (losses)/gains arising on the post-retirement scheme obligations	(81)	5	(76)	105	(67)	38
Changes in assumptions underlying the present value of the post-retirement scheme obligations	(140)	(70)	(210)	(1,323)	243	(1,080)
Actuarial gains/(losses) recognised	23	(69)	(46)	(925)	356	(569)

Included in total assets and obligations for the UK is \$424m 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 \$228m (2009: \$234m).

#### Actuarial gains and losses 2010 2009 2008 2007 2006 UΚ Present value of obligations (\$m) (7,055) (7,352) (6, 554)(5,029) (7,644)Fair value of scheme assets (\$m) 5,149 4,853 3,835 6,310 6,078 Deficit in the scheme (\$m) (1,405) (2,202) (1,194) (1,334) (1,274) Experience adjustments on: Scheme assets Amount (\$m) 244 293 (1,185) (185) (259) Percentage of scheme assets 4.7% 6.0% 30.9% 2.9% 4.3% Scheme obligations (1,218) 972 71 (221)114 Amount (\$m) 19.3% Percentage of scheme obligations 3.4% 17.3% 1.5% 1.0% **Rest of Group** Present value of obligations (\$m) (3,691) (3,591) (3,591) (3,348) (3,109) 2,644 Fair value of scheme assets (\$m) 2,618 2,402 2,013 2,493 Deficit in the scheme (\$m) (1,073) (1, 189)(1,578) (704) (616) Experience adjustments on: Scheme assets Amount (\$m) 180 (700) 55 (4) (24) Percentage of scheme assets 0.2% 7.5% 34.8% 0.9% 2.2% Scheme obligations Amount (\$m) (65) 176 (319) (18) 25 Percentage of scheme obligations 1.8% 4.9% 8.9% 0.5% 0.8% Total Present value of obligations (\$m) (10, 245)(10,646) (8,620) (10, 992)(10,461) Fair value of scheme assets (\$m) 7,767 7,255 5,848 8,954 8,571 Deficit in the scheme (\$m) (2,478) (3,391) (2,772) (2,038) (1,890) Experience adjustments on: Scheme assets Amount (\$m) 240 473 (1,885) (209) (204) Percentage of scheme assets 6.5% 32.2% 2.3% 2.4% 3.1% Scheme obligations Amount (\$m) (286) (1,042) 653 96 96 Percentage of scheme obligations 2.8% 9.8% 7.6% 0.9% 0.9%

# 18 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 \$5m and the amount outstanding at 31 December 2010 was \$5m.

#### Reserves

Included within the retained earnings reserve is the actuarial reserve. Movements on this reserve are as follows:

	2010 \$m	2009 \$m	2008 \$m
At 1 January	(1,800)	(1,371)	(479)
Actuarial losses	(46)	(569)	(1,232)
Deferred tax	(19)	140	340
At 31 December	(1,865)	(1,800)	(1,371)

The cumulative amount of actuarial losses before deferred tax recognised in other comprehensive income is \$2,482m (2009: \$2,436m; 2008: \$1,867m).

# Discount rate sensitivity

The following table shows the US dollar effect of a 1% change in the discount rate on the retirement benefits obligations in our four main defined pension obligation benefit countries.

	2010	200		
+1%	-1%	+1%	-1%	
937	(1,093)	973	(1,129)	
203	(232)	225	(256)	
222	(293)	192	(229)	
37	(44)	35	(42)	
1,399	(1,662)	1,425	(1,656)	
	937 203 222 37	937         (1,093)           203         (232)           222         (293)           37         (44)	+1%         -1%         +1%           937         (1,093)         973           203         (232)         225           222         (293)         192           37         (44)         35	

# Sensitivity of medical cost assumptions

	Effect of change in medical cost assumption increase/(decrease)				
	2010		200		
	+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)	10	(11)	32	(28)	

#### **19 Capital and reserves**

	2010 \$m	2009 \$m	2008 \$m
Cumulative translation differences included within retained earnings			
Balance at beginning of year	1,656	1,323	2,414
Foreign exchange arising on consolidation	26	388	(1,355)
Exchange adjustments on goodwill (recorded against other reserves)	15	13	(27)
Foreign exchange differences on borrowings forming net investment hedges	101	(68)	291
Net exchange movement in retained earnings	142	333	(1,091)
Balance at end of year	1,798	1,656	1,323

#### **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 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 \$682m (2009: \$667m; 2008: \$654m) using year end rates of exchange. At 31 December 2010, 57,717 shares, at a cost of \$3m, have been deducted from retained earnings (2009: 24,178 shares, at a cost of \$1m; 2008: 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

		Allotted, called-up and fu		
	2010 \$m	2009 \$m	2008 \$m	
Issued Ordinary Shares (\$0.25 each)	352	363	362	
Redeemable Preference Shares (£1 each – £50,000)	-	-	-	
	352	363	362	

At 31 December 2010, 1,409,023,452 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)
	2010	2009
At 1 January	1,451	1,447
Issues of shares	12	4
Repurchase of shares	(54)	-
At 31 December	1,409	1,451

#### Share repurchases

During the year, the Company repurchased 53,691,507 Ordinary Shares at an average price of 3111 pence per share (2009: nil; 2008: 13,597,940 Ordinary Shares at an average price of 2397 pence per share).

#### Share schemes

A total of 11,756,397 Ordinary Shares were issued during the year in respect of share schemes (2009: 3,477,014 Ordinary Shares; 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 119.

#### Shares held by subsidiaries

No shares in the Company were held by subsidiaries in any year.

# **21 Dividends to shareholders**

	2010	2009	2008	2010	2009	2008
	Per share	Per share	Per share	\$m	\$m	\$m
Final	\$1.710	\$1.500	\$1.350	2,484	2,171	1,967
Interim	\$0.700	\$0.590	\$0.550	1,010	855	800
	\$2.410	\$2.090	\$1.900	3,494	3,026	2,767

The second interim dividend, to be confirmed as final, is \$1.85 per Ordinary Share and \$2,607m in total. This will be payable on 14 March 2011.

On payment of the dividends, exchange gains of \$19m (2009: gains of \$17m; 2008: gains of \$28m) arose. These exchange gains are included in Note 3.

# 22 Acquisitions of business operations

#### Novexel

On 3 March 2010, AstraZeneca completed the acquisition of Novexel S.A. Novexel is a research company focused on the infection therapy area and is based in France. This acquisition strengthens our research capabilities in the infection therapy area. AstraZeneca acquired one hundred percent of Novexel's shares for an upfront consideration of \$427m. Additional consideration of up to \$75m will become payable to Novexel shareholders on the completion of certain development milestones. At both the date of acquisition and at 31 December 2010, the fair value of this contingent consideration was \$50m. For both the period since acquisition and the full year, Novexel had no revenues and its loss was immaterial.

	Book value \$m	Fair value adjustment \$m	Fair value \$m
Non-current assets	1	548	549
Current assets	89	-	89
Current liabilities	(18)	-	(18)
Non-current liabilities	(85)	(58)	(143)
Total assets acquired	(13)	490	477
Goodwill			-
Fair value of total consideration			477
Less: fair value of contingent consideration			(50)
Total upfront consideration			427

#### 22 Acquisitions of business operations continued

Subsequent to the completion of the acquisition of Novexel, AstraZeneca entered into a collaboration with Forest on the future co-development and commercialisation of two late-stage antibiotic development programmes acquired with Novexel: ceftazidime/NXL-104 (CAZ-104) and ceftaroline/NXL-104 (CEF-104). These antibiotic combinations utilise Novexel's novel investigational beta-lactamase inhibitor NXL-104 to overcome antibiotic resistance and treat the increasing number of infections resistant to existing therapies. In addition, Forest acquired rights to CAZ-104 in North America and bought down payment obligations to Novexel in relation to CEF-104 from previous existing licence arrangements. In consideration for these rights, Forest paid Novexel, then an AstraZeneca group company, a sum of \$210m on 3 March 2010 and will also pay additional sums equivalent to half of any future specified development milestone payments that become payable by AstraZeneca. This consideration is equivalent to the fair value attributed on acquisition to those assets and hence there is no profit impact from this divestment.

#### **Cash flows**

	\$m
Total upfront consideration	427
Cash and cash equivalents included in undertaking acquired	(79)
Net cash consideration	348

#### **Prior period aquisitions**

There were no acquisitions made during either the year ended 31 December 2009 or the year ended 31 December 2008.

#### 23 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 repurchase component. The Board regularly reviews its shareholders' return strategy, and in 2010 adopted a progressive dividend policy, whereby the Board intends to maintain or grow the dividend each year, targeting an average dividend cover of two 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 repurchases.

The Group's net funds position (loans and borrowings net of cash and cash equivalents, current investments and derivative financial instruments) has increased from \$535m at the beginning of the year to a net funds position of \$3,653m at 31 December 2010 as a result of strong net operating cash inflows.

#### 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 flows. 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. 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.

#### 23 Financial risk management objectives and policies continued

In addition to cash and cash equivalents of \$11,068m, fixed deposits of \$1,107m less overdrafts of \$87m at 31 December 2010, the Group has committed bank facilities of \$4.25bn available to manage liquidity. At 31 December 2010, the Group has issued \$1,528m under a Euro Medium Term Note programme and \$7,569m under a SEC-registered programme. The Group 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 2011 and were undrawn at 31 December 2010.

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:

	Bank overdrafts and other Ioans \$m	Bonds \$m	Trade and other payables \$m	Total non-derivative financial instruments \$m	Interest rate swaps \$m	Currency swaps \$m	Total derivative financial instruments \$m	Total \$m
Within one year	128	518	8,640	9,286	(120)	-	(120)	9,166
In one to two years	-	2,268	373	2,641	(121)	-	(121)	2,520
In two to three years	-	423	-	423	(87)	-	(87)	336
In three to four years	-	1,153	-	1,153	(69)	-	(69)	1,084
In four to five years	-	1,379	-	1,379	(50)	-	(50)	1,329
In more than five years	-	10,095	-	10,095	(192)	-	(192)	9,903
	128	15,836	9,013	24,977	(639)	-	(639)	24,338
Effect of interest	(3)	(7,012)	-	(7,015)	639	-	639	(6,376)
Effect of discounting, fair values and issue costs	-	273	-	273	(324)	-	(324)	(51)
31 December 2010	125	9,097	9,013	18,235	(324)	-	(324)	17,911

	Bank overdrafts and other loans \$m	Bonds \$m	Trade and other payables \$m	Total non-derivative financial instruments \$m	Interest rate swaps \$m	Currency swaps \$m	Total derivative financial instruments \$m	Total \$m
Within one year	139	2,373	8,687	11,199	(117)	89	(28)	11,171
In one to two years	-	523	185	708	(117)	-	(117)	591
In two to three years	-	2,246	-	2,246	(116)	-	(116)	2,130
In three to four years	-	429	-	429	(86)	-	(86)	343
In four to five years	-	405	-	405	(64)	-	(64)	341
In more than five years	-	12,209	-	12,209	(239)	-	(239)	11,970
	139	18,185	8,872	27,196	(739)	89	(650)	26,546
Effect of interest	(3)	(7,467)	-	(7,470)	739	-	739	(6,731)
Effect of discounting, fair values and issue costs	-	209	-	209	(262)	1	(261)	(52)
31 December 2009	136	10,927	8,872	19,935	(262)	90	(172)	19,763

	Bank overdrafts and other loans \$m	Bonds \$m	Trade and other payables \$m	Total non-derivative financial instruments \$m	Interest rate swaps \$m	Currency swaps \$m	Total derivative financial instruments \$m	Total \$m
Within one year	345	1,271	7,178	8,794	(60)	-	(60)	8,734
In one to two years	-	2,335	61	2,396	(60)	66	6	2,402
In two to three years	-	465	-	465	(59)	-	(59)	406
In three to four years	-	2,241	-	2,241	(59)	-	(59)	2,182
In four to five years	-	424	-	424	(46)	-	(46)	378
In more than five years	-	12,478	-	12,478	(163)	-	(163)	12,315
	345	19,214	7,239	26,798	(447)	66	(381)	26,417
Effect of interest	(2)	(7,956)	-	(7,958)	447	-	447	(7,511)
Effect of discounting, fair values and issue costs	-	247	-	247	(449)	5	(444)	(197)
31 December 2008	343	11,505	7,239	19,087	(449)	71	(378)	18,709

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.

It is not expected that the cash flows in the maturity profile could occur significantly earlier or at significantly different amounts.

#### 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.

#### 23 Financial risk management objectives and policies continued

At 31 December 2010, 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 2010. At 31 December 2010 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 Group Accounting Policies section from page 142.

The majority of the Group's cash balances are held with third party fund managers with floating rates of interest being earned.

The interest rate profile of the Group's interest-bearing financial instruments, as at 31 December 2010, 31 December 2009 and 31 December 2008 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.

			2010			2009			2008
	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	125	-	125	1,926	1,790	136	993	-	993
Non-current	9,097	6,242	2,855	9,137	6,340	2,797	10,855	8,015	2,840
	9,222	6,242	2,980	11,063	8,130	2,933	11,848	8,015	3,833
Financial assets									
Fixed deposits	1,107	-	1,107	1,466	-	1,466	54	-	54
Cash and cash equivalents	11,068	-	11,068	9,918	-	9,918	4,286	_	4,286
	12,175	-	12,175	11,384	-	11,384	4,340	-	4,340

In addition to the financial assets above, there are \$7,829m (2009: \$7,376m; 2008: \$7,070m) of other current and non-current asset investments and other financial assets on which no interest is received.

#### 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 58% of Group external sales in 2010 were denominated in currencies other than the US dollar, while a significant proportion of manufacturing and research and development costs were denominated in pounds 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 (SEK), pounds sterling (GBP), euro (EUR), Australian dollar (AUD), Canadian dollar (CAD) and Japanese yen (JPY). 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. As at 31 December 2010, 5.8% of interest-bearing loans and borrowings were denominated in pounds sterling and 10.8% of interest-bearing loans and borrowings were denominated in euros. Exchange differences on the retranslation of debt designated 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

One hundred percent 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. In addition, the Group's external dividend, which is paid principally in pounds 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.

#### 23 Financial risk management objectives and policies continued

The table below sets out the principal foreign exchange contracts outstanding at 31 December 2010, 31 December 2009 and 31 December 2008 along with the underlying gross exposure as defined above.

2010	GBP <sup>1</sup> \$m	SEK \$m	EUR \$m	AUD \$m	JPY \$m	CAD \$m
Gross exposure	732	(806)	478	117	133	33
Forward exchange contracts	(38)	806	(478)	(117)	(133)	(33)
Net exposure	694	_	_	_	-	-
2009						
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

<sup>1</sup> The sterling hedge position was updated in early January 2011.

#### 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 2010, with all other variables held constant. Based on the composition of our long-term debt portfolio as at 31 December 2010, a 1% increase in interest rates would result in an additional \$30m 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 2010, 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 2010

		Interest rates	1	Exchange rates
	+1%	-1%	+10%	-10%
Increase/(decrease) in fair value of financial instruments	595	(684)	36	(36)
Impact on profit: gain/(loss)	-	-	(133)	133
Impact on equity: gain/(loss)	-	-	169	(169)

# 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)

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 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.

# 23 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 at the reporting date by geographic region was:

	2010 \$m	2009 \$m	2008 \$m
US	2,168	2,229	2,032
UK	530	482	459
Sweden	285	245	226
Euro zone countries	878	762	833
Other European countries	290	295	257
Japan	1,091	950	955
Other countries	1,005	819	796
	6,247	5,782	5,558

In the US, sales to three wholesalers accounted for approximately 73% of US sales (2009: three wholesalers accounted for approximately 81%; 2008: three wholesalers accounted for approximately 81%).

The ageing of trade receivables at the reporting date was:

	2010 \$m	2009 \$m	2008 \$m
Not past due	5,953	5,542	5,262
Overdue but renegotiated	-	-	3
Past due 0-90 days	104	65	106
Past due 90-180 days	67	75	60
Past due > 180 days	123	100	127
	6,247	5,782	5,558
	2010 \$m	2009 \$m	2008 \$m
Movements in provisions for trade receivables			
Balance at beginning of year	81	99	89
Income statement (credit)/charge	(1)	(20)	23
Amounts utilised, exchange and other movements	1	2	(13)
Balance at end of year	81	81	99

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.

# 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 through 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 AAA-rated liquidity funds, US Treasury bills and short-term bank deposits.

The most significant concentration of financial credit risk at 31 December 2010 was \$8,721m invested in three AAA-rated liquidity funds and \$949m invested in US Treasury bills. The liquidity fund portfolios are managed by the related external third party fund managers to maintain the AAA rating. No more than 10% of fund value is invested within each individual fund. US Treasury bills 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. The Group has 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 2010 was \$13m.

The carrying amount of financial assets, being cash and cash equivalents, derivative assets, other investments and other receivables represents the maximum credit exposure.

## 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.

	2010	2009	2008
Employees			
UK	10,100	10,600	11,000
Continental Europe	20,100	21,200	23,100
The Americas	18,300	19,800	20,900
Asia, Africa & Australasia	13,200	12,300	11,100
Continuing operations	61,700	63,900	66,100

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 2010 was 61,100 (2009: 62,700; 2008: 65,000).

The costs incurred during the year in respect of these employees were:

	2010 \$m	2009 \$m	2008 \$m
Salaries	4,837	4,713	5,080
Social security costs	693	644	743
Pension costs	501 <sup>1</sup>	516	497
Other employment costs	408	560	596
	6,439	6,433	6,916

<sup>1</sup> Pension costs excludes gains of \$791m arising from changes made to benefits under certain of the Group's post-retirement benefit plans.

Severance costs of \$531m are not included above (2009: \$285m; 2008: \$546m).

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 in respect of performance during 2010 will be paid in cash. Bonuses in respect of 2009 and earlier years were paid partly in the form of Ordinary Shares in the Company (under the HM 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, 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. In 2010, the Company introduced a Matching Share element in respect of Partnership Shares, the first award of which will be made in 2011. At the Company's AGM in 2002, shareholders approved the issue of new shares for the purposes of the All-Employee Share Plan.

# 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 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.

**Business Review** 

#### 24 Employee costs and share option plans for employees continued

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 is also one senior staff long-term incentive scheme, under which approximately 60 participants may be eligible for awards granted as AstraZeneca ADSs. AstraZeneca ADSs necessary to satisfy the awards are purchased in the market or funded via a share trust. The AstraZeneca Performance Share Plan and the AstraZeneca Global Restricted Stock 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 2010 under the plan was in March, with further smaller grants in May, August and November. Awards granted under the plan vest after three years and can be subject to the achievement of performance conditions. For awards to all participants in 2010, except employees of MedImmune, 50% of the award will vest subject to the performance of the Company's total shareholder return (TSR) compared with that of a selected peer group of other pharmaceutical companies, and 50% will vest subject to the achievement of a net cash flow 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 in the AstraZeneca Performance Share Plan section from page 125 in the Directors' Remuneration Report.

