



Improving health is one of the toughest challenges facing the world today. As a global biopharmaceutical company, AstraZeneca has a key contribution to make by providing innovative medicines for some of the world's most serious diseases.

We know that if we are to deliver medicines that people really need and value, we cannot do it in isolation. We work closely with all our stakeholders to understand their needs and challenges. We are committed to acting with integrity and high ethical standards in everything we do and our goal is always to improve health for patients and bring benefit for our stakeholders, our business and society.

#### **Financial summary**

\$33.6bn

Sales down 2% at CER to \$33,591 million (\$33,269 million in 2010)

**\$13.2bn** 

Core operating profit down 4% at CER to \$13,167 million (\$13,603 million in 2010)

\$12.8bn

Reported operating profit up 10% at CER to \$12,795 million (\$11,494 million in 2010)

**\$7.28** 

Core EPS for the full year increased by 7% at CER to \$7.28 (\$6.71 in 2010)

\$7.33

Reported EPS for the full year increased by 29% at CER to \$7.33 (\$5.60 in 2010)

\$9.37bn

Net cash shareholder distributions increased by 71% to \$9,370 million including net share repurchases of 5.6 billion



## Welcome to the AstraZeneca Annual Report and Form 20-F Information 2011 (Annual Report)

You will find this Annual Report and all the case studies featured in this document on our website,

#### astrazeneca.com/annualreport2011

#### Important information for readers of this Annual Report

For further information in relation to the inclusion of reported performance, Core financial measures and constant exchange rate (CER) growth rates as used in this Overview from page 1 and throughout the Business Review and Corporate Governance section from pages 29 and 99 respectively, please refer to the Financial Review on page 84. Throughout this Annual Report, growth rates are expressed at CER unless otherwise stated.

#### Definitions

The Glossary and the Market definitions table from page 209 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 and elsewhere in this Annual Report.

#### Use of terms

Use of terms
In this Annual Report, unless the context otherwise requires, 'AstraZeneca', 'the Group', 'we', 'us' and 'our' refer to AstraZeneca PLC and its consolidated entities.

#### 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 2011.

#### Cautionary statement regarding forward-looking statements

A cautionary statement regarding forward-looking statements and other essential information relating to this Annual Report can be found on the inside back cover.

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#### **Directors' Report**

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

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

#### Case studies

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## **Our business**



## We are a global, innovation-driven biopharmaceutical business.

Our primary focus is the discovery, development and commercialisation of prescription medicines for six important areas of healthcare: Cardiovascular, Gastrointestinal, Infection, Neuroscience, Oncology, and Respiratory & Inflammation. We operate in over 100 countries and our innovative medicines are used by millions of patients worldwide.

We want AstraZeneca to be valued as a source of great medicines and trusted as a company that delivers business success responsibly. Our Responsible Business Plan provides the framework for ensuring that we operate with integrity and high ethical standards across all our activities. Russia: We invested \$150 million in a manufacturing plant near Moscow and announced plans to establish a new predictive science centre in St Petersburg.

Regional sales

\$13,426m

(-2%)

External Interactions
Policy reinforces our
commitment to the highest
standards of sales and
marketing practice.

Regional sales Western Europe

\$8,501m

(-11%)

57,200 Around

employees worldwide **Americas**: 17,450 (31%) **EMEA**: 26,600 (46%) **Asia-Pacific**: 13,150 (23%) Brilinta/Brilique has been approved in 64 countries; it has been launched in 37 countries and remains under review in 39 countries.

Regional sales Emerging Markets

\$5,763m

(±10%)

32,300 Around

Sales and Marketing employees: numbers in Established Markets, such as the US, have fallen, whereas the numbers in Emerging Markets are increasing and now represent 47% of the total.