#### The AstraZeneca Pharmaceuticals LP Executive Performance Share Plan

This plan was introduced in 2007 and, up to and including the awards made in 2009, was 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. There were no awards made under this plan in 2010. All awards of performance shares to US employees and employees of MedImmune in 2010 were made under the AstraZeneca Performance Share Plan described above. 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 Investment Plan

This plan was introduced in 2010 and approved by shareholders at the 2010 AGM. The main grant of awards in 2010 under the plan was in May, with a further smaller grant in August. Awards granted under the plan vest after eight years and are subject to performance conditions measured over a period of between three and eight years. For awards granted in 2010, the performance conditions relate to the annual dividend paid to shareholders and dividend cover over a four-year performance period. The awards are then subject to a four-year holding period before they can vest. 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 in the AstraZeneca Investment Plan section from page 126 of the Directors' Remuneration Report.

#### The AstraZeneca Global Restricted Stock Plan

This plan was introduced in 2010 and replaces the AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan and the Medlmmune, Inc. 2008 Restricted Stock Unit Award Plan described below. The main grant of awards in 2010 under the plan was in March, with a further smaller grant in August. This plan provides for the grant of restricted stock unit (RSU) awards to selected below SET-level employees and is used in conjunction with the AstraZeneca Performance Share Plan to provide a mix of RSUs and performance shares. 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 AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan

This plan was introduced in 2007 and previously provided for the grant of RSU awards to selected employees (predominantly in the US). This plan was used in conjunction with the AstraZeneca Share Option Plan to provide a mix of RSUs and share options. There were no awards granted under this plan in 2010. This plan was replaced in 2010 by the Global Restricted Stock Plan described above. The Remuneration Committee had responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated.

#### The Medlmmune, Inc. 2008 Restricted Stock Unit Award Plan

This plan was introduced in 2008 and previously provided for the grant of RSU awards to selected employees of MedImmune. This plan was used in conjunction with the AstraZeneca Share Option Plan to provide a mix of RSUs and share options. There were no awards granted under this plan in 2010. This plan was replaced in 2010 by the Global Restricted Stock Plan described above. The Remuneration Committee had responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated.

#### 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 five times in 2010 to make awards to 24 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.

#### 24 Employee costs and share option plans for employees continued AstraZeneca Performance Share Plan

	Shares '000	WAFV <sup>1</sup> pence	WAFV <sup>1</sup> \$
Shares awarded in March 2008	1,338	941	18.88
Shares awarded in August 2008	14	1326	24.46
Shares awarded in March 2009	1,190	1140	16.70
Shares awarded in August 2009	8	1424	23.18
Shares awarded in March 2010	2,002	1495	22.38
Shares awarded in May 2010	436	1431	21.48
Shares awarded in August 2010	139	1614	24.95
Shares awarded in November 2010	4	N/A	25.11

#### AstraZeneca Pharmaceuticals LP Executive Performance Share Plan

	Shares '000	WAFV <sup>1</sup> \$
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

#### AstraZeneca Investment Plan

	Shares '000	WAFV <sup>1</sup> pence	WAFV <sup>1</sup> \$
Shares awarded in May 2010	76	2575	38.66
Shares awarded in August 2010	15	2904	N/A

# AstraZeneca Global Restricted Stock Plan

	Shares '000	WAFV <sup>1</sup> pence	WAFV <sup>1</sup> \$
Shares awarded in March 2010	2,672	2989	44.75
Shares awarded in August 2010	8	3227	49.89

#### AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan

	Units '000	WAFV <sup>1</sup> \$
Units awarded in March 2008	1,313	37.76
Units awarded in March 2009	1,283	33.39

# MedImmune, Inc. 2008 Restricted Stock Unit Award Plan

	Units '000	WAFV <sup>1</sup> \$
Units awarded in March 2008	130	37.76
Units awarded in March 2009	177	33.39

# AstraZeneca Restricted Share Plan

	intes '000	pence	VVAFV
Shares awarded in March 2008	51	1882	N/A
Shares awarded in May 2008	35	N/A	44.20
Shares awarded in August 2009	9	N/A	46.36
Shares awarded in September 2009	22	N/A	44.61
Shares awarded in February 2010	159	2954	47.70
Shares awarded in May 2010	25	2861	42.96
Shares awarded in August 2010	108	3227	49.89
Shares awarded in November 2010	27	N/A	50.21
Shares awarded in December 2010	20	N/A	48.30

<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 \$120m (2009: \$81m; 2008: \$53m). The plans are equity settled.

#### Share option plans

At 31 December 2010, there were options outstanding under the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca Share Option Plan.

Overview

#### 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 for a period of 10 years. The final grant of options under the plan was in August 2009. There were no grants of options under the plan in 2010 and no further grants will be made. The Remuneration Committee set 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 could be recommended from time to time for the grant of an option. The Remuneration Committee set the policy for the Company's operation of the plan including as regards which employees were eligible to participate.

#### Grant of options

Options were not granted during a close period. The grant of options was supervised by the Remuneration Committee. No payment was required for the grant of an option. Options are not transferable. Options were granted over AstraZeneca Ordinary Shares or ADSs.

#### Acquisition price

The price per Ordinary Share payable upon the exercise of an option is not 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 was 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. There are no longer any options outstanding under the 1994 Scheme, the remaining outstanding options having lapsed or been exercised in 2010.

	AstraZeneca Share Option Plan SAYE Schemes		1	994 Scheme		
	Options	WAEP1	Options	WAEP1	Options	WAEP <sup>1</sup>
	'000	pence	'000	pence	'000	pence
At 1 January 2008						
Options outstanding	42,560	2451	2,720	2226	1,490	2364
Movements during 2008						
Options granted	14,858	1887	483	2398	-	-
Options exercised	(2,577)	2204	(675)	2062	(99)	2620
Options forfeited	(2,273)	2622	(388)	2291	(106)	2594
Weighted average fair value of options granted during the year		404		499		-
At 31 December 2008						
Options outstanding	52,568	2978	2,140	2304	1,285	2934
Movements during 2009						
Options granted	15,246	2281	351	2563	-	-
Options exercised	(2,275)	2213	(286)	2258	(317)	2670
Options forfeited	(3,141)	2604	(169)	2340	(51)	2688
Weighted average fair value of options granted during the year		423		425		-
At 31 December 2009						
Options outstanding	62,398	2601	2,036	2349	917	2734
Movements during 2010						
Options granted	-	-	276	2907	-	-
Options exercised	(10,144)	2538	(455)	2216	(765)	2714
Options forfeited	(3,189)	2470	(183)	2559	(152)	2714
Weighted average fair value of options granted during the year		-		267		-
At 31 December 2010						
Options outstanding	49,065	2439	1,674	2455	-	-
		1882 to		2164 to		
Range of exercise prices		3487		3001		-
Weighted average remaining contractual life		2,185 days		1,062 days		-
Options exercisable	24,292	2799	65	2204	-	-

<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.

	2010	2009	2008
Average share price (pence)	3058	2651	2295
Weighted average exercise price (pence)			
AstraZeneca Share Option Plan	-	2281	1887
SAYE Schemes	2907	2563	2398
Expected volatility (%)	20.0	25.0	25.0
Dividend yield (%)	5.5	4.0	3.4
Risk-free interest rate (%)	2.5	3.7	4.3
Expected lives: AstraZeneca Share Option Plan (years)	6.0	6.0	6.0
Expected lives: SAYE Schemes (years)	4.2	4.2	4.0

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 \$53m (2009: \$105m; 2008: \$125m) which is comprised entirely of equity-settled transactions.

# 25 Commitments and contingent liabilities

	2010 \$m	2009 \$m	2008 \$m
Commitments			
Contracts placed for future capital expenditure on property, plant and equipment and			
software development costs not provided for in these accounts	259	368	178

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.

# Research and development collaboration payments

The Group has various ongoing collaborations including in-licensing and similar arrangements with development partners. Such collaborations may require the Group to make payments on achievement of stages of development, launch or revenue milestones although the Group generally has the right to terminate these agreements at no cost. The Group recognises research and development milestones as intangible assets once it is committed to payment, which is generally when the Group reaches set trigger points in the development cycle. Revenue-related milestones are recognised as intangible assets on product launch at a value based on the Group's long-term revenue forecasts for the related product. The table below indicates potential development and revenue-related payments that the Group may be required to make under such collaborations.

	Total \$m	Under 1 year \$m	Years 1 and 2 \$m	Years 3 and 4 \$m	and greater \$m
Future potential research and development milestone payments	3,106	115	711	646	1,634
Future potential revenue milestone payments	3,234	-	2	70	3,162

The table includes all potential payments for achievement of milestones under ongoing research and development arrangements. Revenuerelated milestone payments represent the maximum possible amount payable on achievement of specified levels of revenue as set out in individual contract agreements, but exclude variable payments that are based on unit sales (eg royalty-type payments) which are recognised as the associated sale is recognised in the comprehensive income statement. The table excludes any payments already capitalised in the financial statements for the year ended 31 December 2010 and excludes payments under the Merck agreements (detailed below).

The future payments we disclose represent contracted payments and, as such, are not discounted and are not risk adjusted. As detailed in the Principal risks and uncertainties section from page 96, the development of any pharmaceutical product candidate is a complex and risky process that may fail at any stage in the development process due to a number of factors (including items such as failure to obtain regulatory approval, unfavourable data from key studies, adverse reactions to the product candidate or indications of other safety concerns). The timing of the payments is based on the Group's current best estimate of achievement of the relevant milestone.

# 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'). AstraZeneca will continue to make contingent payments to Merck until at least 2012. Contingent payments (excluding those in respect of *Prilosec, Nexium* and the authorised generic version of felodipine) ceased in 2010 as AstraZeneca exercised the First Option (as discussed under First Option below); contingent payments in respect of *Prilosec* and *Nexium* will cease in late 2012 if AstraZeneca exercises the Second Option that year (as discussed under Second Option below); contingent payments in respect of the authorised generic version of felodipine will continue at least until June 2011.

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
- > Second Option.

# **25 Commitments and contingent liabilities** continued 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.

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.

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.

#### 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. Under the Agreements AstraZeneca could exercise the First Option in the first two months of 2010 for a sum equal to the 2008 Appraised Value.

In 2010, AstraZeneca gave Merck an irrevocable notice of its intention to exercise the First Option. Payment of \$647m to Merck was made on 30 April 2010. This payment resulted in AstraZeneca acquiring Merck's interests in products covered by the First Option including Entocort, Atacand, Plendil and the authorised generic version of felodipine, and certain products still in development (principally Brilinta and lesogaberan (AZD3355)). On 30 April 2010, contingent payments on these products ceased with respect to periods after this date (except for contingent payments on the authorised generic version of felodipine, which will continue at least until June 2011) and AstraZeneca obtained the ability to exploit these products and other opportunities in the Cardiovascular and Neuroscience therapy areas. As detailed in Note 9, the intangible asset relating to lesogaberan (AZD3355) of \$128m was subsequently impaired to a value of nil following a decision to terminate further development of this compound.

#### Second Option

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). In September 2010, AstraZeneca and Merck reached an agreement with respect to the treatment of *Vimovo* under the Agreements, pursuant to which AstraZeneca will pay Merck certain amounts with respect to *Vimovo* only if it exercises the Second Option and as part of the exercise price for the Second Option.

The exercise price for the Second Option is the net present value of the future annual contingent payments on *Nexium* and *Prilosec* as determined at the time of exercise and the net present value of up to 5 percent of future US sales of *Vimovo*, with the precise amount dependent on the level of annual sales and the timing of the option exercise. 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.

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.

25 Commitments and contingent liabilities continued

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 (\$1,656m) represented 'non-refundable deposits' for future product rights associated with the First and Second Options. In 2010, \$647m was recognised as an intangible asset as a result of payment of the Appraised Value for the First Option (see above). Together with the \$1,656m non-refundable deposits recognised in 2008, the total sum of \$2,303m was allocated as follows: \$689m to contingent payment relief, \$1,140m to intangible assets reflecting the ability to fully exploit the products in the cardiovascular and neuroscience therapy areas, and \$474m as non-refundable deposits associated with the Second Option. The intangible assets recognised on exercise of the First Option give rise to an additional amortisation expense in the range of \$20m to \$50m per annum charged to cost of sales in respect of contingent payment relief, the precise amount dependent upon the launch status of the covered pipeline compounds, and an additional charge to SG&A of around \$60m per annum. Amortisation on these intangible assets began when the \$647m payment was made on 30 April 2010. The remaining \$474m relating to the non-refundable deposits will not be subject to amortisation until the Second Option is exercised and the related product rights are acquired. If the Second Option is exercised then amortisation related to the ability to exploit opportunities in the gastrointestinal therapy area will commence, in the amount of around \$25m per annum (charged to SG&A), as well as an as yet indeterminable amount of amortisation related to relief from contingent payments.

The intangible assets relating to purchased product rights and the intangible assets relating to non-refundable deposits are subject to impairment testing and would be partially or wholly impaired if a product is withdrawn or if activity in any of the affected therapy areas is significantly curtailed. Consequently, following the discontinuation of the development of lesogaberan (AZD3355) in the third quarter of 2010, an impairment of \$128m was recognised. If it becomes probable that the Second Option will not be exercised, the non-refundable deposits 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 2008, 2009 or 2010.

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 environmental investigation, remediation, 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 31 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 pharmaceutical 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, 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 2010 in the aggregate of \$106m, 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 \$20m to \$40m, 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 business, including actual or threatened litigation and/ or actual or potential government investigations relating to employment matters, 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 (1) the stage of the proceedings (in many cases trial dates have not been set) and the overall length and extent of pre-trial discovery; (2) the entitlement of the parties to an action to appeal a decision; (3) clarity as to theories of liability, damages and governing law; (4) uncertainties in timing of litigation; and (5) 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.

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, and we consider recovery to be virtually certain, 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 have a materially adverse effect on our future results. 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.

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

#### Accolate (zafirlukast)

#### Patent litigation – US

As previously reported, in June 2008, AstraZeneca commenced patent infringement litigation against Dr. Reddy's Laboratories, Ltd and Dr. Reddy's Laboratories, Inc. (together, DRL) in the US District Court for the District of New Jersey for infringement of US Patent Nos. 5,319,097 (the '097 patent), 5,482,963 (the '963 patent) and 6,143,775 (the '775 patent). In 2009, the parties agreed to dismiss without prejudice all claims and counterclaims based on the '097 and '775 patents. In February 2010, DRL filed a motion for summary judgment based on prosecution history estoppel. AstraZeneca applied for summary judgment in response. In November 2010, the US District Court for the District of New Jersey denied AstraZeneca's motion and granted DRL a summary judgment that DRL's zafirlukast tablets did not infringe the '963 patent. In December 2010, AstraZeneca filed a Notice of Appeal to the US Court of Appeals for the Federal Circuit. In January 2011, AstraZeneca and DRL entered into a settlement agreement under which AstraZeneca will dismiss its appeal and give DRL a covenant-not-to-sue respecting DRL's zafirlukast ANDA product.

#### Arimidex (anastrozole)

#### Patent litigation - Canada

In 2009, AstraZeneca received a Notice of Allegation from Mylan Pharmaceuticals ULC (Mylan) in respect of Canadian Patent No. 1,337,420 (the '420 patent) listed on the Canadian Patent Register for *Arimidex*. AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance to Mylan for its anastrozole tablets until the expiration of the '420 patent. In October 2010, the hearing in this matter was scheduled for three days commencing on 31 May 2011.

#### Atacand (candesartan cilexetil)

#### Patent litigation - US

In November 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Apotex Inc. (Apotex) informing AstraZeneca that Apotex was seeking approval to market a generic version of *Atacand* prior to the expiration of US Patent No. 5,534,534 (the '534 patent). Apotex alleged that its product did not infringe the '534 patent. AstraZeneca did not file suit in response to Apotex's letter.

#### Patent litigation - Canada

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

**25 Commitments and contingent liabilities** continued In May 2009, AstraZeneca filed a Notice of Application in federal court seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance to Sandoz for its 4, 8 and 16mg candesartan cilexetil tablets until the expiration of the '305 patent. In December 2009, AstraZeneca discontinued the proceeding.

In March 2010, AstraZeneca received a Notice of Allegation from Cobalt Pharmaceuticals Inc. (Cobalt) in respect of the '955 and '305 patents listed on the Canadian Patent Register for *Atacand*. Cobalt has confirmed it will await the expiry of the '955 patent. For the '305 patent, Cobalt alleges that the patent is not infringed, is invalid, irrelevant and not properly listed. AstraZeneca did not commence an application in response.

In April 2010, AstraZeneca received a Notice of Allegation from Pharmascience Inc. (PMS) in respect of the '305 patent listed on the Canadian Patent Register for *Atacand*. PMS alleges that the formulation patent is not infringed. PMS has not addressed the '955 patent and must await its expiry in April 2011 before it may receive its marketing authorisation. AstraZeneca did not commence an application in response.

In May 2010, AstraZeneca received a Notice of Allegation from Mylan Pharmaceuticals ULC (Mylan) in respect of the '955 and '305 patents listed on the Canadian Patent Register for *Atacand*. Mylan has confirmed it will await the expiry of the '955 patent. Mylan alleged that the '305 patent is not infringed, is improperly listed and is invalid. AstraZeneca did not commence an application in response.

In June 2010, AstraZeneca received a Notice of Allegation from Sandoz in respect of the '305 patent and relating to the 32mg strength of *Atacand*, not previously addressed by Sandoz. Sandoz alleges that the '305 patent is not infringed and is improperly listed. Sandoz does not address the '955 patent and must await its expiry before it may receive its marketing authorisation. AstraZeneca did not commence an application in response.

In August 2010, AstraZeneca received a Notice of Allegation from Teva Canada Limited (Teva) in respect of the '955 patent and the '305 patent listed on the Canadian Patent Register for *Atacand*. AstraZeneca did not commence an application in response. In December 2010, AstraZeneca received another Notice of Allegation from Teva in respect of the '955 and '305 patents listed on the Canadian Patent Register for *Atacand*. Teva has confirmed it will await the expiry of the '955 patent. AstraZeneca is evaluating the allegations.

None of Sandoz, Cobalt, PMS, Mylan or Teva may receive a marketing authorisation before April 2011.

#### Patent litigation - Brazil

In October 2010, an infringement action with a request for an interlocutory injunction was filed against Sandoz do Brasil Industria Farmaceutica Ltda (Sandoz) in the Central Court of São Paolo. The Court denied the request for an interlocutory injunction on 22 October 2010. Takeda Pharmaceutical Company Ltd. and AstraZeneca have filed a joint appeal. Sandoz has responded and a decision is expected in the first quarter of 2011.

#### Patent litigation - EU

In Portugal, a request was filed with the Lisbon Administrative Court of First Instance in December 2009 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. The Court denied the preliminary injunction. The decision has been appealed. A similar preliminary injunction request was filed in April 2010 with respect to PTR Pharma Consulting Lda as an interested party. Other similar preliminary injunction requests were filed in October 2010, with respect to Laboratórios Azevedos – Industria Farmacêutica (Laboratórios Azevedos), S.A. Ceamed, Servico e Consultadoria Farmacêutica Lda (Ceamed) and Teva Pharma – Produtos Farmacêuticos Lda, as interested parties regarding candesartan cilexetil and also in combination with hydrochlorothiazide. Corresponding main actions have been initiated regarding all the above mentioned matters.

In addition to the previously reported cases, a preliminary injunction request was filed in December 2010, with respect to Laboratórios Azevedos and Ceamed as interested parties, in the capacity of owners of the marketing authorisations, and of applicants of the retail prices regarding candesartan cilexetil containing generics. The corresponding main action was filed in the administrative courts also in December 2010, with the aim of declaring null, or to annul, the decisions taken by administrative bodies in Portugal granting Laboratórios Azevedos and Ceamed marketing authorisations for generic candesartan cilexetil, or to defer the effects of the said decision, and to prevent the decision being taken by administrative bodies regarding the retail prices of the generic products. A preliminary injunction request was filed in December 2010, with respect to Labesfal - Laboratorios Almiro, S.A. (Labesfal) as an interested party, in the capacity of owner of the marketing authorisations and of applicants of the retail prices regarding candesartan cilexetil and a combination of candesartan cilexetil and hydrochlorothiazide containing generics. The corresponding main action was filed in the administrative courts in December 2010, with the aim of declaring null, or to annul, the decisions taken by administrative bodies in Portugal granting Labesfal marketing authorisations for generic candesartan cilexetil and a combination of candesartan cilexetil and hydrochlorothiazide, or to defer the effects of the said decision, and to prevent the decision being taken by administrative bodies regarding the retail prices of the generic products.

#### Atacand HCT/Atacand Plus

#### (candesartan cilexetil/hydrochlorothiazide) Patent litigation – US

As previously reported, in 2008 and 2009, AstraZeneca and Takeda Pharmaceutical Company Limited (Takeda) received Paragraph IV Certification notice-letters from Matrix Laboratories Limited (Matrix) and Sandoz Inc. (Sandoz) notifying the parties that ANDAs had been submitted to the FDA seeking approval to market generic versions of *Atacand HCT* in 32/12.5, 32/25 and 16/12.5mg dose forms. Matrix is a subsidiary of Mylan, Inc.

Neither Matrix nor Sandoz challenged the two listed compound patents, US Patent Nos. 5,705,517 and 5,196,444, the latest of which expires in June 2012. As a result, neither generic filer can market its candesartan cilexetil/hydrochlorothiazide (HCT) combination product before December 2012, when the six-month Paediatric Exclusivity period expires. Matrix and Sandoz have alleged that the remaining Orange Book patents listed for *Atacand HCT*, US Patent Nos. 5,534,534, 5,721,263, 5,958,961 and 7,538,133 are invalid, unenforceable or not infringed. AstraZeneca and Takeda did not file a complaint for patent infringement in response to either notice-letter.

#### Patent litigation - Canada

In 2009, AstraZeneca received a Notice of Allegation from Sandoz Canada Inc. (Sandoz) 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 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, is 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 Notice of Compliance to Sandoz for its 16/12.5mg candesartan cilexetil-HCT tablets until the expiration of the '305 and '251 patents. In January 2010, the court scheduled a hearing in the Sandoz matter for four days beginning on 9 May 2011.

#### 25 Commitments and contingent liabilities continued

In January 2010, AstraZeneca received a Notice of Allegation from Mylan Pharmaceuticals ULC (Mylan) in respect of the '955, '305 and '251 patents. On 12 January 2011, Mylan withdrew its Notice of Allegation and AstraZeneca discontinued its application on 17 January 2011.

In April 2010, AstraZeneca received two Notices of Allegation from Cobalt Pharmaceuticals Inc. (Cobalt) in respect of the '305 and '251 patents listed on the Canadian Patent Register for *Atacand Plus*. Cobalt alleges that the '305 patent is not infringed, is invalid, and is irrelevant and not properly listed. Cobalt alleges that the '251 patent is not infringed and is invalid. Cobalt has indicated that it is prepared to await its marketing approval until after the '955 patent expires in April 2011. AstraZeneca commenced a proceeding in response in June 2010.

In April 2010, AstraZeneca received a Notice of Allegation from Pharmascience Inc. (PMS) in respect of the '305 patent listed on the Canadian Patent Register for *Atacand Plus*. PMS alleges that the '305 patent is not infringed. AstraZeneca commenced a proceeding in response on 17 June 2010. On 20 December 2010, AstraZeneca received a Notice of Allegation from PMS in respect of the '251 patent. AstraZeneca is evaluating the allegations. PMS has not addressed the '955 patent.

In September 2010, AstraZeneca received a Notice of Allegation from Teva Canada Limited (Teva) in respect of the '305 patent listed on the Canadian Patent Register for *Atacand Plus*. Teva withdrew its Notice of Allegation on 17 November 2010, and in response, on 30 November 2010, AstraZeneca discontinued its application responding to Teva's Notice of Allegation.

#### Crestor (rosuvastatin calcium)

#### Patent litigation - US

#### US Patent No. RE 37,314 (the '314 patent)

As previously reported, in 2007 and 2008, AstraZeneca and AstraZeneca's licensor, Shionogi Seiyaku Kabushiki Kaisha (Shionogi) (together, the Plaintiffs), filed lawsuits in the US District Court for the District of Delaware, against various parents or subsidiaries of eight generic ANDA filers for infringement of the '314 patent, the patent covering rosuvastatin calcium, the active ingredient in *Crestor* tablets.

On 3 March 2010, Judge Joseph Farnan, in the US District Court for the District of Delaware, completed the trial of the consolidated matter. Following the trial, on 26 March 2010, the Court approved and signed the stipulation and consent order of the Plaintiffs and co-defendants, Aurobindo Pharma Ltd and Aurobindo Pharma USA Inc., whereby Aurobindo Pharma Ltd consented to jurisdiction and venue. Aurobindo Pharma USA Inc. agreed to be bound by any judgment against Aurobindo Pharma Ltd and the Plaintiffs agreed in exchange to dismiss the action against Aurobindo Pharma USA Inc.

In June 2010, the Court issued a decision finding infringement and rejecting the defendants' arguments of invalidity and unenforceability with respect to the '314 patent. In August 2010, the defendants filed Notices of Appeal to the US Court of Appeals for the Federal Circuit. The defendants filed their opening briefs with the appellate court in December 2010.

For trial, the Court retained jurisdiction over Apotex Corp., which participated in the trial. However, the Court transferred the infringement matter as it pertained to co-defendant, Apotex Inc. to the US District Court for the Southern District of Florida. The Florida Court stayed the Apotex Inc. case pending the outcome of the appeal to the Federal Circuit. In May 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Glenmark Generics Inc., USA (formerly, Glenmark Pharmaceuticals, Inc., USA) (Glenmark), challenging the '314 patent. In June 2010, the Plaintiffs filed a patent infringement action against Glenmark in the US District Court for the District of Delaware. On 15 November 2010, the Court approved the parties' stipulation and proposed order requesting the Court to enter judgment in favour of the Plaintiffs and to stay the Glenmark action in its entirety. As part of the stipulation, Glenmark conceded infringement of the '314 patent and agreed to be bound by the Court's June 2010 decision. The parties also agree to be bound by the results of any subsequent appeal in the Plaintiffs' other *Crestor* ANDA litigation, which found the '314 patent valid and enforceable.

#### 505(b)(2) NDA for rosuvastatin zinc tablets (the '314 patent)

In September 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Watson Laboratories, Inc. informing AstraZeneca of the filing of its section 505(b)(2) NDA for rosuvastatin zinc tablets, and challenging the '314 patent and the Crestor formulation patent (US Patent No. 6,316,460 (the '460 patent)). On 26 October 2010, AstraZeneca and Shionogi (together, the Plaintiffs) commenced a patent infringement action in the US District Court for the District of Delaware (the Delaware Action) against Watson Pharmaceuticals, Inc., Watson Pharma, Inc., Watson Laboratories, Inc. and other related entities for infringement of the '314 patent. On 10 November 2010, for jurisdictional reasons, the Plaintiffs filed a duplicate protective lawsuit in the US District Court for the District of Nevada (the Nevada Action) against Watson Pharmaceuticals, Inc., Watson Pharma Inc. and Watson Laboratories, Inc. On 23 December 2010, pursuant to the parties' joint stipulation in the Delaware Action setting forth the agreement of Watson Laboratories, Inc. to personal jurisdiction in the District of Delaware and other admissions, conditions, and agreements, the Court dismissed all of the Watson co-defendants without prejudice, except Watson Laboratories, Inc. Watson Pharmaceuticals, Inc., Watson Pharma, Inc., Watson Laboratories, Inc. and other named Watson entities were dismissed without prejudice from the Delaware action. In January 2011, AstraZeneca dismissed the Nevada Action.

# US Patent Nos. 6,858,618 (the '618 patent) and 7,030,152 (the '152 patent)

In April 2010, AstraZeneca commenced new patent infringement actions involving Crestor in the US District Court for the District of Delaware, based on the '618 and '152 patents. Later in April 2010, AstraZeneca amended nine complaints, adding a co-plaintiff, The Brighams & Women's Hospital (BWH), AstraZeneca's licensor of the '152 patent, to the suits. In these new infringement actions, AstraZeneca and BWH (together, the Plaintiffs) allege that the defendants' original filings or amendments of ANDAs seeking approval to market generic rosuvastatin calcium tablets prior to the expiration of these patents, infringe the '618 and '152 patents under 35 USC §271(e)(2). The '618 and '152 patents, which AstraZeneca lists in the FDA's Orange Book, relate respectively to the use of rosuvastatin calcium for primary prevention of cardiovascular disease and the treatment of heterozygous familial hypercholesterolemia (HeFH). AstraZeneca obtained FDA approval for the use of Crestor tablets for primary prevention of cardiovascular disease in February 2010 and for paediatric treatment of HeFH in October 2009. The new infringement actions were brought against: (a) Aurobindo Pharma Ltd, Aurobindo Pharma USA Inc. (together, Aurobindo) (b) Apotex Corp., (c) Cobalt Pharmaceuticals Inc., Cobalt Laboratories, Inc. (together, Cobalt) (d) Par Pharmaceuticals, Inc. (e) Sandoz Inc. (Sandoz), (f) Mylan Pharmaceuticals, Inc. (g) Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Inc., Caraco Pharmaceutical Laboratories Ltd. (together, Sun) and (h) Teva Pharmaceuticals USA, Inc. These eight defendant groups were also defendants in the '314 patent litigation described above. In addition, AstraZeneca commenced a first patent infringement action against Glenmark Generics Inc. USA.

25 Commitments and contingent liabilities continued

In May 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Torrent Pharmaceuticals Limited (Torrent Pharmaceuticals), challenging the '460 patent (the formulation patent). In July 2010, the Plaintiffs filed a patent infringement action against Torrent Pharmaceuticals and Torrent Pharma Inc. (together, Torrent) in the US District Court for the District of Delaware, based on the '618 and '152 patents. Torrent did not challenge the '314 patent in its Paragraph IV notice-letter.

In July and August 2010, all of the defendants, except Sandoz, filed Motions to Dismiss for lack of subject matter jurisdiction and failure to state a claim.

In November 2010, the Court approved a stipulation and proposed order of the Plaintiffs and Torrent jointly requesting the Court to stay the Torrent action. As part of the stipulation, Torrent agrees to be bound by the results of the first final decision and any appeals of that decision, as prosecuted by the remaining defendants.

In December 2010, the Court granted the Motions to Dismiss and dismissed the infringement actions for lack of subject matter jurisdiction. The Court also ordered the Plaintiffs to show cause why the claims against Sandoz, the sole non-movant, should not also be dismissed. In 2011, the Plaintiffs filed Notices of Appeal to the US Court of Appeals for the Federal Circuit. In January 2011, the Plaintiffs and Sandoz also filed a joint response to the show cause order, requesting that the Sandoz action be stayed until after the Federal Circuit renders its decision on the appeals or, alternatively, dismisses it without prejudice.

#### Patent litigation - Canada

In 2008, AstraZeneca received Notices of Allegation from Novopharm Limited (now, Teva Canada Limited) (Teva) and Apotex Inc. (Apotex), respectively, regarding Canadian Patent Nos. 2,072,945 (the '945 patent) and 2,313,783 (the '783 patent) listed on the Canadian Patent Register for *Crestor*. AstraZeneca commenced proceedings in response. The Canadian Federal Court conducted consecutive hearings on the two matters beginning on 22 March 2010 and 29 March 2010 respectively. In July 2010, AstraZeneca reached comprehensive settlement agreements with each of Teva and Apotex to resolve litigation between them. As part of the agreements, Teva and Apotex may enter the Canadian market in April 2012, or earlier, in certain circumstances. The Canadian substance patent expires in July 2012.

In 2009, AstraZeneca received a Notice of Allegation from Cobalt Pharmaceuticals, Inc. (Cobalt) in respect of the '945 and '783 patents. In November 2010, AstraZeneca reached a comprehensive settlement agreement with Cobalt, resolving the litigation, and as part of the agreement, Cobalt may enter the Canadian market in April 2012, or earlier, in certain circumstances. The Canadian substance patent expires in July 2012.

Also in 2009, AstraZeneca received a Notice of Allegation from Sandoz Canada Inc. (Sandoz) in respect of the '945 and '783 patents. In January 2011, AstraZeneca reached a comprehensive settlement agreement resolving the litigation, and as part of the agreement, Sandoz may enter the Canadian market in April 2012, or earlier, in certain circumstances.

In August 2009, AstraZeneca received a Notice of Allegation from ratiopharm Inc. (ratiopharm) with respect to the '945 and '783 patents. AstraZeneca commenced an application in response. In August 2010, AstraZeneca discontinued the application as a result of Teva's acquisition of ratiopharm.

In February 2010, AstraZeneca received a Notice of Allegation from Pharmascience Inc. (Pharmascience) in respect of the '945 and '783 patents. Pharmascience alleges that the '945 and '783 patents are not infringed and are invalid. AstraZeneca commenced an application in response in April 2010. In July 2010, AstraZeneca received a Notice of Allegation from Ranbaxy Pharmaceuticals Canada Inc. (Ranbaxy) regarding the '945 patent, the '783 patent and Canadian Patent No. 2,315,141 (the '141 patent). Ranbaxy alleges certain of the claims of the '945, '783 and '141 patents are not infringed and that the patents are invalid. AstraZeneca commenced an application in response in August 2010.

In August 2010, AstraZeneca received a Notice of Allegation from Mylan Pharmaceuticals ULC (Mylan) regarding the '945, '783 and '141 patents. Mylan alleges certain of the claims of the '945, '783 and '141 patents are not infringed and that the patents are invalid. AstraZeneca commenced an application in response in September 2010.

#### Patent litigation - EU

In Portugal, a preliminary injunction request was filed with the Lisbon Administrative Court of First Instance in May 2010 seeking a suspension of the effect of decisions taken by administrative bodies in Portugal to grant Teva Pharma Lda (Teva) marketing authorisations for generic rosuvastatin calcium, and to prevent the approval of the retail price. A similar preliminary injunction request was filed with respect to Sandoz Farmaceutica Lda in June 2010. In October 2010, the Court granted the preliminary injunction request to suspend the effect of the decisions taken by the administrative bodies in Portugal to grant Teva marketing authorisation for generic rosuvastatin. The decision has been appealed by the administrative body, Infarmed, and by Teva. In November 2010, the Court granted the preliminary injunction request to suspend the marketing authorisations for generic rosuvastatin granted to Sandoz Farmaceutica Lda. The decision has been appealed by Infarmed. In November 2010, the Court granted the preliminary injunction request to suspend the marketing authorisations for generic rosuvastatin granted to Hexal AG. The decision has been appealed by Infarmed. Corresponding main actions have been initiated regarding all the above mentioned matters.

#### Patent litigation - Brazil

Torrent do Brasil (Torrent) launched its generic versions of *Crestor* in early October 2010 and AstraZeneca filed a request for a preliminary injunction. On 13 October 2010, the court of first instance granted the requested injunction and ordered Torrent to discontinue the sale and marketing of these generic products in Brazil and to recall products already on the market. Torrent appealed the decision. The effects of the preliminary injunction were suspended by the court of first instance until the decision by the Court of Appeal. The Court of Appeal is likely to make its decision in the first quarter of 2011.

#### Other US patent litigation

In October 2010, in the Teva Pharmaceuticals Industries Ltd. (Teva) patent infringement lawsuit against AstraZeneca, with regard to *Crestor*, the US District Court for the Eastern District of Pennsylvania granted AstraZeneca's motion for summary judgment invalidating Teva's patent based on prior inventorship. AstraZeneca thereafter filed a motion for attorneys' fees, which was denied by the Court without prejudice pending Teva's appeal, which it filed in November 2010.

#### Entocort EC (budesonide)

In 2008, AstraZeneca initiated patent infringement actions against Barr Laboratories, Inc. (Barr) and Mylan Pharmaceuticals, Inc. (Mylan) for infringement of US Patent Nos. 6,423,340 (the '340 patent) and 5,643,602 (the '602 patent) in the US District Court for the District of Delaware.

In May 2010, AstraZeneca entered into a settlement agreement with Barr (acquired by Teva Pharmaceutical Industries Ltd. in 2009, now, Teva). Under the terms of the agreement, AstraZeneca has granted Teva a licence to enter the US market with its generic version of oral budesonide on 15 February 2012, subject to regulatory approval. Also in May 2010, AstraZeneca proceeded to trial against Mylan before Judge Gregory Sleet on the sole issue of infringement of the '602 patent. The Court has reserved judgment.

# Overview

# 25 Commitments and contingent liabilities continued *Faslodex* (fulvestrant)

Patent litigation – US

In 2009, AstraZeneca received a Paragraph IV Certification noticeletter from Teva Parenteral Medicines, Inc. (Teva Parenteral), informing AstraZeneca that it had filed an ANDA to market a generic form of *Faslodex* before the expiration of the Orange Book listed patents covering *Faslodex*. In January 2010, AstraZeneca filed a patent infringement lawsuit against Teva Parenteral, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd (together, Teva) in the US District Court for the District of Delaware for infringement of US Patent Nos. 6,774,122 and 7,456,160. The case was assigned to Judge Joel Pisano, sitting by designation due to judicial vacancy in the District of Delaware. On 24 December 2010, Teva advised AstraZeneca that it had requested the FDA to withdraw its ANDA without prejudice to refile. The Court has stayed the litigation to permit the parties to resolve the matter pending the FDA's acknowledgement of the withdrawal.

#### Iressa (gefitinib)

Between 2004 and 2008, seven claims were filed against AstraZeneca in Japan, in the Osaka and Tokyo District Courts. In these claims, it is alleged that *Iressa* caused a fatal incidence of interstitial lung disease in a Japanese patient. AstraZeneca believes the claims are without merit and has defended all the cases. Decisions are expected from the Courts in the first quarter of 2011.

#### Losec/Prilosec (omeprazole)

#### Patent litigation - US

As previously reported, by 2006, AstraZeneca had initiated patent infringement actions in the US District Court for the Southern District of New York against several generic companies and their suppliers, all alleging infringement of AstraZeneca's patents relating to omeprazole. As previously reported, following trials against numerous defendants, in 2007, the District Court upheld both formulation patents covering the Prilosec omeprazole product and ruled that the generic omeprazole formulations of Impax Laboratories Inc. (Impax) (manufacturers of the generic product distributed in the US by Teva Pharma Ltd (Teva)) and Apotex Corp. and Apotex Inc. (together, Apotex Group) infringed AstraZeneca's patents. The Court found that the generic products sold by Lek Pharmaceutical and Chemical Company d.d. and Lek Services USA, Inc. (together, Lek), Mylan Pharmaceuticals, Inc. and Mylan, Inc. (together, Mylan) and Laboratorios Esteve, S.A. and Esteve Quimica, S.A. (together, Esteve) did not infringe AstraZeneca's patents. In 2008, the US Court of Appeals for the Federal Circuit upheld the rulings that Mylan and Esteve did not infringe. The Federal Circuit also upheld that the generic omeprazole formulations of Impax and Apotex Group infringed AstraZeneca's patents. In January 2010, AstraZeneca settled with Impax and Teva for their infringing commercial sales, obtaining a one-time payment for past infringement. In 2010, AstraZeneca continued efforts to recover infringement damages and other remedies against Andrx Pharmaceuticals, Inc. 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 Inc. launched a generic omeprazole capsule product in Canada in January 2004.