## Our top 10 medicines by sales value in 2011 were:

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

#### Losec/Prilosec

for the treatment of acid related diseases

#### Infection

#### Synagis

for RSV, a respiratory infection in infants

#### Neuroscience

#### Seroquel IR

for schizophrenia and bipolar

#### Seroquel XR

for schizophrenia, bipolar disorder and major depressive disorder

#### Oncology

#### **Zoladex**

for prostate and breast cancer

#### **Respiratory & Inflammation**

#### **Symbicort**

for asthma and chronic obstructive pulmonary disease



#### 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 physicians, we provide medicines for some of the world's most serious diseases.
- > For the people who pay for healthcare, we work to make sure that our medicines offer real 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 work closely with all our stakeholders to understand their challenges and how we can combine our skills and resources to achieve a common goal: improved health.

Around 11,300

employees work in our R&D organisation and we have 14 principal R&D centres in eight countries.

China: We announced our decision to invest \$200 million in a manufacturing facility in Taizhou, Jiangsu province and our agreement to acquire Guangdong BeiKang Pharmaceutical Company Limited.

Around 9,600

employees work at our 23 Supply and Manufacturing sites in 16 countries.

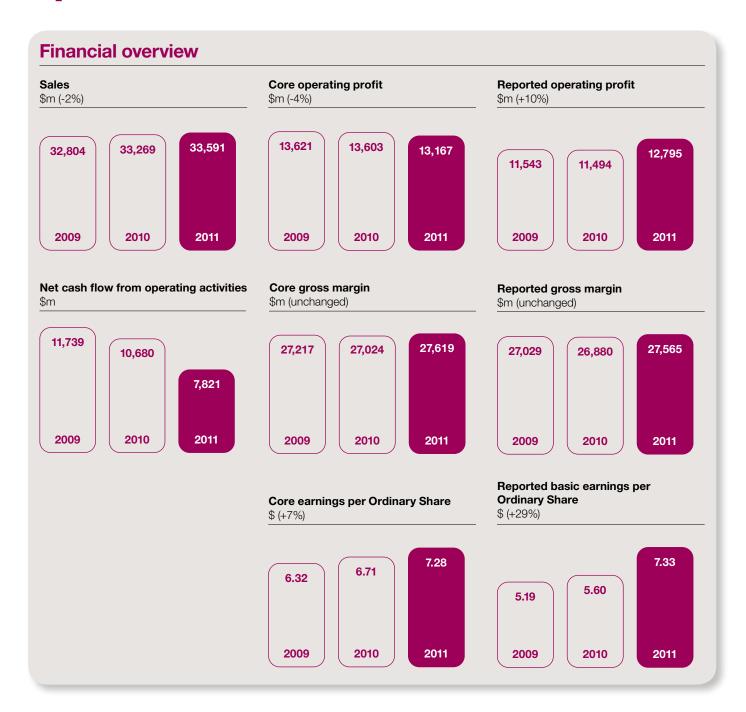
Regional sales Established ROW

\$5,901m

(+4%)



## Summary financial and operational information for 2011

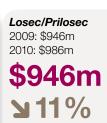


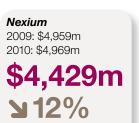
#### **Product performance summary**

Top 10 products by sales value

### 2009: \$1,436m 2010: \$1,483m **\$1,450m 36%**









#### **Operational overview**

**79** 

79 projects in clinical development, including nine in Phase III or under regulatory review; 21 withdrawn during the year

1,150

In line with our commitment to transparency, by the end of 2011 we had published the results of over 1,150 clinical trials on public websites

**-2%** 

Revenue in the US was down 2%

+10%

Emerging Markets revenue increased by 10%

**\$1.8bn** 

Sold Astra Tech, our dental and healthcare products business, for approximately \$1.8 billion in cash

**7%** 

Ranked in the top 7% in the sector in the Dow Jones Sustainability World and European Indexes, with our highest assessment score to date of 85%

#### **Pipeline**

- > Brilinta approved in the US and Canada; Caprelsa (vandetanib) approved in the US and positive CHMP opinion in the EU; Axanum, Komboglyze™ and Fluenz approved in the EU; Nexium and Faslodex 500mg approved in Japan
- > Complete Response Letter received from the FDA for dapagliflozin in January 2012
- > Recorded an impairment charge of \$435 million reflecting the decision not to progress olaparib into Phase III development and Phase III studies for TC-5214 which did not meet their primary endpoints