In 2006, AstraZeneca was served with a claim in the Federal Court of Canada for payment of an undetermined sum based on damages allegedly suffered by Apotex Inc. due to the delay from January 2002 to January 2004 in the issuance to Apotex Inc. of a Notice of Compliance 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 Inc.

In May 2010, the Federal Court scheduled the trial for the pending matters to be heard concurrently commencing in March 2012.

#### European Commission case

In July 2010, the General Court of the European Union (the General Court) handed down its judgment in AstraZeneca's appeal against the European Commission's 2005 Decision fining AstraZeneca €60m for abuse of a dominant position regarding omeprazole. The General Court upheld most of the European Commission's arguments but reduced the fine to €52.5m as it said that the European Commission's case had not been proven in relation to Denmark and Norway. The fine was paid in 2005 in accordance with the original Decision and €7.5m plus interest has been repaid to AstraZeneca. AstraZeneca was ordered to pay 90% of the European Commission's costs and the European Commission was ordered to pay 10% of AstraZeneca's costs. AstraZeneca has appealed the General Court's judgment in relation to market definition, that AstraZeneca's behaviour was abusive (even if AstraZeneca was dominant at the time) and the level of fine. The European Commission has cross appealed the General Court's judgment regarding Denmark and Norway. It is possible that third parties could seek damages for alleged losses arising from this matter. Any such claims would be vigorously resisted.

#### *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, consumers and third party payers was unfair, unlawful and deceptive, particularly as the promotion relates to comparisons of *Nexium* with *Prilosec*. Some of the cases 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 Californian 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 the Delaware Federal Court.

The Florida and Arkansas cases have been dismissed at the trial court level. Both of those dismissals were affirmed on appeal and no further appeal is possible. Similarly, in May 2010, the Delaware Federal Court dismissed the complaint for failure to state a claim and the plaintiffs did not appeal.

In March 2009, the California trial court granted AstraZeneca's motions for summary judgment and denied plaintiffs' motion for class certification. That decision was appealed. In August 2010, the California Court of Appeal affirmed the trial court's orders denying class certification and granting summary judgment in favour of AstraZeneca in an unpublished decision. The time for further appeals has lapsed.

In July 2010, the Massachusetts trial court entered an order granting plaintiffs' motion to certify a class of Massachusetts purchasers of *Nexium* denying AstraZeneca's motion for summary judgment as to two plaintiffs, and granting AstraZeneca's motion for summary judgment as to one plaintiff. AstraZeneca filed a petition for discretionary interlocutory review of those rulings, which was denied by a single justice of the Massachusetts Appeals Court in September 2010.

25 Commitments and contingent liabilities continued

The Delaware state case in Superior Court has been stayed since May 2005 in favour of the Delaware federal court case. In August 2010, the plaintiffs filed a request to lift the stay based on the final resolution of the Delaware federal case and to enter a scheduling order setting deadlines for the plaintiffs to file an amended complaint and for the briefing of AstraZeneca's expected motion to dismiss. The Delaware Superior Court has not yet acted on the plaintiffs' request and the case remains stayed.

#### Patent litigation - US

In 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 licence from AstraZeneca on 27 May 2014.

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

In 2007, AstraZeneca received a Paragraph IV Certification noticeletter from Dr. Reddy's Laboratories, Ltd and Dr. Reddy's Laboratories, Inc (together, DRL) stating that DRL had submitted an ANDA for 20 and 40mg esomeprazole magnesium delayed-release capsules. In 2008, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against DRL in response to DRL's ANDA and Paragraph IV Certifications regarding *Nexium*.

In 2008, AstraZeneca, IVAX Group and DRL filed declaratory judgment suits in the US District Court for the District of New Jersey for patents that were not previously included in the ongoing *Nexium* patent infringement litigations.

In January 2010, AstraZeneca entered into an agreement to settle the IVAX Group/Teva Group litigation. Teva Group conceded that all patents-at-issue in its US *Nexium* patent litigations are valid and enforceable. Teva Group also conceded that its ANDA product would infringe six of the *Nexium* patents-in-suit. AstraZeneca granted Teva Group a licence for its ANDA product to enter the US market, subject to regulatory approval, on 27 May 2014. This market entry date, and the settlement, are consistent with AstraZeneca's prior 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. In January 2010, as part of the settlement between AstraZeneca and IVAX Group, the 2008 declaratory judgment actions involving IVAX Group were also dismissed.

In January 2011, AstraZeneca entered into an agreement to settle the DRL litigation. DRL conceded that the patents-at-issue in its US *Nexium* patent litigations are valid and enforceable with reference to DRL's US esomeprazole magnesium ANDA product. DRL also conceded that its ANDA product would infringe three *Nexium* patents-in-suit. AstraZeneca granted DRL a licence for its ANDA product to enter the US market, subject to regulatory approval, on 27 May 2014. This market entry date, and the settlement, are consistent with AstraZeneca's settlement with Ranbaxy and the January settlement with the IVAX Group, Teva Pharmaceutical Ltd., and their affiliates. As a result of the DRL settlement and entry of a consent judgment, the DRL litigation was dismissed. As part of the settlement, DRL's declaratory judgment actions were also dismissed. In January 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Sun Pharma Global FZE and its affiliates (together, Sun) stating that Sun had filed an ANDA and notifying of Sun's challenge to patents listed in the FDA's Orange Book in reference to *Nexium i.v.* In February 2010, AstraZeneca filed suit against Sun in the US District Court for the District of New Jersey. In August 2010, upon AstraZeneca's motion, Magistrate Judge Bongiovanni stayed the Sun litigation. In December 2010, among other actions, the Court vacated the stay and referred the matter back to Magistrate Judge Bongiovanni for a scheduling conference. No trial date has been set in the Sun patent litigation.

In 2008, AstraZeneca received a Paragraph IV Certification noticeletter from Sandoz Inc. (Sandoz) stating that Sandoz had submitted an ANDA for approval to market 20 and 40mg esomeprazole magnesium delayed-release capsules. In 2009, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey. In July 2009, the Court stayed the Sandoz patent infringement litigation until after trial in the above referenced DRL *Nexium* 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. In March 2010, the Court stayed the Lupin patent infringement litigation until after trial in the DRL *Nexium* patent infringement litigation. No trial date has been set in the Lupin patent litigation.

In December 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Hanmi USA Inc. (Hanmi) stating that it had submitted an NDA under section 505(b)(2) for FDA approval to market 20 and 40mg esomeprazole strontium capsules. Hanmi alleges non-infringement or invalidity of 11 patents listed in the FDA's Orange Book with reference to *Nexium*. AstraZeneca is evaluating Hanmi's notice and certifications.

#### Patent litigation - Canada

AstraZeneca received several Notices of Allegation from Apotex Inc. (Apotex) in 2007 in respect of patents listed on the Canadian Patent Register for *Nexium*. AstraZeneca responded by commencing seven applications in 2008 under the Patented Medicines (Notice of Compliance) Regulations.

In June 2010, after a hearing, the Federal Court of Canada dismissed AstraZeneca's application to prohibit the Minister of Health from issuing a Notice of Compliance (marketing authorisation) for generic esomeprazole magnesium to Apotex, and Apotex received its marketing authorisation in June 2010. In October 2010, AstraZeneca commenced a patent infringement action against Apotex alleging infringement of five Canadian patents related to *Nexium*.

As previously reported, in 2009, AstraZeneca received a Notice of Allegation from Mylan Pharmaceuticals ULC. AstraZeneca commenced an application in response in January 2010. A hearing has been set for 24 October 2011.

In September 2010, AstraZeneca received several Notices of Allegation from Pharmascience Inc. in respect of the patents listed on the Canadian Patent Register for *Nexium*. AstraZeneca commenced applications in response in October 2010.

In October 2010, AstraZeneca received a Notice of Allegation from Ranbaxy Pharmaceuticals Canada Inc. (Ranbaxy) in respect of the patents listed on the Canadian Patent Register for *Nexium*. AstraZeneca commenced a proceeding in response in December 2010.

Additional Information

AstraZeneca has filed two law suits before the Federal Courts of Brasilia seeking judicial declaration to confirm that all conditions established in the Trade-Related Aspects of Intellectual Property Rights Agreement have been satisfied and thereby entitling AstraZeneca to exclusive marketing rights for *Nexium* to July 2012. The Court rejected one suit in 2008 and the other one on 1 May 2010. AstraZeneca has appealed both decisions and the Federal Court of Appeals is expected to issue decisions on the merits by the middle of 2011.

#### Patent litigation – EU

Most major European markets (Belgium, France, Italy, Luxembourg, the Netherlands, Germany, Sweden and the UK) had regulatory data protection for *Nexium* until 10 March 2010 and other markets had six years regulatory data protection. To date, there are generic products in several 6-year countries and in Germany, Sweden and the Netherlands among the 10-year countries.

#### Patent litigation - EU: 10-year countries

In July 2010, Consilient Health Limited (Consilient) was granted marketing approval in the UK for a generic esomeprazole product manufactured by Krka, d.d., Novo Mesto (Krka) in Slovenia. AstraZeneca initiated infringement proceedings against Consilient and Krka on 8 September 2010. Consilient and Krka agreed not to launch their generic esomeprazole product pending the outcome of the main infringement case. AstraZeneca has undertaken to be liable for losses of the defendants and third parties if the injunction is lifted at a later date. The trial will not be held before 3 October 2011.

In October 2010, AstraZeneca was served an invalidity case in which Ranbaxy (UK) Ltd claimed that the *Nexium* esomeprazole magnesium patent (EP 1020461) and the esomeprazole magnesium trihydrate patent (EP 0984957) are invalid in the UK. Ranbaxy (UK) Ltd further requested the Court to confirm that its generic esomeprazole product does not infringe either patent if launched in the UK. The trial of the non-infringement part will not be held before May 2011. The invalidity part has been stayed pending the non-infringement trial.

#### In Germany, Krka, d.d., Novo Mesto, TAD Pharma GmbH,

Abz-Pharma GmbH, CT Arzneimittel GmbH, ratiopharm GmbH and Teva GmbH launched generic esomeprazole magnesium products during September and October 2010. In October 2010, AstraZeneca filed requests for preliminary injunctions to restrain said companies from marketing and selling these products in Germany. In November 2010, AstraZeneca added Hexal AG and Sandoz Pharmaceuticals GmbH as defendants. The trial was held on 10 December 2010, and the court rejected the request for preliminary injunctions on 17 December 2010. The decision has not yet been published. AstraZeneca has four weeks from the date of publication to determine whether it will appeal. In November 2010, AstraZeneca was served with a law suit filed by Ethypharm S.A. claiming that the two *Nexium* cloud point patents (EP 0984773 and EP 1124539) are invalid in Germany.

In Sweden, AstraZeneca filed a request for an interlocutory injunction on 26 October 2010 against Krka Sverige AB to restrain this company from marketing and selling its generic esomeprazole magnesium product in Sweden. In January 2011, AstraZeneca was served with a lawsuit filed by ratiopharm GmbH and ratiopharm AB claiming that the *Nexium* esomeprazole magnesium patent (EP 1020461) is invalid in Sweden.

In the Netherlands, Sandoz B.V. and Hexal AG (both in the Sandoz group) and Stada Arzneimittel AG and Centrafarm Services B.V. (both in the Stada group) filed lawsuits in June 2010, in accelerated proceedings, claiming that the *Nexium* esomeprazole magnesium patent (EP 1020461) is invalid in the Netherlands. The trials were held on 14 January 2011. The decision has not yet been published.

In Italy, EG s.p.a. (a company in the Stada group) filed a law suit in June 2010 claiming that the *Nexium* esomeprazole magnesium patent (EP 1020461) is invalid in Italy. AstraZeneca has added a counterclaim of infringement. An initial hearing was held on 23 November 2010.

In France, ratiopharm GmbH and Laboratoire ratiopharm S.A. filed a law suit against AstraZeneca on 18 August 2010 claiming that the *Nexium* esomeprazole magnesium patent (EP 1020461) is invalid in France. Ethypharm S.A. filed a law suit against AstraZeneca in August 2010 claiming that the *Nexium* esomeprazole magnesium patent (EP 1020461) and the cloud point patent (EP 1124539) are invalid in France. The next hearing in these cases will be on 17 March 2011.

In Belgium, AstraZeneca was served in October 2010 with a revocation action by Teva Pharmaceutical Industries Ltd and Teva Pharma Belgium NV claiming that the *Nexium* esomeprazole magnesium patent (EP 1020461) is invalid in Belgium. The next hearing is scheduled for 23 September 2011.

#### Patent litigation - EU: 6-year countries

In Denmark, Sandoz A/S (Sandoz) launched its generic product in June 2009 and AstraZeneca filed a request for a preliminary injunction in the same month. In January 2010, the court granted AstraZeneca a preliminary injunction preventing Sandoz from continuing to sell the products based on an infringement of a Nexium esomeprazole magnesium patent (EP 1020461). Sandoz appealed this decision and the appeal will be heard on 22 to 25 February 2011. In March 2010, the court granted a preliminary injunction based on infringement of a Nexium process patent (EP 0773940). Sandoz appealed this decision and the appeal was heard on 17 to 24 January 2011. The decision will be announced on 28 February 2011. In July 2010, AstraZeneca filed an application with the District Court of Copenhagen, seeking an interlocutory injunction to restrain Krka Sverige AB from selling and marketing its generic esomeprazole magnesium products in Denmark. The hearing took place in November 2010. On 10 December 2010, the court denied AstraZeneca's request for a preliminary injunction. AstraZeneca has appealed this decision.

In Austria, Hexal Pharma GmbH and 1A Pharma GmbH (both in the Sandoz group) launched generic products in October 2009. Requests for preliminary injunctions were filed in December 2009. Preliminary injunctions have been granted by the Vienna Commercial Court against Hexal Pharma GmbH on 10 March 2010 and against 1A Pharma GmbH on 11 March 2010. The decisions were appealed by the Sandoz companies. The Higher Regional Court of Vienna upheld the injunction against 1A Pharma GmbH in July 2010 and against Hexal Pharma GmbH in September 2010. In December 2010, the Supreme Court rejected 1A Pharma GmbH's request for extraordinary appeal. In July 2010, AstraZeneca filed an application for a preliminary injunction to be granted against Krka Pharma GmbH and Krka, d.d., Novo Mesto. In October 2010, the Vienna Commercial Court granted the preliminary injunction against Krka Pharma GmbH. This decision has been appealed by Krka Pharma GmbH. The case is still pending against Krka, d.d., Novo Mesto. On 29 November 2010, a similar request for a preliminary injunction was filed with the Vienna Commercial Court against ratiopharm Arzneimittel Vertriebs-GmbH.

In July 2008, AstraZeneca initiated a declaratory action in Finland requesting the District Court of Helsinki 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 (all in the Sandoz group) initiated an invalidity case requesting the Court to invalidate the same patent. These cases will be heard jointly and were scheduled to be heard in September 2010. The hearing has been postponed to a date to be determined later.

25 Commitments and contingent liabilities continued

AstraZeneca initiated similar declaratory actions in Finland at the District Court of Helsinki against Ranbaxy (UK) Limited in December 2009, against Mylan AB in March 2010, against Stada Arzneimittel AG in April 2010 and against Teva Sweden AB on 17 January 2011, requesting an order that these companies would infringe a patent relating to esomeprazole if they were to commercialise their generic products in Finland.

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 products. In October 2009, the Court granted AstraZeneca a preliminary injunction suspending the efficacy of the marketing authorisations and the price approvals for Sandoz Farmacêutica Limitada's generic esomeprazole magnesium products. The decision was appealed by the Portuguese authorities. In a decision on 22 December 2010, the court upheld the preliminary injunction. In January 2010, Mepha AG and Mepha Investigacao Fabricacao Farmacêutica, Limitada filed a nullity action to revoke the esomeprazole magnesium patent (EP 1020461) for Nexium. In February 2010, AstraZeneca filed a similar request for a preliminary injunction regarding the marketing approval for Mepha Farmacêutica Limitada. The preliminary request was denied by the Court in June 2010. AstraZeneca has appealed this decision.

During 2009, Lek Farmacevtska Druzba d.d. (a company within the Sandoz group), (Lek) initiated an invalidity case regarding two esomeprazole related patents in Slovenia. AstraZeneca filed a request for an interlocutory injunction in January 2010 against Lek to restrain this company from commercialising, manufacturing and selling products containing esomeprazole magnesium in Slovenia. The interlocutory injunction was granted in June 2010. Lek appealed in July 2010, and in September 2010 the Appeal Court upheld the injunction. In July 2010, AstraZeneca filed an application with the District Court of Ljublijana in Slovenia seeking an interlocutory injunction to restrain Krka, d.d., Novo Mesto from manufacturing and selling generic esomeprazole magnesium products. On 20 October 2010, the court rejected the request for an injunction. AstraZeneca appealed this decision on 28 October 2010.

In Spain, AstraZeneca filed a request for a preliminary injunction in April 2010 against Sandoz Farmacéutica S.A., Bexal Farmacéutica S.A., and Acost Comercial Genericpharma, S.L. (all in the Sandoz group) to restrain the companies from selling their generic esomeprazole magnesium products in Spain. In May 2010, the Court of Barcelona granted AstraZeneca a preliminary injunction against these Sandoz companies. A hearing in court took place in July 2010. Six days later, the court revoked the preliminary injunction. AstraZeneca has appealed.

In Poland, AstraZeneca filed in May 2010 a request for an interlocutory injunction against Lek Farmacevtska Druzba d.d. and Sandoz GmbH (both in the Sandoz group) to restrain them from manufacturing, using and selling their generic esomeprazole magnesium product in Poland. In June 2010, the application was granted regarding commercialising the product. AstraZeneca has appealed to have the injunction extended to manufacturing and Lek and Sandoz appealed in August 2010. In November 2010, the Appeal Court denied both appeals and thereby confirmed the interlocutory injunction.

In Ireland, AstraZeneca initiated a main action in August 2010 against Krka, d.d., Novo Mesto and Pinewood Laboratories Ltd claiming that the sale and marketing of their generic esomeprazole magnesium products infringes the *Nexium* esomeprazole magnesium patent (EP 102046). In Estonia, AstraZeneca filed a request for an interlocutory injunction in June 2010 against Krka, d.d., Novo Mesto (Krka) to restrain this company from commercialising its magnesium esomeprazole product in Estonia. In July 2010, the court granted the requested interlocutory injunction. Krka appealed. In September 2010, the Appeal Court rejected the appeal and upheld the injunction. Krka, d.d., Novo Mesto filed an appeal with the Supreme Court, which denied leave to appeal. In July 2010, AstraZeneca filed a similar request for an interlocutory injunction against Krka in Lithuania. In July 2010, the injunction was granted. In September 2010, Krka appealed. Krka and Zentiva k.s. have challenged *Nexium* esomeprazole magnesium patents in courts in Estonia, Latvia and Lithuania. In January 2011, Zentiva k.s. waived its invalidity claim in Lithuania.

#### Patent litigation - Norway

In Norway, Hexal AG, Sandoz AS and Sandoz A/S (together, Sandoz) initiated an invalidity case regarding two esomeprazole related patents in July 2008. In December 2009, the Court of Oslo invalidated a formulation patent while it upheld a substance patent related to esomeprazole. Both parties have appealed and the case was heard by the Appeal Court in January 2011. In September 2010, AstraZeneca filed a request for an interlocutory injunction against Krka Sverige AB to restrain the company from marketing and selling its generic esomeprazole magnesium product in Norway. In December 2010, the Court granted AstraZeneca's application, thereby prohibiting Krka Sverige AB's commercialisation of its generic esomeprazole product in Norway. Krka Sverige AB has appealed this decision.

#### Patent proceedings

In July 2009, the European Patent Office (EPO) published the grant of two patents that relate to *Nexium* (EP 1020461) and *Nexium i.v.* (EP 1020460). 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 claims of EP 1020461 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.

The period for filing Notices of Opposition to the grant of these patents expired in April 2010. Thirteen Notices of Opposition have been filed in relation to EP 1020461 and six Notices of Opposition in relation to EP 1020460. No hearing date has been set.

#### European Commission Investigation

On 30 November 2010, the European Commission commenced an investigation relating to certain alleged practices regarding Nexium and dawn raided several AstraZeneca sites. The European Commission is investigating whether AstraZeneca may have acted individually or jointly to delay generic entry, in alleged breach of Articles 101 and/or 102 of the Treaty on the Functioning of the European Union, which prohibit anti-competitive practices between third parties and abuse of a dominant position. Dawn raids are a preliminary step in investigating suspected anti-competitive practices. The European Commission is continuing its investigation. AstraZeneca remains of the view that the investigation is unfounded and that it has complied with all relevant competition laws. AstraZeneca has, in accordance with its corporate policy, co-operated with the European Commission's investigation. AstraZeneca will continue to co-operate with the European Commission should it decide to take the matter further.

#### 25 Commitments and contingent liabilities continued

Dutch Competition Authority Nexium investigation On 30 November 2010, the Dutch Competition Authority (NMa) commenced an investigation relating to alleged breach of Article 24 of Dutch competition law and Article 102 of the Treaty on the Functioning of the European Union. The NMa's investigation relates to alleged foreclosure of generic versions of certain proton pump inhibitors (PPIs). The NMa is continuing its investigation. AstraZeneca remains of the view that the investigation is unfounded and that it has complied with all relevant competition laws. AstraZeneca has, in accordance with its corporate policy, co-operated with the NMa's investigation. AstraZeneca will continue to co-operate with the NMa should it decide to take the matter further.

#### Federal Trade Commission (FTC) inquiry

In July 2008, AstraZeneca received a Civil Investigative Demand from the FTC seeking information regarding the *Nexium* patent litigation settlement with Ranbaxy (UK) Limited. AstraZeneca is co-operating fully with the request.

#### Pulmicort Respules (budesonide inhalation suspension)

In 2008, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Breath Ltd. (now owned by Watson Pharmaceuticals) (Watson) for patent infringement resulting from an ANDA filed by Watson seeking approval to market generic copies of *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents.

In 2009, AstraZeneca filed a patent infringement lawsuit in the US District Court for the District of New Jersey against Apotex Inc. and Apotex Corp. (together, Apotex Group) seeking declaratory judgments and injunctive relief following the FDA's approval of Apotex Group's ANDA for a generic version of *Pulmicort Respules* in the US prior to the expiration of AstraZeneca's patents. In May 2009, due to concerns about Apotex Group's intent to market its generic ANDA product, AstraZeneca obtained a preliminary injunction barring Apotex Group from launching its generic version of *Pulmicort Respules* until further order of the Court. In November 2010, the Court of Appeals for the Federal Circuit affirmed the District Court's decision to issue a preliminary injunction. Apotex Group has filed a petition in the Court of Appeals for rehearing *en banc*.

In April 2009, AstraZeneca listed in the FDA's Orange Book a newly issued US 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 litigation involving Apotex Group and Watson has been consolidated under a common scheduling order. In December 2010, the Court scheduled a claim construction hearing to commence on 9 May 2011.

In September 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Sandoz Inc. notifying AstraZeneca that it was seeking approval to market a generic version of 0.25, 0.50 and 1mg doses of *Pulmicort Respules* prior to expiration of the patents covering *Pulmicort Respules*. In November 2010, AstraZeneca commenced patent infringement litigation against Sandoz Inc. in the US District Court for the District of New Jersey.

#### Seroquel (quetiapine fumarate)

AstraZeneca has made provisions in the year totalling \$592m in respect of the ongoing *Seroquel* product liability litigation and state attorney general investigations into sales and marketing practices in the aggregate.

#### Sales and marketing practices

As previously reported, AstraZeneca reached a civil settlement with the US Attorney's Office (Department of Justice) and the state Attorneys General National Medicaid Fraud Control Unit (NMFCU) to resolve an investigation relating to the marketing of *Seroquel*, pursuant to which AstraZeneca paid to the United States Federal Government a fine of \$302m plus accrued interest and to participating states a proportional share of up to \$218m plus accrued interest. In September 2010, AstraZeneca entered into individual settlement agreements with 41 states and Washington, D.C. for an aggregate amount of approximately \$210m.

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 NMFCU. AstraZeneca has reached an agreement in principle to settle *Seroquel*-related state consumer protection and deceptive trade practice claims under state law with 37 states and Washington, D.C., as part of the National Association of Attorneys General and has recorded a provision for the agreed amount. Some states may also be conducting individual investigations.

Some states are separately suing AstraZeneca. As previously reported, the Commonwealth of Pennsylvania and the states of Arkansas, Montana, New Mexico, South Carolina, Mississippi and Utah have sued AstraZeneca under various state laws generally alleging that AstraZeneca made false and/or misleading statements in connection with the marketing and promotion of *Seroquel*. In December 2010, the State of Alaska also sued AstraZeneca, making similar allegations. In September 2010, the Commonwealth of Pennsylvania voluntarily dismissed its lawsuit, and in December 2010, a federal judge dismissed Utah's suit in its entirety and gave the State until 2 February 2011 to amend its complaint and refile. AstraZeneca believes that the remaining claims, which are in various stages of litigation, are without merit and intends to vigorously defend them.

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 Seroguel 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. The plaintiffs have appealed this decision. AstraZeneca intends to vigorously defend the appeal, which was heard by the Eleventh Circuit Court of Appeals in February 2010 and remains pending.

In September 2008, the Pennsylvania Employees Benefit Trust Fund (PEBTF) served AstraZeneca 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 the 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 elected to forego a federal appeal of that decision, and instead pursued an appeal in the Pennsylvania Superior Court on the dismissal of an earlier-filed state court action. In August 2010, PEBTF voluntarily dismissed its appeal to the Pennsylvania Superior Court. Overview

#### **25 Commitments and contingent liabilities** continued Product liability

AstraZeneca, 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.

AstraZeneca has defended *Seroquel* product liability litigation in federal courts, including a Multi-District Litigation (MDL) in the Middle District of Florida, as well as in multiple state courts, including Delaware, New York and New Jersey courts, where cases were consolidated in order to manage the large volume of claims pending in those jurisdictions.

As of 31 December 2010, AstraZeneca was aware of approximately 3,950 *Seroquel* US product liability claims that have not been settled in principle (see below). The majority of these remaining claims are pending in New Jersey and New York state courts, although some claims are pending in a handful of other state courts and in the federal MDL. Some of the cases pending against AstraZeneca also include claims against other pharmaceutical manufacturers such as Eli Lilly & Company, Janssen Pharmaceutica, Inc. and/or BMS. At present, trial dates remain pending in multiple jurisdictions, including New Jersey and New York, beginning mid 2011 and continuing through 2012.

There are four additional putative Canadian class actions raising allegations that AstraZeneca failed to provide adequate warnings in connection with an alleged association between *Seroquel* and the onset of diabetes. These actions have been filed in the Canadian provinces of British Columbia, Alberta, Ontario and Quebec. The Quebec court dismissed the action, and the petitioner's appeal of that decision is scheduled for hearing in April 2011. A class certification hearing has been set in the Ontario action for the week of 21 November 2011.

In September 2010, the court presiding over the Delaware *Seroquel* litigation issued an opinion dismissing three cases on the basis that the claims were time-barred under the statute of limitations.

The only case that has gone to trial resulted in a defence verdict in favour of AstraZeneca. The plaintiffs have appealed that verdict, and the appeal is pending before the New Jersey appellate court.

In November 2009, Judge Anne Conway, who is presiding over the *Seroquel* federal MDL, ordered the parties to mediate their claims with a court-appointed mediator. AstraZeneca remains committed to a strong defence effort, but will also continue to participate in good faith in the court-ordered mediation process.

As of 31 December 2010, the mediation process has resulted in agreements in principle on monetary terms, subject to various subsequent conditions, approvals and agreement on non-monetary terms, with the attorneys representing 24,591 claimants. The claims that have settled in principle include both claims that have been filed in the courts as well as claims that had not yet been filed. The specific terms of those conditional agreements in principle are by agreement, and at the request of the mediator, confidential at this time. Written settlement agreements have been finalised in connection with 18,072 claims and payments have been made in connection with certain of those claims. The parties are finalising written settlement agreements in respect of the other claims that have been resolved in principle. The mediation process is ongoing with regard to other currently unsettled claims.

A provision has been established in respect of the *Seroquel* product liability claims regarding both current and anticipated future settlement costs as well as anticipated future defence costs associated with resolving all or substantially all remaining claims. The amount of this provision remains subject to a number of significant uncertainties and is based on AstraZeneca's best estimate of (1) the number of claims that are outstanding and may be subject to mediation, (2) the financial terms of any future agreements to settle claims not subject to settlement agreements in principle at the balance sheet date, and (3) the likely cost of defending those claims and finalising settlement agreements through to substantial completion. Each of these estimates is subject to future adjustment based on multiple variables, such as the number of asserted claims, the success of future mediations, and further developments in the litigation. It is therefore not possible at this time to provide any reasonable indication as to when remaining claims may be settled. Furthermore, it is possible that the actual cost of ultimately settling or adjudicating the *Seroquel* product liability claims may differ significantly from the total amount provided.

As of 31 December 2010, legal defence costs of approximately \$738m have been incurred in connection with *Seroquel*-related product liability claims.

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 cover for legal defence costs and potential damages amounts. The insurers that issued the applicable policies for 2003 have disputed coverage for *Seroquel*-related product liability claims on various grounds. In April 2010, AstraZeneca settled its claims against several of its insurers for legal costs incurred defending the *Seroquel*-related product liability claims immediately in excess of AstraZeneca's self-insured retention of \$39m for an amount approximately equal to the receivable that had been recorded at 31 December 2009.

Disputes continue with insurers about the availability of coverage under additional insurance policies. As of 31 December 2010, legal costs of approximately \$123m have been incurred in connection with *Seroquel*-related product liability claims which AstraZeneca believes to be covered by these additional insurance policies. However, the combined amount charged to the income statement to date in respect of legal costs and settlements which AstraZeneca believes to be covered by these additional policies, including the provisions taken in the third and fourth quarters of 2010, now significantly exceeds the total stated upper limits of these insurance policies.

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

#### Patent litigation - 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. A preliminary order was granted shortly thereafter. At the end of July 2010, Pró Genéricos and the Brazilian Patent Trademark Office (Brazilian PTO) appealed the preliminary order granted in favour of AstraZeneca. The judge decided in favour of Pró Genéricos and the Brazilian PTO. AstraZeneca appealed this decision. In November 2010, the Court of Appeal decided in favour of Pró Genéricos and the Brazilian PTO and revoked the prelimary order previously granted to AstraZeneca. The main action continues.

#### 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 marketing authorisations in the preliminary injunction suntil a definitive decision on the merits in the main actions (or until AstraZeneca's patent rights expire, in March 2012, if

#### 25 Commitments and contingent liabilities continued

this occurs first). Only in one case did the administrative courts not suspend the grant of the marketing authorisation (decision of December 2009, confirmed in July 2010). Accordingly, the Portuguese administrative bodies have granted the retail price in respect of that product. In July and November 2010, AstraZeneca filed preliminary injunction proceedings with the aim of suspending the effect of the retail price decision. AstraZeneca has filed corresponding main actions.

#### Seroquel XR

#### Patent litigation - US

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.

As previously reported, in 2008 and 2009, AstraZeneca filed patent infringement actions in the US District Court for the District of New Jersey against various entities of Handa Pharmaceuticals, LLC (Handa), Accord Healthcare Inc. (Accord), and Biovail Laboratories International SRL (Biovail) for ANDAs seeking approval to market generic copies of *Seroquel XR* tablets.

In March 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Anchen Pharmaceuticals, Inc. (Anchen) seeking approval to market generic versions of 150, 200, 300 and 400mg *Seroquel XR* tablets before the expiration of the '437 patent. In its Certification notice-letter, Anchen claims that certain of the claims of the '437 patent will not be infringed by its proposed ANDA products and that the '437 patent is invalid. In April 2010, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Anchen and Anchen, Inc. alleging infringement of the '437 patent.

In July 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Torrent Pharmaceuticals Ltd. (Torrent) indicating that it was seeking approval to market generic versions of 150, 200, 300 and 400mg Seroquel XR tablets before the expiration of the '437 patent. Torrent claims that certain of the claims of the '437 patent will not be infringed by its proposed ANDA products and that the '437 patent is invalid. In August 2010, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Torrent alleging infringement of the '437 patent. In September 2010, AstraZeneca received another Certification notice-letter similar to that described above from Torrent with respect to the 50mg Seroquel XR tablets. In September 2010, AstraZeneca filed another lawsuit in the US District Court for the District of New Jersey against Torrent for patent infringement alleging infringement of the '437 patent with respect to the 50mg tablet.

In July 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Osmotica Pharmaceutical Corporation (Osmotica) indicating that it was seeking approval to market generic versions of 200, 300 and 400mg *Seroquel XR* tablets before the expiration of the '437 patent. In its Certification notice-letter, Osmotica claims that certain of the claims of the '437 patent will not be infringed by its proposed ANDA products and that the '437 patent is invalid. In August 2010, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Osmotica.

In October 2010, AstraZeneca received a Paragraph IV Certification notice-letter from Mylan Pharmaceuticals Inc. (Mylan) indicating that it was seeking approval to market a generic version of 200mg *Seroquel XR* tablets before the expiration of the '437 patent. In its Certification notice-letter, Mylan claims that certain of the claims of the '437 patent will not be infringed by its proposed ANDA products and that the '437 patent is invalid. In October 2010, AstraZeneca filed a patent infringement action in the US District Court for the District of New Jersey against Mylan and Mylan Inc. The patent infringement actions against all seven ANDA filers proceed in discovery before US District Court Judge Joel Pisano.

On 22 November 2010, the Court conducted a claim construction hearing, and on 30 November 2010, Judge Pisano issued a decision interpreting claims of the '437 patent. In December 2010, Torrent filed a Motion for Clarification and Reconsideration of the Court's decision in response.

In December 2010, Handa and Accord reported that they have received tentative FDA approval of their ANDAs.

On 8 January 2011, AstraZeneca and Handa submitted a joint stipulation and proposed order concerning the '288 patent staying litigation between the parties until and including 26 March 2012. Upon expiration of the stay, AstraZeneca's infringement claims against Handa relating to the '288 patent, and Handa's related counterclaims, will be dismissed as moot. Under the stipulation, Handa agrees not to engage in the commercial sale of the extended release quetiapine fumarate products that are the subject of its ANDA before the 26 March 2012 expiration of AstraZeneca's Paediatric Exclusivity relating to the '288 patent. The Court entered the consent order described above on 10 January 2011. The Court has set a pre-trial schedule and trial to begin on 3 October 2011.

#### Patent litigation – EU

In the UK, Teva UK Limited and Teva Pharmaceuticals Limited (Teva) issued revocation proceedings against AstraZeneca in December 2010. Teva claims that the patent EP (UK) 0907364 is invalid.

In Hungary, AstraZeneca was notified in late 2010 that Teva Pharmaceuticals Limited and Teva Gyógyszergyár Zrt (together, Teva) had filed a request for nullity of the Hungarian formulation patent for *Seroquel XR* with the Hungarian Patent Office. Teva claims that Hungarian Patent No. 225 152 should be declared null and void. AstraZeneca is considering its response.

#### 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 sought 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 the more favourable royalty terms that MedImmune contends 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, an action PDL later explained was based on an allegation that Medlmmune had underpaid royalties on ex-US sales of Synagis by Abbott International, Inc. (Abbott), and that MedImmune failed to co-operate in a royalty audit. After the purported termination, PDL amended its answer to add counterclaims for breach of contract and patent infringement. PDL's claims seek actual and exemplary damages and an injunction. MedImmune responded to the new claims by adding its own claims for damages and recoupment of past royalties. In December 2010, the Court heard motions for summary judgment that could resolve certain issues, including patent invalidity, without a trial. On 7 January 2011, the Court granted some of those motions. The Court held that the single patent claim asserted by PDL as a basis for MedImmune's royalty obligation is invalid, and also that MedImmune properly paid royalties on ex-US sales by Abbott. On 12 January 2011, the Court held a case management conference and scheduled

#### 25 Commitments and contingent liabilities continued

the remaining claims for trial on 4 March 2011 with a further hearing scheduled on 4 February 2011 to finalise the trial date.

As at 31 December 2010, MedImmune had provided for \$38m in respect of accrued royalties not paid to PDL for the period from December 2009 to the end of 2010.

#### Symbicort (budesonide/formoterol)

Symbicort Maintenance and Reliever Therapy (Symbicort SMART) In December 2008, oppositions were filed against patent EP 1 085 877 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 European Patent Office 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 and the matter continues.

#### Toprol-XL (metoprolol succinate)

In the first quarter of 2006, AstraZeneca was served with 14 complaints filed in the US District Court for the Districts of Delaware, Massachusetts and Florida against AstraZeneca and Aktiebolaget Hässle. The complaints were putative class actions filed on behalf of both direct purchasers and indirect purchasers that allege that AstraZeneca 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 for the District of 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 Pharmaceuticals Co., Andrx Pharmaceuticals, LLC and Eon Labs, Inc. 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 cases. In March 2010, the court ordered the parties to begin discovery and in April 2010 issued an order denying AstraZeneca's motions to dismiss.

In July 2010, a non-class action anti-trust complaint was filed in federal court in Delaware against AstraZeneca by Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company LLP and Supervalu Inc. In October 2010, a similar complaint was filed in Delaware by CVS Pharmacy Inc., Caremark LLC, Rite Aid Corp, Rite Aid Headquarters Corp, JCG (PJC) USA LLC, Maxi Drug, Inc. (doing business as, Brooks Pharmacy) and Eckerd Corp. These two complaints are based on the same anti-trust allegations that were already alleged in the direct purchaser actions and, if upheld, would reduce the damages available to the plaintiffs in the direct purchaser actions.