#### **Deliver the business**

- > Strong double digit sales growth for Crestor, Seroquel XR and Symbicort
- > Revenue performance reflected the loss of nearly \$2 billion of revenue from generic competition, as well as a further \$1 billion lost due to government price interventions
- > Seroquel XR patent infringement actions settled against Handa and Accord
- > New access to healthcare strategy provided platform for increasing access in a sustainable way

#### **Business shape**

- > Restructuring programmes since 2007 are delivering planned savings; new initiatives are expected to deliver a further \$1.6 billion in annual benefits by 2014
- > Expanded responsible procurement audit programme (727 suppliers in 55 countries in 2011; 42 suppliers in 2010)

#### People

- > Improvement in employee engagement and senior leader communications
- Net reduction of nearly 4,000 employees since 2010 included recruitment of approximately 6,400 employees to replace leavers and drive our expansion in Emerging Markets

#### **Responsible Business**

> Launched new Responsible Business Plan aligned with business strategy and created Responsible Business Council strengthening governance in this area

#### Seroquel IR

2009: \$4,171m 2010: \$4,148m

\$4,338m

#### Seroquel XR

2009: \$695m 2010: \$1,154m

\$1,490m 7127%

#### Symbicort

2009: \$2,294m 2010: \$2,746m

\$3,148m 711%

#### Synagis

2009: \$1,082m 2010: \$1,038m

\$975m

#### Zoladex

2009: \$1,086m 2010: \$1,115m

\$1,179m 713%



In the face of intensified pressures we delivered a good performance in 2011 and took difficult decisions to ensure the future success of AstraZeneca.

Louis Schweitzer Chairman

#### **Dear Shareholder**

I write to you at the end of a year in which research-based pharmaceutical companies faced a tough marketplace and operating environment. Against this challenging background, disciplined execution of our strategy delivered a good performance. Our strong cash flow supported a significant increase in cash distributions to shareholders and continued investment to drive future growth and value. These conditions also provided the backdrop to the annual review by your Board of our business strategy – which remains to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business.

Distributions to shareholders \$m	2011	2010	2009
Dividends	3,764	3,361	2,977
Share repurchases	6,015¹	2,6042	-
Total	9,779	5,965	2,977

Dividend for 2011	\$	Pence	SEK	Payment date
First interim dividend	0.85	51.9	5.33 1	2 September 2011
Second interim dividend	1.95	123.6	13.21	19 March 2012
Total	2.80	175.5	18.54	

<sup>&</sup>lt;sup>1</sup> Share repurchases in 2011, net of proceeds from the issue of share capital equal to \$409 million, were \$5,606 million.

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

#### Chairman's Statement

I would like to take this opportunity to review AstraZeneca's financial performance in 2011 and the decisions we took to ensure we continue to deliver sustainable value for you.

**Financial performance** 

Group sales in 2011 were down 2% at CER to \$33,591 million (2010: \$33,269 million) and reported operating profit was up 10% at \$12,795 million (2010: \$11,494 million), which included the gain on the sale of Astra Tech. Performance for the year reflected strong double digit sales growth for *Crestor*, *Seroquel XR* and *Symbicort*. It was also impacted by government pricing interventions and generic competition, which combined to reduce revenue by some \$3 billion. Revenue in the US was down 2%, as was revenue in markets outside the US: revenue was down 11% in Western Europe, up 4% in Established ROW and up 10% in Emerging Markets.

Reported earnings per share for the full year were up 29% at \$7.33 (2010: \$5.60), which also included the non-taxable gain of \$1.08 from the Astra Tech sale. Our effective tax rate also benefited from an adjustment in respect of prior periods following the announcement in March 2011 that HM Revenue & Customs in the UK and the US Internal Revenue Service had agreed the terms of an Advance Pricing Agreement regarding transfer pricing arrangements for AstraZeneca's US business.