#### 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 Inc. (Apotex), alleging infringement of Merck Group's lisinopril patent. AstraZeneca and the Merck Group were ultimately successful. In March 2010, AstraZeneca and the Merck Group filed Statements of Issues to commence the reference to quantify the damages related to Apotex's infringement. The damages matter proceeds.

#### Other product liability litigation Pain pump litigation

Since February 2008, AstraZeneca has been named among other defendants in approximately 300 lawsuits, involving approximately 489 plaintiffs, filed in various US jurisdictions, alleging injuries caused by third party pain pumps. The complaints in these cases generally allege that the use of *Marcaine*, *Sensorcaine*, *Xylocaine* and/or *Naropin*, with or without epinephrine, in pain pumps that were implanted into patients in connection with arthroscopic surgery, caused chondrolysis. As of the end of 2010, AstraZeneca has been dismissed from all but two of these cases, each with only one plaintiff.

It was previously reported that AstraZeneca was among 20 defendants named in a putative class action lawsuit pending in Federal District Court in Texas that was brought by a single plaintiff on behalf of 'several hundred' class members who received local anaesthetics intra-articularly for up to 72 hours or more via a pain pump. In April 2010, the District Court dismissed AstraZeneca from this lawsuit, and no appeal was taken.

AstraZeneca intends to vigorously defend against this matter.

#### Other commercial litigation

#### Verus Pharmaceuticals litigation

In May 2009, Verus Pharmaceuticals Inc. (Verus) filed a lawsuit in the New York State Supreme Court, New York County against AstraZeneca and its subsidiary, Tika Läkemedel AB (Tika), alleging breaches of several related collaboration agreements to develop novel paediatric asthma treatments. The complaint purported to state claims for fraud, breach of contract, unjust enrichment and conversion. AstraZeneca and Tika removed the lawsuit to the US District Court for the Southern District of New York and moved to dismiss the complaint. In August 2010, the federal district court granted the defendants' motion to dismiss in its entirety. In September 2010, Verus filed a Notice of Appeal from that decision with the US Court of Appeals for the Second Circuit.

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

In May 2010, Dr. George Pieczenik (the Plaintiff) filed a lawsuit against AstraZeneca and numerous other companies in the US District Court for the District of New Jersey alleging that defendants' 'research, commercial and licensing activities' infringe US Patent No. 5,866,363 (the '363 patent), purportedly owned by the Plaintiff. The Plaintiff also alleged violations of the Racketeering Institution and Corrupt Organization Act. In June 2010, the Court, sua sponte, dismissed without prejudice the Plaintiff's suit, determining that the asserted claims failed to meet federal pleading requirements. In July 2010, the Plaintiff filed an amended complaint again claiming infringement of the '363 patent as well as other legal theories. In October 2010, defendants filed a motion to dismiss the lawsuit asserting that the Plaintiff had failed to state a legally cognisable cause of action. The Plaintiff opposed the motion in November 2010 and filed several unsuccessful ancillary motions, which the Plaintiff has improperly appealed to the Federal Circuit Court. The Court has not yet ruled on the motion to dismiss the amended complaint.

#### Other pricing litigation

#### 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.

25 Commitments and contingent liabilities continued 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 were consolidated with the Massachusetts action for pre-trial purposes, pursuant to federal Multi-District Litigation (MDL) procedures. As previously reported, 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. In September and November 2010 respectively, AstraZeneca was separately served with two new such cases brought by the Attorneys General of Oklahoma and Louisiana. The Attorneys 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 were consolidated with the Massachusetts action for pre-trial purposes, pursuant to federal MDL procedures. Private insurers and consumers filed putative statewide 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 AstraZeneca: a nationwide class of consumers who made co-payments for *Zoladex* reimbursed under the Medicare Part B programme (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). In September 2008, the MDL Court also provisionally certified multi-state versions of Class 2 and Class 3 relating to *Zoladex*. For all of these classes, the only AstraZeneca drug at issue is *Zoladex*.

As previously reported, in December 2008, the MDL Court approved a settlement to resolve the Class 1 claims for up to \$24m to reimburse individual class members submitting claims, plus attorneys' fees of \$8.58m, with any unclaimed settlement amounts being donated to charitable organisations that fund cancer patient care and research. A portion of this settlement was paid in June 2010, but the administration of claims continues.

In June 2007 and November 2007, the MDL Court issued decisions, after a bench trial, on liability and damages on the Massachusetts Classes 2 and 3. The Court found AstraZeneca liable in connection with the pricing of *Zoladex* during the period 1998 to 2003 and 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. On 18 June 2010, AstraZeneca executed a settlement agreement to resolve, inclusive of pre- and post-judgment interest, administration fees and plaintiffs' attorney fees, the Massachusetts Class 2 and Class 3 claims for a total of \$13m. The Court granted preliminary approval of the settlement on 12 August 2010 and a hearing regarding final approval is scheduled to take place on 2 February 2011.

In June 2010, AstraZeneca executed a settlement agreement to resolve, inclusive of pre- and post-judgment interest, administration fees and plaintiffs' attorney fees, both the *Zoladex* claims of the provisionally certified multi-state class and the *Zoladex* claims in the lawsuit but not certified for class action treatment for a total of \$90m. The Court granted preliminary approval of the settlement on 12 August 2010. A hearing regarding final approval is scheduled to take place on 2 February 2011.

With regard to the above-referenced MDL class settlements, AstraZeneca had already taken provisions, prior to 2010, in the aggregate amount of approximately \$130m.

Many of the multiple attorney general and state putative class action 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.

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 and the trial court subsequently awarded statutory penalties of \$5.4m. AstraZeneca filed a motion for a new trial and a motion for judgment notwithstanding the verdict, both of which were denied on 19 January 2011. AstraZeneca believes the verdict and the Court's order are in error and intends to appeal.

As previously reported, the cases brought by the Attorneys General of Nevada, Montana, Hawaii, and Pennsylvania have been resolved through settlements. In the fourth quarter of 2010, AstraZeneca finalised agreements to settle the lawsuits brought by Arizona, Iowa, and the New York Counties. In September 2010, AstraZeneca also finalised an agreement to settle the claims of the three named plaintiffs in the putative New Jersey consumer class action case. All of these settlements, the aggregate amount of which is approximately \$19m, have been paid in full and AstraZeneca consequently owes no further obligations as a result of those underlying lawsuits.

As previously reported, in 2009 AstraZeneca prevailed in the Alabama Attorney General lawsuit and the Arizona consumer class action.

AstraZeneca remains in litigation with 10 state attorney generals.

AstraZeneca continues to vigorously defend the lawsuits brought by the Attorneys General of Alaska, Idaho, Illinois, Kansas, Kentucky, Louisiana, Mississippi, Oklahoma, Utah and Wisconsin, and denies the allegations therein.

#### 340B Class Action litigation

In August 2005, AstraZeneca was named as a defendant, along with multiple other pharmaceutical manufacturers, in a putative 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 federal section 340B of the drug pricing programme (42 USC §256b). The 340B programme entitles hospitals and clinics that treat a substantial portion of uninsured patients to preferential drug pricing for outpatient drugs.

On 28 September 2010, the US Supreme Court granted the defendants' petition for *certiorari* from a decision of the US Court of Appeals for the Ninth Circuit. The issue before the Supreme Court is whether covered entities under the 340B programme have enforceable rights to sue as third party beneficiaries of the Pharmaceutical Pricing Agreement that implements the statute. Following the grant of *certiorari*, the trial court stayed all proceedings in the matter pending a decision by the US Supreme Court.

The case was argued on 19 January 2011. A decision is expected by the end of June 2011.

AstraZeneca intends to vigorously defend these claims.

#### **25 Commitments and contingent liabilities** continued **Other anti-trust litigation and investigations** 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 determining that any alleged damages suffered by plaintiffs were 'passed-on' to their customers and the case was subsequently dismissed. The plaintiffs appealed that decision and the Court of Appeal of the State of California affirmed the lower Court's decision. The plaintiffs appealed to the California Supreme Court. In July 2010, the California Supreme Court reversed the decisions by the lower courts, rejecting the 'pass-on' defence and remanded the case back to the lower court for further proceedings.

As previously reported, in September 2006, the defendants filed a motion for summary judgment arguing that the plaintiffs have failed to prove their allegations of a conspiracy and that the defendants are entitled to judgment as a matter of law. The Superior Court will hear argument on that motion on 17 February 2011. The Court has scheduled a trial of the matter to commence on 1 August 2011.

AstraZeneca denies the material allegations in the California action and is vigorously defending this matter.

#### US secondary wholesalers

In July 2006, AstraZeneca 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. In August 2010, the Court of Appeal for the Second Circuit affirmed the dismissal and the time period for RxUSA to seek review by the Supreme Court expired, rendering the matter concluded.

#### European Commission patent settlements monitoring

In January 2010, the European Commission requested copies of settlement agreements entered into between July 2008 and December 2009 from a number of companies, including AstraZeneca. AstraZeneca co-operated fully with the request. The European Commission published its First Report on Monitoring of Patent Settlements in July 2010. The report noted a decrease in the number of settlement agreements which might be problematic (pursuant to EU competition laws) in the relevant period, compared to the period covered by the European Commission's sector inquiry into the pharmaceutical industry (January 2000-June 2008). In January 2011, the European Commission requested copies of settlement agreements which were entered into or amended in 2010 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.

# Other actual and threatened government investigations and related litigation

AstraZeneca is involved in various governmental investigations considered typical to its business. The more significant matters are discussed below.

#### Foreign Corrupt Practices Act

In connection with an investigation into Foreign Corrupt Practices Act issues in the pharmaceutical industry, AstraZeneca has received inquiries from the US Department of Justice and the SEC regarding, among other things, sales practices, internal controls, certain distributors and interactions with healthcare providers in several countries. AstraZeneca is co-operating with these inquiries. AstraZeneca is investigating indications of inappropriate conduct in certain countries, including China. These investigations are ongoing, and it is not currently possible to predict the scope, duration or outcome of these matters, including the extent to which, if at all, they will result in any liability to AstraZeneca.

#### Medco qui tam litigation (Schumann)

AstraZeneca has been named as a defendant in a lawsuit filed in Federal Court in Philadelphia 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. In October 2010, the district court denied AstraZeneca's motion to dismiss the amended complaint. In November 2010, AstraZeneca filed a separate motion to dismiss for lack of jurisdiction under the False Claims Act. Briefing is complete and this motion remains pending before the district court.

#### 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. The US Attorney's Offices for the Districts of Delaware, Texas and Alabama are conducting investigations related to sales and marketing activities potentially involving more than one product, including *Crestor* and *Seroquel XR*, and likely in response to the filing of *qui tam* (whistleblower) lawsuits. The precise parameters of these inquiries are unknown, and AstraZeneca is not in a position at this time to predict the scope, duration or outcome of these matters, including whether they will result in any liability to AstraZeneca.

In addition to the investigations described above, and as previously reported, various federal and state law enforcement offices have requested information relating to contracting and disease management programmes, a leading provider of pharmacy services to long-term care facilities, prior interactions with physicians in the State of Delaware, and nominal pricing under the Medicaid rebate program respectively. There have been no material developments in these matters.

#### **Employment litigation**

#### Employment - wage/hour litigation

In September 2006, Marc Brody filed a putative class action lawsuit against AstraZeneca 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 the present. The plaintiff alleged he and the proposed class members were unlawfully classified as exempt employees and denied overtime compensation and meal breaks in violation of the California Labor 25 Commitments and contingent liabilities continued 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, seeking civil penalties and adding claims for alleged 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 and unfair competition. AstraZeneca denied 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. 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 the plaintiff and finding the motion for class certification to be moot. The plaintiff has filed a Notice of Appeal with the Ninth Circuit Court of Appeals in California. Briefing in that appeal is currently on hold.

In separate lawsuits against AstraZeneca, the firms representing the Brody plaintiff filed additional state and wage-and-hour class actions. One case 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 a putative class of approximately 473 sales specialists working in Pennsylvania from March 2004. The Court, however, granted summary judgment in favour of AstraZeneca, dismissing all claims filed by plaintiff Baum and finding the motion for class certification to be moot. The plaintiff filed an appeal with the Third Circuit Court of Appeals, but that appeal was denied. On 4 October 2010, the US Supreme Court denied the plaintiff's *certiorari* petition, which denied *certiorari*, preserving the favourable decision for AstraZeneca. The Baum lawsuit is now concluded.

Additionally, in June 2007, the firms representing the Brody plaintiff filed a nationwide collective action based on federal wage-and-hour law 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 from June 2004. The parties have negotiated a stipulation of dismissal of this lawsuit and the action was dismissed.

In November 2010, a separate group of plaintiffs' counsel filed a new nationwide collective action in the US District Court for the Southern District of Indiana. In this case, Shatto v. AstraZeneca PLP, the plaintiffs allege violations of federal wage-and-hour law for non-payment of overtime wages. AstraZeneca denies the allegations made by the plaintiff and intends to defend the litigation vigorously.

#### Bildman v. Astra USA

In March 2010, Bildman filed a petition for a writ of *certiorari* with the US Supreme Court, seeking appeal of the Massachusetts Supreme Judicial Court's dismissal of his defamation claim against AstraZeneca. In May 2010, the US Supreme Court denied Bildman's petition for a writ of *certiorari*, declining to review the lower court's decision and preserving a favourable outcome for AstraZeneca.

#### Tax

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.

#### Transfer pricing and other international tax contingencies

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 Group Financial Statements to cover the worldwide exposure to transfer pricing audits is \$2,310m, a decrease of \$17m due to negotiated settlements offset by the impact of an additional year of transactions relating to contingencies for which accruals had already been established, revisions of estimates relating to existing audits, a number of new tax contingencies and exchange rate effects.

Tax accruals have been made in respect of two individually significant exposures:

- > The tax accrual at 31 December 2008 and 2009 included amounts in relation to a long running transfer pricing dispute between AstraZeneca and HM Revenue & Customs (HMRC) covering all periods from 1996 onwards. In February 2010, AstraZeneca announced that the company had entered into an agreement with HMRC in the UK to settle this dispute. As a consequence of the settlement, AstraZeneca and HMRC have withdrawn the joint referral of this issue to the UK Tax Court. The agreement will result in AstraZeneca paying £505m to HMRC to resolve all claims made by HMRC in relation to this issue for the 15-year period from 1996 to the end of 2010. The £505m settlement is payable in two instalments of which the first instalment of £350m (\$562m) was paid in February 2010. A second final instalment of £155m is due to be paid in March 2011 and is included in ordinary tax payable at 31 December 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 \$565m (2009: \$575m); however, management believes that it is unlikely that these additional losses will arise. It is possible that some of these contingencies may reduce in the future to the extent that any tax authority challenge is unsuccessful, or matters lapse following expiry of the relevant statutes of limitation resulting in a reduction in the tax charge in future periods.

#### Other tax contingencies

Included in the tax accrual is \$1,429m relating to a number of other tax contingencies, an increase of \$468m mainly due to the impact of an additional year of transactions relating to contingencies for which accruals had already been established and exchange rate effects. For these tax exposures, AstraZeneca does not expect material additional losses. It is, however, possible that some of these contingencies may reduce in the future if any tax authority challenge is unsuccessful or matters lapse following expiry of the relevant statutes of limitation resulting in a reduction in the tax charge in future periods.

#### Timing of cash flows and interest

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 \$608m (2009: \$565m). Interest is accrued as a tax expense.

#### 26 Leases

Total rentals charged to profit were as follows:

2010 \$m	2009 \$m	2008 \$m
212	198	206
	\$m	<b>2010</b> 2009 <b>\$m</b> \$m

The future minimum lease payments under operating leases that have initial or remaining terms in excess of one year at 31 December 2010 were as follows:

	2010 \$m	2009 \$m	2008 \$m
Obligations under leases comprise:			
No later than one year	161	132	101
Rentals due after more than one year:			
Later than five years	103	131	145
Later than one year and not later than five years	242	208	212
	345	339	357
	506	471	458

#### 27 Statutory and other information

	2010 \$m	2009 \$m	2008 \$m
Fees payable to KPMG Audit Plc and its associates: Group audit fee	2,3	2.4	3.2
Fees payable to KPMG Audit Plc and its associates for other services:	2.5	2.4	0.2
The audit of subsidiaries pursuant to legislation	6.5	6.6	7.1
Other services pursuant to legislation	3.3	2.9	3.3
Taxation	1.1	1.0	0.9
All other services	0.1	0.7	1.7
Fees payable to KPMG Audit Plc in respect of the Group's pension schemes:			
The audit of subsidiaries' pension schemes	0.6	0.5	0.6
	13.9	14.1	16.8

Other services pursuant to legislation include fees of \$2.4m (2009: \$2.3m; 2008: \$2.5m) 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 include 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 members of the Board and the members of the SET.

	2010 \$000	2009 \$000	2008 \$000
Short-term employee benefits	21,925	20,784	21,973
Post-employment benefits	1,793	2,080	2,290
Termination benefits	-	3,639	-
Share-based payments	11,563	12,547	13,210
	35,281	39,050	37,473

Total remuneration is included within employee costs (see Note 24).

#### Subsequent events

There were no material subsequent events.

# **Principal Subsidiaries**

At 31 December 2010	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
Novexel SA	France	100	Research
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 254 subsidiaries worldwide. Products are manufactured in 16 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 2010.

# 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 2010 set out on pages 199 to 203. 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 136, 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, and express an opinion on, 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/private.cfm.

#### **Opinion on financial statements**

In our opinion, the Parent Company Financial Statements:

- > Give a true and fair view of the state of the Company's affairs as at 31 December 2010.
- > 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 where the Companies Act 2006 requires us 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.
- > 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.

#### **Other matters**

We have reported separately on the Group Financial Statements of AstraZeneca PLC for the year ended 31 December 2010.

#### Jimmy Daboo

Senior Statutory Auditor

For and on behalf of KPMG Audit Plc, Statutory Auditor Chartered Accountants 15 Canada Square, London, E14 5GL

27 January 2011

# **Company Balance Sheet** at 31 December

#### AstraZeneca PLC

At 31 December	Notes	2010 \$m	2009 \$m
Fixed assets		+	
Fixed asset investments	1	25,232	25,230
Current assets			
Debtors – other		1	1
Debtors – amounts owed by Group undertakings		3,558	8,966
		3,559	8,967
Creditors: Amounts falling due within one year			
Non-trade creditors	2	(194)	(252)
Interest-bearing loans and borrowings	3	-	(1,790)
		(194)	(2,042)
Net current assets		3,365	6,925
Total assets less current liabilities		28,597	32,155
Creditors: Amounts falling due after more than one year			
Amounts owed to Group undertakings	3	(283)	(283)
Interest-bearing loans and borrowings	3	(8,486)	(8,582)
		(8,769)	(8,865)
Net assets		19,828	23,290
Capital and reserves			
Called-up share capital	6	352	363
Share premium account	4	2,672	2,180
Capital redemption reserve	4	107	94
Other reserves	4	3,020	2,922
Profit and loss account	4	13,677	17,731
Shareholders' funds	5	19,828	23,290

\$m means millions of US dollars.

The Company Financial Statements on pages 199 to 203 were approved by the Board on 27 January 2011 and were signed on its behalf by

**David R Brennan** Director

Simon Lowth Director

Company's registered number 2723534

# **Company 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 142 to 146.

The following paragraphs describe the main accounting policies under UK GAAP, which have been applied consistently.

#### New accounting standards

The Company has adopted the Amendments to FRS 20 (IFRS 2) 'Share-based Payment – Group Cash-settled Share-based Payment Transactions' during the year. The adoption had no impact on the net results or net assets of the Company.

The Amendments to FRS 25 (IAS 32) 'Financial Instruments: Presentation Classification of Rights Issues' has been issued but not yet adopted by the Company. 'Improvements to Financial Reporting Standards 2010' (November 2010) has also 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, the AstraZeneca Group 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 subsidiaries		
	Shares \$m	Loans \$m	Total \$m	
Cost and net book value at 1 January 2010	16,367	8,863	25,230	
Capital contribution	98	-	98	
Exchange	-	(100)	(100)	
Amortisation	-	4	4	
Cost and net book value at 31 December 2010	16,465	8,767	25,232	

#### 2 Non-trade creditors

		2010 \$m	2009 \$m
Amounts due within one year			
Short-term borrowings (unsecured)		12	12
Other creditors		169	226
Amounts owed to Group undertakings		13	14
		194	252
3 Loans			
	Repayment dates	2010 \$m	2009 \$m
Amounts due within one year Interest-bearing loans and borrowings (unsecured)			
Euros			
4.625% Non-callable bond	2010	-	1,073
5.625% Non-callable bond	2010	_	717
		-	1,790
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	1,747	1,744
5.4% Callable bond	2014	749	748
5.9% Callable bond	2017	1,744	1,743
6.45% Callable bond	2037	2,718	2,717
Euros			
5.125% Non-callable bond	2015	993	1,072
Pounds sterling			
5.75% Non-callable bond	2031	535	558
		8,486	8,582
		2010 \$m	2009 \$m
Loans or instalments thereof are repayable:			
After five years from balance sheet date		5,280	6,373
From two to five years		1,742	2,492
From one to two years		1,747	-
Within one year		-	1,790
Total unsecured		8,769	10,655

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.

Overview

#### 4 Reserves

	Share premium account \$m	Capital redemption reserve \$m	Other reserves \$m	Profit and loss account \$m	2010 Total \$m	2009 Total \$m
At beginning of year	2,180	94	2,922	17,731	22,927	22,981
Profit for the year	-	-	-	2,043	2,043	2,658
Dividends	-	-	-	(3,494)	(3,494)	(3,026)
Amortisation of loss on cash flow hedge	-	-	-	1	1	1
Share-based payment	-	-	98	-	98	179
Share repurchases	-	13	-	(2,604)	(2,591)	-
Share premium	492	-	-	-	492	134
At end of year	2,672	107	3,020	13,677	19,476	22,927
Distributable reserves at end of year	-	-	1,841	13,677	15,518	19,572

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 2010, \$13,677m (31 December 2009: \$17,731m) 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.

Included within other reserves at 31 December 2010 is \$1,179m (31 December 2009: \$1,081m) in respect of cumulative share-based payment awards. These amounts are not available for distribution.

#### 5 Reconciliation of movement in shareholders' funds

	2010 \$m	2009 \$m
At beginning of year	23,290	23,343
Net profit for the financial year	2,043	2,658
Dividends	(3,494)	(3,026)
Amortisation of loss on cash flow hedge	1	1
Share-based payment	98	179
Issue of AstraZeneca PLC Ordinary Shares	494	135
Repurchase of AstraZeneca PLC Ordinary Shares	(2,604)	-
Net decrease in shareholders' funds	(3,462)	(53)
Shareholders' funds at end of year	19,828	23,290

Details of dividends paid and payable to shareholders are given in Note 21 to the Group Financial Statements on page 167.

#### 6 Share capital

o onare capital	Allotted, called-up and fu	ully paid
	2010 \$m	2009 \$m
Issued Ordinary Shares (\$0.25 each)	352	363
Redeemable Preference Shares (£1 each – £50,000)	-	-
	352	363

At 31 December 2010, 1,409,023,452 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 share capital during the year can be summarised as follows:

	No. of shares (million)	\$m
At 1 January 2010	1,451	363
Issues of shares	12	2
Repurchase of shares	(54)	(13)
At 31 December 2010	1,409	352

#### Share repurchases

During the year, the Company repurchased 53,691,507 Ordinary Shares at an average price of 3111 pence per share (2009: nil).

#### Share schemes

A total of 11,756,397 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.

#### EU Commission patent settlements monitoring

In January 2010, the European Commission requested copies of settlement agreements entered into between July 2008 and December 2009 from a number of companies, including AstraZeneca. AstraZeneca co-operated fully with the request. The European Commission published its First Report on Monitoring of Patent Settlements in July 2010. The report noted a decrease in the number of settlement agreements which might be problematic (pursuant to EU competition laws) in the relevant period, compared to the period covered by the European Commission's sector inquiry into the pharmaceutical industry (January 2000-June 2008). In January 2011, the European Commission requested copies of settlement agreements which were entered into or amended in 2010 from a number of companies, including AstraZeneca. AstraZeneca will co-operate fully with the request.

#### **Foreign Corrupt Practices Act**

In connection with an investigation into Foreign Corrupt Practices Act issues in the pharmaceutical industry, AstraZeneca has received inquiries from the US Department of Justice and the SEC regarding, among other things, sales practices, internal controls, certain distributors and interactions with healthcare providers in several countries. AstraZeneca is co-operating with these inquiries. AstraZeneca is investigating indications of inappropriate conduct in certain countries, including China. These investigations are ongoing, and it is not currently possible to predict the scope, duration or outcome of these matters, including the extent to which, if at all, they will result in any liability to AstraZeneca.

#### Bildman v. Astra USA

In March 2010, Bildman filed a petition for a writ of *certiorari* with the US Supreme Court, seeking appeal of the Massachusetts Supreme Judicial Court's dismissal of his defamation claim against AstraZeneca. In May 2010, the US Supreme Court denied Bildman's petition for a writ of *certiorari*, declining to review the lower court's decision and preserving a favourable outcome for AstraZeneca.

#### **EU** Commission investigation

On 30 November 2010, the European Commission commenced an investigation relating to certain alleged practices regarding *Nexium*, and dawn raided several AstraZeneca sites. The European Commission is investigating whether AstraZeneca may have acted individually or jointly to delay generic entry, in alleged breach of Articles 101 and/or 102 of the Treaty on the Functioning of the European Union, which prohibit anti-competitive practices between third parties and abuse of a dominant position. Dawn raids are a preliminary step in investigating suspected anti-competitive practices. The European Commission is continuing its investigation. AstraZeneca remains of the view that the investigation is unfounded and that it has complied with all relevant competition laws. AstraZeneca has, in accordance with its corporate policy, co-operated with the European Commission's investigation. AstraZeneca will continue to co-operate with the European Commission should it decide to take the matter further.

#### Dutch Competition Authority Nexium investigation

On 30 November 2010, the Dutch Competition Authority (NMa) commenced an investigation relating to alleged breach of Article 24 of Dutch competition law and Article 102 of the Treaty on the Functioning of the European Union. The NMa's investigation relates to alleged foreclosure of generic versions of certain proton pump inhibitors. The NMa is continuing its investigation. AstraZeneca remains of the view that the investigation is unfounded and that it has complete with all relevant competition laws. AstraZeneca has, in accordance with its corporate policy, co-operated with the NMa's investigation. AstraZeneca will continue to co-operate with the NMa should it decide to take the matter further.

#### Other

The Company has guaranteed the external borrowing of a subsidiary in the amount of \$288m.

#### 8 Statutory and other information

The Directors were paid by another Group company in 2010 and 2009.

# **Group Financial Record**

For the year ended 31 December	2006 \$m	2007 \$m	2008 \$m	2009 \$m	2010 \$m
Revenue and profits	ψm	ψΠ	ψΠ	φιτι	ψΠ
Revenue	26,475	29,559	31,601	32,804	33,269
Cost of sales	(5,559)	(6,419)	(6,598)	(5,775)	(6,389)
Distribution costs	(226)	(248)	(291)	(298)	(335)
Research and development	(3,902)	(5,162)	(5,179)	(4,409)	(5,318)
Selling, general and administrative costs	(9,096)	(10,364)	(10,913)	(11,332)	(10,445)
Other operating income and expense	524	728	524	553	712
Operating profit	8,216	8,094	9,144	11,543	11,494
Finance income	888	959	854	462	516
Finance expense	(561)	(1,070)	(1,317)	(1,198)	(1,033)
Profit before tax	8,543	7,983	8,681	10,807	10,977
Taxation	(2,480)	(2,356)	(2,551)	(3,263)	(2,896)
Profit for the period	6,063	5,627	6,130	7,544	8,081
Other comprehensive income for the period, net of tax	931	342	(1,906)	(54)	25
Total comprehensive income for the period	6,994	5,969	4,224	7,490	8,106
Profit attributable to:	,	,	,	,	,
Equity holders of the Company	6,043	5,595	6,101	7,521	8,053
Non-controlling interests	20	32	29	23	28
Earnings per share					
Earnings per \$0.25 Ordinary Share (basic)	\$3.86	\$3.74	\$4.20	\$5.19	\$5.60
Earnings per \$0.25 Ordinary Share (diluted)	\$3.85	\$3.73	\$4.20	\$5.19	\$5.57
Dividends	\$1.410	\$1.750	\$1.900	\$2.090	\$2.410
Return on revenues				¥	
Operating profit as a percentage of revenues	31.0%	27.4%	28.9%	35.2%	34.5%
Ratio of earnings to fixed charges	92.7	15.6	13.5	19.9	24.0
	-				-
	2006	2007	2008	2009	2010
At 31 December	\$m	\$m	\$m	\$m	\$m
Statement of Financial Position					
Property, plant and equipment, goodwill and intangible assets	11,657	29,649	29,240	29,422	28,986
Other investments	146	299	605	446	535
Deferred tax assets	1,220	1,044	1,236	1,292	1,475
Current assets	16,909	16,996	15,869	23,760	25,131
Total assets	29,932	47,988	46,950	54,920	56,127
Current liabilities	(9,447)	(15,218)	(13,415)	(17,640)	(16,787)
Non-current liabilities	(5,069)	(17,855)	(17,475)	(16,459)	(15,930)
Net assets	15,416	14,915	16,060	20,821	23,410
Share capital	383	364	362	363	352
Reserves attributable to equity holders	14,921	14,414	15,550	20,297	22,861
Non-controlling interests	112	137	148	161	197
Total equity and reserves	15,416	14,915	16,060	20,821	23,410
For the year ended 31 December	2006 \$m	2007 \$m	2008 \$m	2009 \$m	2010 \$m
Cash flows	·	·			
Net cash inflow/(outflow) from:					
Operating activities	7,693	7,510	8,742	11,739	10,680
Investing activities	(272)	(14,887)	(3,896)	(2,476)	(2,340)
Financing activities	(5,366)	6,051	(6,362)	(3,629)	(7,220)

For the purpose of computing the ratio of earnings to fixed charges, 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.

Where can find out more? **This section** contains more information about our business and about being an **AstraZeneca** shareholder

# Development Pipeline at 27 January 2011

#### **Line Extensions**

				Estimated Filing				
Compound	Mechanism	Area Under Investigation	Phase	US	EU	Japan	Emerging	
Cardiovascular								
Kombiglyze™ XR/ Onglyza™/ metformin IR FDC <sup>#*</sup>	DPP-4 inhibitor + metformin FDC	diabetes	III	Launched	Filed		Filed	
Dapagliflozin/metformin FDC#	SGLT2 inhibitor + metformin FDC	diabetes		H1 2012	H1 2012			
Onglyza™ SAVOR#	DPP-4 inhibitor	outcomes study	III	2016				
Brilinta PEGASUS-TIMI	ADP receptor antagonist	outcomes study		2014	2014	2014	2014	
Crestor	statin	outcomes in subjects with elevated CRP	III	Launched	Launched	TBC	Filed	
Axanum	proton pump inhibitor + low dose aspirin FDC	low dose aspirin associated peptic ulcer	III	Filed***	Filed	2014	Filed	
Gastrointestinal								
Nexium	proton pump inhibitor	peptic ulcer bleeding		Filed	Launched			
Nexium	proton pump inhibitor	GERD	III	Launched	Launched	Filed	Launched	
Neuroscience								
Seroquel XR	D <sub>2</sub> /5HT <sub>2</sub> antagonist	major depressive disorder	III	Launched**	Launched**		Launched	
Diprivan#	sedative and anaesthetic	conscious sedation	III		Launched	H2 2012	Launched	
EMLA#	local anaesthetic	topical anaesthesia	III		Launched	Filed	Launched	
Oncology								
Iressa	EGFR tyrosine kinase inhibitor	1st line EGFR mut+ NSCLC	III		Launched	Filed	Launched	
Faslodex	oestrogen receptor antagonist	high dose (500mg) 2nd line advanced breast cancer	III	Launched	Launched	Filed	Filed	
Infection								
FluMist/Fluenz	live, attenuated, intranasal influenza virus vaccine	influenza	III	Launched	Filed			
<b>Respiratory &amp; Inflammation</b>								
Oxis	long-acting $\beta_2$ agonist	COPD			Launched	Q3 2011		
Symbicort	inhaled steroid/ long-acting β₂ agonist	COPD		Launched	Launched	Q4 2011	Launched	
Symbicort	inhaled steroid/ long-acting B2 agonist	SMART	III		Launched	Q3 2011	Launched	

# Partnered product <sup>\*</sup> Kombiglyze<sup>™</sup> XR in the US; Onglyza<sup>™</sup>/metformin IR FDC in the EU <sup>\*\*</sup> Adjunct only, monotherapy withdrawn <sup>\*\*\*</sup> Complete Response Letter received

#### Phase III/Registration

				Estimated Filing				
Compound	Mechanism	Area Under Investigation	Phase	US	EU	Japan	Emerging	
Cardiovascular								
Brilinta/Brilique	ADP receptor antagonist	arterial thrombosis		Filed*	Launched	2013	Approved	
Dapagliflozin#	SGLT2 inhibitor	diabetes		Filed	Filed	2013	Q2 2011	
Neuroscience								
Vimovo#	naproxen + esomeprazole	signs and symptoms of OA, RA and AS		Launched	Launched		Filed	
TC-5214#	neuronal nicotinic receptor modulator	major depressive disorder (adjunct)	III	H2 2012	2015			
Oncology								
Vandetanib (Zactima)	VEGFR/EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer		Filed	Filed	Q3 2011	Q3 2011	
Zibotentan	endothelin A receptor antagonist	castrate resistant prostate cancer		H1 2012	H1 2012		H1 2012	
Infection								
MEDI-3250	live, attenuated, intranasal influenza virus vaccine (quadrivalent)	seasonal influenza		H1 2011	TBC			
Zinforo# (ceftaroline)	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections	III		Filed		Q3 2011	
Respiratory & Inflammati	on							
Fostamatinib#	spleen tyrosine kinase (SYK) inhibitor	rheumatoid arthritis	III	2013	2013		2013	

# Partnered product \* Complete Response Letter received

# **Development Pipeline**

#### Phases I and II

					Estimated Fi	ling	
Compound	Mechanism	Area Under Investigation	Phase	US	EU	Japan	Emerging
Cardiovascular							
AZD1656	GK activator	diabetes	Ш				
AZD6714	GK activator	diabetes	Ι				
AZD8329	11BHSD inhibitor	diabetes/obesity	1				
AZD7687	diacylglycerol acyl transferase –1 inhibitor	diabetes/obesity	I				
AZD5658	GK activator	diabetes/obesity	I				
AZD4017	11BHSD inhibitor	glaucoma	Ι				
Neuroscience							
AZD3480#	alpha₄/beta₂ neuronal nicotinic receptor agonist	ADHD	II				
AZD6765	NMDA receptor antagonist	major depressive disorder		2016	2016		
AZD2066	metabotropic glutamate receptor 5 antagonist	chronic neuropathic pain	II				
AZD2066	metabotropic glutamate receptor 5 antagonist	major depressive disorder	II				
NKTR-118 <sup>#</sup>	oral peripherally-acting opioid antagonist	opioid-induced constipation	II	2013	2013		
TC-5214#	neuronal nicotinic receptor modulator	major depressive disorder (monotherapy)	II				
TC-5619#	alpha <sub>7</sub> neuronal nicotinic receptor agonist	cognitive disorders in schizophrenia	II				
AZD1446#	alpha₄/beta₂ neuronal nicotinic receptor agonist	Alzheimer's disease/ADHD	II				
AZD2423	chemokine antagonist	chronic neuropathic pain					
AZD3241	myeloperoxidase (MPO) inhibitor	Parkinson's disease					
AZD3043#	GABA-A receptor modulator	short acting sedative/anaesthetic	I				
MEDI-578	anti-NGF MAb	OA pain	I				
AZD5213	H3AN	Alzheimer's disease/ADHD					
Oncology							
Recentin	VEGFR tyrosine kinase inhibitor	NSCLC	II	2016	2016		
Selumetinib <sup>#</sup> (AZD6244) (ARRY-142886)	MEK inhibitor	solid tumours	II	2015	2015		
Olaparib	PARP inhibitor	serous ovarian cancer		2015	2015	2016	2016
AZD1152	aurora kinase inhibitor	haematological malignancies					
AZD8931	erbB kinase inhibitor	breast cancer chemo combi/ solid tumours	II	2015	2015		
MEDI-575#	anti PDGFR-alpha MAb	solid tumours					
AZD2461	PARP inhibitor	solid tumours	I				
AZD3514	androgen receptor downregulator	prostate cancer					
AZD7762	CHK1 kinase inhibitor	solid tumours	I				
AZD8330# (ARRY-424704)	MEK inhibitor	solid tumours	I				
CAT-8015	anti-CD22 recombinant immunotoxin	haematological malignancies	I				
MEDI-551	anti-CD19 MAb	haematological malignancies	I				
AZD8055	TOR kinase inhibitor	range of tumours	I				
MEDI-573#	anti-IGF MAb	solid tumours					
AZD1480	JAK2 inhibitor	myeloproliferative diseases/ solid tumours	I				
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	I				
AZD2014	TOR kinase inhibitor	solid tumours	I				
Selumetinib (AZD6244) (ARRY-142886)/MK2206#	MEK/AKT inhibitor	solid tumours	I				
MEDI-3617	anti-ANG-2 MAb	solid tumours	I				
AZD5363	AKT inhibitor	solid tumours	I				
MEDI-565	anti-CEA BiTE	solid tumours	1				

# Partnered product

#### Phases I and II continued

					Estimated F	iling		
Compound	Mechanism	Area Under Investigation	Phase	US	EU	Japan	Emerging	
Infection								
AZD9773#	anti-TNF-alpha polyclonal antibody	severe sepsis	II	2015	2015	2015	2015	
CAZ104#	beta lactamase inhibitor/ cephalosporin	serious infections	II		2013		2014	
Motavizumab#	humanized MAb binding to RSV F protein	early and late treatment of RSV in paeds >1 yr	II					
CXL104# (CEF104)	beta lactamase inhibitor/ cephalosporin	MRSA	II		2015			
MEDI-534	RSV/PIV-3 vaccine	RSV/PIV prophylaxis						
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis						
MEDI-559	RSV vaccine	RSV prophylaxis						
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis						
AZD9742	BTGT4 IV	MRSA						
Respiratory & Inflamm	ation							
AZD1981	CRTh2 receptor antagonist	asthma/COPD	II					
MEDI-528#	anti-IL-9 MAb	asthma	II					
CAT-354	anti-IL-13 MAb	asthma	Ш					
AZD3199	ilaba	asthma/COPD	Ш					
MEDI-563#	anti-IL-5R MAb	asthma	II					
MEDI-545#	anti-IFN-alpha MAb	SLE, myositis	II					
AZD8848	Toll-like receptor 7 agonist	asthma	II					
CAM-3001#	anti-GM-CSFR MAb	rheumatoid arthritis	Ш					
AZD2423	CCR2b antagonist	COPD	II					
AZD8683	muscarinic antagonist	COPD	II					
AZD5423	inhaled SEGRA	COPD	Ш					
AZD5069	CXCR2	COPD	II					
AZD9819	neutrophil elastase inhibitor	COPD						
MEDI-546#	anti-IFN-alphaR MAb	scleroderma						
MEDI-551	anti-CD19 MAb	scleroderma	1					
MEDI-570#	anti-ICOS MAb	SLE						
MEDI-557	RSV MAb – extended half-life	COPD	1					

# Partnered product

# **Development Pipeline**

#### **Discontinued Projects**

Compound	Area Under Investigation
Cardiovascular	
AZD6370	diabetes
Certriad	dyslipidaemia
AZD4017	diabetes/obesity
AZD0837	thrombosis
AZD6482	thrombosis
Gastrointestinal	
Lesogaberan (AZD3355)	GERD
AZD1386	GERD
AZD2066	GERD
AZD2516	GERD
Infection	
MEDI-560	PIV prophylaxis
Motavizumab	RSV prevention
AZD7295	Hepatitis C
Neuroscience	
AZD6280	anxiety
AZD8418	schizophrenia
AZD8529	schizophrenia
AZD7268	depression/anxiety
AZD2327	depression/anxiety
AZD2516	chronic neuropathic pain
Seroquel XR	generalised anxiety disorder US

Compound	Area Under Investigation
Oncology	
MEDI-547	solid tumours
AZD4769	solid tumours
Faslodex	1st line advanced breast cancer
Olaparib	gBRCA breast
Recentin	CRC
Recentin	recurrent glioblastoma
Respiratory & Inflammation	
AZD9668	COPD
AZD6553	COPD
AZD2551	COPD
AZD5122	COPD
AZD5985	asthma/COPD
AZD8075	asthma/COPD
AZD8566	COPD
AZD1236	COPD
AZD9164	COPD

#### Comments

As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed in this section has not been disclosed at this time.