#### A challenging marketplace

The world pharmaceutical market grew by 4.5% in 2011 and the fundamentals of the industry remain strong. First, the world population continues to increase and age: it passed the seven billion mark in 2011, while the number of people over 65 in 2030 is estimated to be almost one billion, double the 2005 figure. Secondly, we are seeing the emergence of expanding numbers of patients in new markets who can access our medicines for the first time. Thirdly, there remains considerable unmet medical need. Chronic diseases are on the increase, not only in wealthy countries but also in middle income and, increasingly, lower income countries. For example, some 346 million people around the world have diabetes while 24 million are affected by Alzheimer's Disease. Finally, advances in science and technology promise the continued delivery of new medicines that can make a real difference to patient health.

Yet, while the fundamentals remain strong, the challenges facing the industry have been unprecedented in recent years. Patents on some of the world's most successful innovative medicines are starting to expire and we face increasing competition from generic alternatives. Additionally, the need to improve R&D productivity and the number of product launches remains a critical challenge for the whole sector.

Around the world, rising healthcare costs, coupled with the difficult economic climate and continued austerity measures being implemented by governments, have resulted in pressure on prices. This includes pricing interventions in many countries. The regulatory landscape is changing, becoming more global and more complex. It is no longer enough for new medicines to be safe and effective. Health authorities increasingly require additional information regarding a medicine's comparative clinical and cost effectiveness.

#### Our strategic response

It was with these challenges in mind that your Board undertook its strategy review process in 2011. We are confident that long-term growth in demand for innovative biopharmaceuticals will remain strong. We believe there continue to be 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 our medicines. We also recognise that the industry is going through a period of fundamental change as it seeks to overcome the serious challenges we face.

For us, that means a continued focus on ensuring we drive:

- > world class productivity in R&D
- > increased external collaboration
- > a global orientation, reflecting the growth in Emerging Markets
- > stronger customer orientation, particularly towards payers
- > operational efficiency with a flexible cost base.

Our 2011 review highlighted the ongoing need for a substantial improvement in R&D productivity if we are to sustain acceptable returns to shareholders. We are therefore planning to accelerate our R&D strategy. We intend to take a new approach to Neuroscience, closing our existing research centres and creating a new virtual innovative medicines unit for our R&D in this challenging field. We also plan to reshape our other R&D global functions to better support a more focused portfolio and create a simpler organisation with greater flexibility in all functional areas.

In his Chief Executive Officer's Review on the following pages, David Brennan outlines the steps we took in 2011 to secure our future business success. David also emphasises that *how* we do business is as important as *what* we do. We need to continue to work with integrity and to high ethical standards if we are to deliver on our promise of bringing benefits to patients, creating sustainable value for shareholders and contributing to economic and social welfare. In this regard, the Board has an important role to play in setting high standards and monitoring performance.

#### Outlook

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. However, based on the evolution of the base case assumptions since 2010, such as the downward pressure on revenue from government interventions, revenue for the remainder of the period is likely to be in the lower half of the range.

#### **Returns to shareholders**

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 \$1.95, a 5% increase over the second interim dividend awarded in 2010. This brings the dividend for the full year to \$2.80 (175.5 pence, SEK 18.54), an increase of 10% from 2010. In 2011, cash distributions to shareholders through dividends totalled \$3,764 million and net share repurchases totalled \$5,606 million.

#### **Appreciation**

In the face of intensified pressures we delivered a good performance in 2011 and took difficult decisions to ensure the future success of AstraZeneca. 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 for their effort in working to deliver on our promise.

Louis Schweitzer

Chairman

AstraZeneca has a proud tradition of developing great medicines that make a meaningful difference to patient health. Looking ahead, we remain committed to developing innovative and valued medicines that improve the health of people around the world, benefit society and provide an acceptable return for our shareholders.

In my review I want to outline some of the steps we took and decisions we made in 2011 to secure our future business success.



If we are to be one of the winners in the sector we need to make the necessary changes both to what we do and how we do it.

David R Brennan Chief Executive Officer

**Operational highlights** 

**-2%** 

+10%

Revenue in the US was down 2%

Emerging Markets revenue increased by 10%

**79** 

7%

79 projects in clinical development, including 9 in Phase III or under regulatory review; 21 withdrawn during the year

Ranked in the top 7% in the sector in the Dow Jones Sustainability World and European Indexes, with our highest assessment score to date of 85%

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

#### A trusted partner

We cannot secure our success if we do not have good relationships with those with whom we do business. Trust is critical to achieving this: we need to connect with our stakeholders, including patients, physicians, regulators, governments and payers, if we are to understand their needs and challenges. We also need to earn and maintain the trust of our customers, partners and other stakeholders. This requires us to do things in the right way and to behave in accordance with our core values.

That is why I set such store by our Global External Interactions Policy, launched in April 2011, which provides a single, common, principle-based approach to all our interactions worldwide with public officials, healthcare professionals and community organisations. The introduction of the policy drove changes in the way we market and sell our products and I believe we now lead the industry in this area of business.

Our commitment to acting responsibly and the sustainable development of our Group was further reinforced in 2011 by the publication of our new Responsible Business Plan, which is closely aligned to our business strategy and its priorities.

The growing importance of compliance and ethics to our reputation and business operations was demonstrated during the year by the appointment of Katarina Ageborg, our new Chief Compliance Officer, to the SET.

#### **World class Research and Development**

At the core of our strategy to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business is the need to have an R&D function with world class productivity. In his Chairman's Statement on page 6, Louis Schweitzer outlined how we are redoubling our efforts to deliver this through the use of innovative and collaborative ways of working. Our focus is on ensuring more effective and efficient delivery of our research objectives across our therapeutic portfolio.

Our results in 2011 were mixed. We were pleased by the FDA's approval in July of *Brilinta*, our treatment for acute coronary syndromes. *Brilinta*, or *Brilique*, its trade name in Europe, is now approved in 64 countries, launched in 37 and under review in a further 39. Also on a positive note, *Caprelsa* (vandetanib), for the treatment of thyroid cancer, has been launched in the US and received a positive CHMP opinion in the EU. *Axanum*, for the prevention of cardiovascular events, Komboglyze<sup>TM</sup>, for diabetes, and *Fluenz*, our influenza vaccine, were also approved in the EU. In Japan, both *Nexium* and *Faslodex* were launched following approvals earlier in the year.

During 2011, two of the Phase III trials for TC-5214, our neuroscience collaboration with Targacept, did not meet their primary endpoint. In December, we also announced that our investigational compound olaparib (AZD2281) for the treatment of ovarian cancer will not progress into Phase III. As a result of these two events we recorded an impairment charge of \$435 million.

We were also disappointed during the year by the withdrawal of zibotentan (for prostate cancer). *Axanum* was also withdrawn in the US. In January 2012, we received a Complete Response Letter from the FDA for our submission for dapagliflozin. We, together with BMS, remain committed to this treatment for diabetes and will work closely with the FDA to provide additional clinical data.

#### Increased collaboration

Our focus on developing in-house capabilities is matched by our desire to develop a more outward-looking organisation committed to accessing the best science, regardless of its origin. Indeed, six of our nine projects in Phase III/Registration and 12 out of 24 in Phase II were sourced externally.

During 2011, we completed a number of transactions to strengthen our long-term development. These included the in-licensing of tremelimumab from Pfizer, and our groundbreaking collaboration

with the UK Medical Research Council providing academic researchers with access to over 20 AstraZeneca compounds. Our plans for R&D will see us build further on this collaborative way of working.

#### **Global orientation**

Our future success requires us to develop global strategies to commercialise our products effectively. These need to be tailored to local needs in both mature and emerging markets.

As part of that drive, we announced our decision to invest \$200 million in a manufacturing facility in China and our agreement to acquire a Chinese company that will give us access to a portfolio of medicines used to treat infections. In Russia, we invested \$150 million in a manufacturing plant and announced plans to establish a new predictive science centre.