# **Shareholder Information**

#### AstraZeneca PLC share listings and prices

2006	2007	2008	2009	2010
1,532	1,457	1,447	1,451	1,409
1,564	1,495	1,453	1,448	1,438
3529	2984	2888	2947	3385
2574	2093	1748	2147	2732
2744	2164	2807	2910.5	2922
	1,532 1,564 3529 2574	1,5321,4571,5641,4953529298425742093	1,5321,4571,4471,5641,4951,453352929842888257420931748	1,5321,4571,4471,4511,5641,4951,4531,44835292984288829472574209317482147

#### Percentage analysis of issued share capital at 31 December

By size of account No. of shares	2006 %	2007 %	2008 %	2009 %	<b>2010</b> %
1 – 250	0.5	0.5	0.5	0.5	0.5
251 – 500	0.7	0.7	0.7	0.7	0.6
501 – 1,000	0.9	0.9	0.9	0.8	0.8
1,001 – 5,000	1.3	1.3	1.2	1.1	1.1
5,001 – 10,000	0.2	0.2	0.2	0.2	0.2
10,001 – 50,000	1.0	1.0	1.0	1.1	1.0
50,001 - 1,000,000	12.3	12.9	13.6	13.0	12.8
Over 1,000,000 <sup>1</sup>	83.1	82.5	81.9	82.6	83.0

<sup>1</sup> Includes VPC and ADR holdings.

At 31 December 2010, the Company had 120,304 registered holders of 1,409,023,452 Ordinary Shares. At 31 December 2010, there were approximately 205,000 holders of ADRs representing 6.5% of the issued share capital of the Company and 149,000 holders of shares held under the VPC Services Agreement representing 18.2% of the issued share capital of the Company. The ADRs, each of which is equivalent to one Ordinary Share, are issued by JPMorgan Chase Bank (JPMorgan).

During 2010, under AstraZeneca's share repurchase programme, which was introduced in 1999, 53.7 million shares were repurchased and subsequently cancelled at a total cost of \$2,604 million, representing 3.8% of the total issued share capital of the Company. The average price paid per share in 2010 was 3111 pence. This brings the total number of shares repurchased to date since the beginning of the repurchase programme in 1999, to 430.0 million Ordinary Shares (at an average price of 2717 pence per Ordinary Share) for a consideration, including expenses, of \$20,702 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 11.8 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.

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 NYSE. The table overleaf sets out, for the four quarters of 2009 and for the first two quarters and last six months of 2010, 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).

### **Shareholder Information**

			Ordinary LSE	ADS		Ordinary SS	
		High (pence)	Low (pence)	High (US\$)	Low (US\$)	High (SEK)	Low (SEK)
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
	– Quarter 3	2878.0	2644.0	47.54	43.01	356.0	305.0
	– Quarter 4	2930.0	2690.5	47.00	43.64	339.5	308.0
2010	– Quarter 1	3102.5	2732.0	50.40	43.05	363.8	310.1
	– Quarter 2	3169.0	2772.0	48.74	40.91	368.0	314.0
	– July	3289.0	3051.5	51.51	47.05	371.9	353.4
	– August	3348.0	3216.5	53.41	49.43	382.2	365.1
	– September	3385.0	3233.5	52.69	50.49	376.1	345.0
	– October	3359.0	3129.5	53.50	50.43	354.7	336.7
	– November	3144.0	2995.5	50.34	46.93	336.9	325.7
	– December	3153.0	2922.0	49.28	45.80	336.5	309.3

<sup>1</sup> Principally held in bearer form.

#### **Major shareholdings**

At 27 January 2011, 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:

Shareholder	Number of shares	Date of disclosure to Company <sup>1</sup>	Percentage of issued share capital
BlackRock, Inc.	100,885,181	8 December 2009	7.18
Invesco Limited	72,776,277	6 October 2009	5.18
Axa SA	56,991,117	3 February 2009	4.06
Investor AB	51,587,810	3 February 2009	3.67
Legal & General Investment Management Limited	57,675,232	5 August 2010	4.10

<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 repurchase of shares under the Company's share repurchase 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.

		Pe	rcentage of issue	d share capital
Shareholder	27 Jan 2011	28 Jan 2010	29 Jan 2009	31 Jan 2008
BlackRock, Inc.	7.18	6.94	-	-
Invesco Limited	5.18	5.01	-	-
Axa SA	4.06	3.92	4.90	4.87
Investor AB	3.67	3.55	4.38	4.36
Legal & General Investment Management Limited	4.10	4.64	4.09	4.06
Capital Research and Management Company	-	-	4.92	4.89
Wellington Management Co., LLP	-	-	4.18	4.16
Barclays PLC	-	-	4.26	4.24

ADSs evidenced by ADRs issued by JPMorgan, as depositary, are listed on the NYSE. At 27 January 2011, the proportion of Ordinary Shares represented by ADSs was 6.55% of the Ordinary Shares outstanding.

Number of registered holders of Ordinary Shares at 27 January 2011:

> In the US 771 > Total 120,325

Number of record holders of ADRs at 27 January 2011:

> In the US 2,211 > Total 2,237 So far as the Company is aware, it is neither directly nor indirectly owned or controlled by one or more corporations or by any government.

At 27 January 2011, 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	390,106	0.03

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 2011 to 27 January 2011, 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 196).

#### Options to purchase securities from registrant or subsidiaries

(a) At 27 January 2011, options outstanding to subscribe for Ordinary Shares were:

Number of shares	Subscription price (pence)	Normal expiry date
50,058,484	1882 – 3487	2011 – 2019

The weighted average subscription price of options outstanding at 27 January 2011 was 2446 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:

Number of shares	Subscription price (pence)	Normal expiry date
1,928,024	1882 – 3487	2011 – 2019

(c) Included in paragraph (b) are options granted to individually named Directors. Details of these option holdings at 31 December 2010 are shown in the Share option plans table on page 134.

During the period 1 January 2011 to 27 January 2011, 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 2010, payable on 14 March 2011, is 4 February 2011 and the ex-dividend date is 2 February 2011.

The record date for the first interim dividend for 2011, payable on 12 September 2011, is 5 August 2011.

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 online 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 on their website, 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 2011 will be published on 28 April 2011 and results in respect of the first six months of 2011 will be published on 28 July 2011.

Overview

# **Shareholder Information**

#### **Documents on display**

The 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 2 Kingdom Street, London W2 6BD.

#### **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 summary 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 could be affected by actions that may be taken by parties to whom ADRs are pre-released.

This summary 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 paid out 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 2013 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 2010, 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 or the Articles 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 krona, 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 krona 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)		
2008	6.5130	1.8728
2009	7.6552	1.5496
2010	6.9256	1.5852
End of year spot rates (balance sheet)		
2008	7.7740	1.4437
2009	7.1636	1.6072
2010	6.7511	1.5422

# **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 2 Kingdom Street, London W2 6BD (telephone +44 (0)20 7604 8000). 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 MedImmune, 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 2 Kingdom Street, London W2 6BD.

#### Articles

#### Objects

The Company's objects were originally set out in its Memorandum of Association. By operation of law, on 1 October 2009, these objects were deemed to be provisions of the Articles. However, by a special resolution of the shareholders at the Company's AGM held on 29 April 2010, those deemed objects were deleted from the Articles. The Company's objects are now unrestricted.

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 repurchase 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 election or 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

As at 31 December 2010, the Company had 1,409,023,452 Ordinary Shares and 50,000 Redeemable Preference Shares in issue. The Ordinary Shares represent 99.99% 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). As agreed by the shareholders at the Company's AGM held on 29 April 2010, the Articles were amended with immediate effect to remove the requirement for the Company to have an authorised share capital, the concept of which was abolished under the Companies Act 2006. Each Ordinary Share carries the right to vote at general meetings of the Company. 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.

There are no specific restrictions on the transfer of shares in the Company, which is governed by the Articles and prevailing legislation.

The Company is not aware of any agreements between holders of shares that may result in restrictions on the transfer of shares or that may result in restrictions on voting rights.

#### 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 unless each of the two persons present are corporate representatives of the same corporation; or each of the two persons present are proxy of the same shareholder.

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.

# Glossary

#### **Market definitions**

United States of America	Other Established Markets		Emerging Markets		
US	Western Europe	Japan	Emerging Europe	China	Other Emerging ROW
	Austria		Albania*		Egypt
	Belgium	Canada	Belarus*	<b>Emerging Asia Pacific</b>	Gulf States
	Denmark		Bosnia-Herzegovina*	Bangladesh*	Israel*
	Finland	Other Established ROW	Bulgaria*	Cambodia*	Latin America
	France	Australia	Croatia*	Hong Kong*	Lebanon
	Germany	New Zealand*	Czech Republic	India	Maghreb
	Greece		Estonia*	Indonesia*	Saudi Arabia
	Holland		Georgia*	Laos*	South Africa
	Iceland*		Hungary*	Malaysia*	
	Ireland		Kazakhstan*	Philippines	
	Italy		Latvia*	Singapore	
	Luxembourg*		Lithuania*	South Korea	
	Norway		Macedonia*	Sri Lanka*	
	Portugal		Poland	Taiwan	
	Spain		Romania*	Thailand	
	Sweden		Russia	Vietnam*	
	Switzerland		Serbia/Montenegro*		
	UK		Slovakia		
			Slovenia*		
			Turkey		
			Ukraine*		

Rest of World means Other Established Markets and Emerging Markets. Established Markets means the US and Other Established Markets. Established ROW means Canada, Japan and Other Established ROW.

Latin America includes Argentina, Brazil, Chile, Colombia, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru and Venezuela. Gulf States includes Bahrain\*, Dubai\*, Kuwai\*, Oman\*, Qatar\* and UAE\*. Maghreb means Algeria, Morocco\* and Tunisia\*.

"HIS 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
Called-up share capital	Issued share capital
Creditors	Liabilities/payables
Debtors	Receivables and prepaid expenses
Earnings	Net income
Employee share schemes	Employee stock benefit plans
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

# Glossary

The following abbreviations and expressions have the following meanings when used in this Annual Report:

**Abbott** – Abbott Pharmaceuticals PR Ltd. with respect to Trilipix<sup>™</sup> and/or *Certriad* and Abbott Laboratories, Inc. with respect to *Crestor*.

Affordable Care Act – the Patient Protection and Affordable Care Act which was signed into law on 23 March 2010 as amended by the Health Care and Education Reconciliation Act which was signed into law on 30 March 2010.

ADR – an American Depositary Receipt evidencing title to an ADS.

**ADS** – an American Depositary Share representing one underlying Ordinary Share.

AGM - an Annual General Meeting of the Company.

**ANDA** – an abbreviated new drug application, which is a marketing approval application for a generic drug submitted to the FDA.

**Annual Report** – this Annual Report and Form 20-F Information 2010.

Articles - the Articles of Association of the Company.

Astellas – Astellas Pharma, Inc.

**Astra** – Astra AB, being the company with whom the Company merged in 1999.

AstraZeneca – the Company and its subsidiaries.

Bureau Veritas - Bureau Veritas UK Limited.

BMS - Bristol-Myers Squibb Company.

Board - the Board of Directors of the Company.

BRIC-MT - Brazil, Russia, India, China, Mexico and Turkey.

CEO - the Chief Executive Officer of the Company.

CER – constant exchange rates.

**CFO** – the Chief Financial Officer of the Company.

**CHMP** – the Committee for Medicinal Products for Human Use, being a committee of the EMA.

CIS - Commonwealth of Independent States.

Code of Conduct - the Group's Code of Conduct.

**Combined Code** – the UK Combined Code on Corporate Governance published by the Financial Reporting Council in June 2008 that sets out standards of good practice in corporate governance for the UK.

**Company** or **Parent Company** – AstraZeneca PLC (formerly Zeneca Group PLC (**Zeneca**)).

**Complete Response Letter** – a letter issued by the FDA communicating its 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.

**Corporate Integrity Agreement** – the agreement described in the US Corporate Integrity Agreement reporting section on page 43.

**cost growth rates** – percentage growth of a particular cost category over the comparable cost category for the previous year.

Daiichi Sankyo - Daiichi Sankyo Company, Limited.

**Dainippon Sumitomo** – Dainippon Sumitomo Pharmaceuticals Co., Ltd.

**Director** – a director of the Company.

**earnings per share (EPS)** – profit for the year after tax and minority interests, divided by the weighted average number of Ordinary Shares in issue during the year.

**EMA** – the European Medicines Agency.

EU - the European Union.

**FDA** – 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 – Forest Laboratories Holdings Limited.

GAAP - Generally Accepted Accounting Principles.

**GDP** – gross domestic product.

GIA - AstraZeneca's group internal audit.

**gross margin** – 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 – AstraZeneca PLC and its subsidiaries.

IAS – the International Accounting Standards.

**IASB** – the International Accounting Standards Board.

**IFRS** – the International Financial Reporting Standards or an International Financial Reporting Standard, as the context requires.

**KPI** – key performance indicator.

krona or SEK – references to the currency of Sweden.

**MAA** – 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** – monoclonal antibody, a biologic that is specific; that is, it binds to and attacks one particular antigen.

MedImmune – MedImmune, LLC (formerly MedImmune, Inc.).

Merck – Merck Sharp & Dohme Corp (formerly Merck & Co., Inc.).

**moving annual total (MAT)** – a figure that represents the financial value of a variable for 12 months.

 $\ensuremath{\textbf{NDA}}\xspace -$  a new drug application to the FDA for approval to market a new medicine in the US.

**Nektar** – Nektar Therapeutics.

NGOs - non-governmental organisations.

Novexel - Novexel S.A.

NSAID - a non-steroidal anti-inflammatory drug.

NYSE - the New York Stock Exchange.

**operating profit** – sales, less cost of sales, less operating costs, plus operating income.

**Ordinary Share** – an ordinary share of \$0.25 each in the share capital of the Company.

**Orphan Drug** – 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** – over-the-counter.

**Paediatric Exclusivity** – 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 (eg European SPC paediatric extensions).

**Patent Term Extension** – 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** – 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** – 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** – 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,  $\mathbf{\hat{z}}$ , GBP, pence or  $\mathbf{p}$  – references to the currency of the UK.

**R&D** – research and development.

**Redeemable Preference Share** – a redeemable preference share of  $\pounds$ 1 each in the share capital of the Company.

**Regulatory Data Protection** – see the Intellectual Property section from page 30.

**Regulatory Exclusivity** – any of the intellectual property rights arising from generation of clinical data and includes Regulatory Data Protection (as explained in the Intellectual Property section from page 30), Paediatric Exclusivity and Orphan Drug status.

Rigel - Rigel Pharmaceuticals, Inc.

Sarbanes-Oxley Act - the US Sarbanes-Oxley Act of 2002.

**SEC** – the US Securities and Exchange Commission, the governmental agency that regulates the US securities industry/ stock market.

Seroquel – Seroquel IR and Seroquel XR unless otherwise stated.

SET - the Senior Executive Team.

SG&A costs - selling, general and administrative costs.

**sNDA** – 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 – Targacept, Inc.

Teva – Teva Pharmaceuticals USA, Inc.

Torrent - Torrent Pharmaceuticals Ltd.

**TSR** – total shareholder return, being the total return on a share over a period of time, including dividends reinvested.

**UK** – the United Kingdom of Great Britain and Northern Ireland.

**UK Corporate Governance Code** – the new UK Corporate Governance Code published by the Financial Reporting Council in May 2010 that sets out standards of good practice in corporate governance for the UK.

US - the United States of America.

US dollar, US\$, USD or \$ - references to the currency of the US.

**WHO** – the World Health Organization, the United Nations' specialised agency for health.

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#### Trade marks

**Trade marks** Trade marks of the AstraZeneca group of companies appear throughout this Annual Report in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trade marks of the AstraZeneca group of companies. Trade marks of companies other than AstraZeneca appear with a <sup>™</sup> sign and include: Abraxane<sup>™</sup>, a trade mark of Abraxis BioScience, LLC.; Advair Diskus<sup>™</sup>, a trade mark of Glaxo Group Limited; Celebrex<sup>™</sup>, a trade mark of G. D. Searle LLC; Cubicin<sup>™</sup>, a trade mark of Cubist Pharmaceuticals, Inc.; CytoFab<sup>™</sup>, a trade mark of Protherics Inc.; Ethyol<sup>™</sup>, a trade mark of Scherico Ltd in certain countries and AstraZeneca in others; Iscover<sup>™</sup>, a trade mark of Bristol-Myers Squibb Company; Plavix<sup>™</sup>, a trade mark of Sanofi-Aventis; Teflaro<sup>™</sup>, a trade mark of Forest Laboratories, Inc.; and Trilipix<sup>™</sup>, a trade mark of Fournier Industrie et Santé.

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