We are also committed to playing our part in the global challenge of providing sustainable access to healthcare for all those who need it. Our strategy recognises the complexities surrounding the issue which range from the affordability of medicines to the availability of healthcare systems and the resources to make them effective.

#### Stronger customer orientation

As the Chairman noted, there is no let up in sight on the downward pressure we face on the price of medicines. More than ever, we need to demonstrate their value to those who buy them. Our collaborations with HealthCore and IMS will help us undertake 'real world' studies to understand how to treat disease most effectively and economically. We also need to undertake more studies such as the *Brilinta PLATO* study demonstrating that, even at a higher price, it is a more cost effective treatment than the generic alternative.

Equally, we need to recognise the changing shape of healthcare systems. Those who work in them are working more intensively and with less time to research medicines. We are therefore piloting new ways of working to meet their needs. These include the use of digital channels which offer information that is available when it is needed, and without having to leave the office.

#### **Operational efficiency**

Our continued drive for operational efficiency is typified by the design and construction of our new plant in China, which is using 'Lean' production principles from the outset. We are also streamlining processes and moving to a more flexible cost base in order to remain competitive.

As we reshape our business to meet the needs of our customers efficiently, we are seeing reductions in the workforce across much of our organisation, particularly in our mature Established Markets and in our R&D organisation. This reshaping includes plans for further R&D site consolidation. These are difficult decisions as they go to the heart of AstraZeneca, our people. Where possible, we seek to redeploy staff or assist with outplacement and, together with my colleagues, I remain committed to managing these changes in the right way, in accordance with local employment laws, our standards and core values.

#### A confident future

Our industry is undergoing a period of fundamental change. If we are to be one of the winners in the sector we need to make the necessary changes both to what we do and how we do it. I am confident that within AstraZeneca we have people with the skills to do that and pay tribute to their continued efforts in 2011 to ensure we deliver on our commitments to patients, society and our shareholders. I look forward to working with them to build on those efforts in 2012.

**David R Brennan**Chief Executive Officer

Saince Munn

## Life-cycle of a medicine

## Find potential medicine

Identify the unmet medical need and market opportunity. 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.

#### **Preclinical 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 tolerable dose estimate in humans.

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

#### Phase I studies

Studies designed 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. These typically take place in small groups of healthy human volunteers or, in certain cases, patients.

Confirm the most appropriate formulation and 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.

#### Time (years)

Phase

Overall probability of success

0-1-2-3-4-5-6-7-8-9

Phase I

63%

**Discovery** 

**Preclinical** 

·····>

Clinical

Phase II 30%

Phase III 7%

#### Phase II studies

Studies designed to evaluate effectiveness of the medicine, typically using small groups of patients.

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.

#### Phase III studies

Studies, typically in large groups of patients, designed to gather information about effectiveness and safety of the medicine and evaluate the overall benefit/risk profile in the specific disease and patient segments in which the medicine will be used.

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

## Regulatory submission and pricing

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 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.

The process of getting a drug to market, from initial discovery, through development to approval and launch is risky, costly and time consuming. 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 nor of the probability of success or approval of any AstraZeneca medicine.

#### Launch new medicine

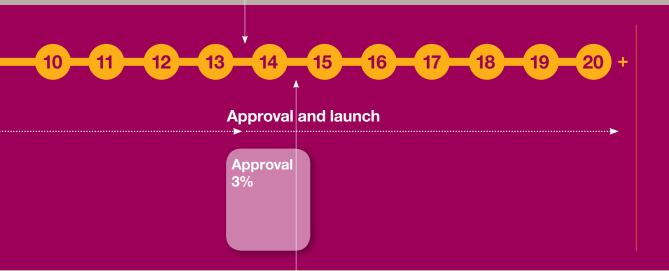
Raise awareness of patient benefit and appropriate use.

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.

## Patent expiry and generic entry

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



## Post-launch research and development

Studies to further understand the safety profile of the medicine in larger populations.

Sponsors and regulatory authorities monitor the safety of medicines post-approval and update prescribing information as necessary.

Includes 'life-cycle management' activities to broaden understanding of the medicine's full potential.

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 benefits and risks of using the medicine in the new disease or population and issue a decision.

<sup>&</sup>lt;sup>1</sup> The line marked 'Overall probability of success' is the probability that a compound in preclinical development will reach each phase of development and subsequent approval. For example, only 7% of preclinical compounds enter Phase III studies. (Source: Pharmaceutical Benchmarking Forum, 2011.)





Innovation drives progress in society. Successful biopharmaceutical innovation, delivered responsibly, brings benefit for patients, creates value for stakeholders and contributes to the social and economic development of the communities we serve.

We are a global R&D-based biopharmaceutical company with a long-standing commitment to delivering valued innovation in healthcare.

- > We remain dedicated to the discovery, development, manufacturing and commercialisation of differentiated, value adding medicines for some of the world's most serious health challenges: cancer, heart disease, gastrointestinal disorders, infection, neurological disorders and respiratory conditions.
- > We work continuously to understand, anticipate and adapt to the needs of a changing world.



> The Manchester Collaborative Centre for Inflammation Research is being created by the University of Manchester, GSK and AstraZeneca to establish a world-leading centre for inflammatory diseases. It is a unique collaboration that began with an initial investment of £5 million from each partner over a three-year period and will bring together scientists from both the pharmaceutical industry and academia.

> A groundbreaking agreement with the UK Medical Research Council (MRC) means a wide range of chemical compounds developed by AstraZeneca is to be made available free of charge to UK medical researchers. As part of the collaboration with AstraZeneca, the MRC is inviting research proposals from across the UK academic community to use the compounds in new areas. The MRC will judge and select the best scientific proposals, and award up to £10 million in total to fund research across a broad range of human diseases. Sir John Savill, Chief Executive of the MRC said: "The initiative marks a new era in medical discovery, open innovation and public-private collaboration."

Our contribution to better health is founded on the R&D of innovative medicines that make a real difference in the treatment of disease.

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#### For more information:

> See from page 30 in the Business Review

> In the US, we used social media channels to support the recruitment of patients into Phase III clinical trials for NKTR-118 which seek to determine whether the medicine is safe and effective for patients suffering from opioid-induced constipation.





## Our Strategy and Performance

More people than ever before had access to innovative medicines in 2011. At the same time, the pharmaceutical industry is facing the expiry of patents on some of the world's most successful medicines, is experiencing pressure on R&D returns and is increasingly being challenged to prove the value of its drugs. In this section, we describe the key growth drivers and challenges that we face. We then describe AstraZeneca's response, strategy and business model for creating value, through which we deliver benefits to our stakeholders. Finally, we outline the indicators that we use to measure our delivery against our objectives.

## The pharmaceutical industry

As the figure overleaf shows, the world pharmaceutical market grew by 4.5% in 2011. Average revenue growth in Established Markets was 2.8% while that in Emerging Markets was over four times higher at 12%. The top five pharmaceutical markets in the world remained the US, Japan, Germany, France and China, with the US representing 38.1% of global prescription pharmaceutical sales (2010: 38.5%).

While demand for medicines and world pharmaceutical markets continued to grow in 2011, research-based pharmaceutical companies faced a challenging marketplace. Industry returns are under pressure from declining R&D productivity and intensifying pricing pressures, particularly in Established Markets facing rising healthcare costs. We also face increased competition from generic medicines as some of the world's most successful drugs come off patent. In addition, greater regulatory constraints are being placed on the pharmaceutical industry by governments and those who pay for our medicines.

The industry remains highly competitive. Our competitors are other large research-based pharmaceutical companies that develop and sell innovative, patent-protected prescription medicines and vaccines, as well as smaller biotechnology and vaccine companies, and companies that produce generic medicines. While many of our peers are confronting similar challenges, strategically these challenges are being met in different ways. For example, some companies have chosen to diversify by acquiring or building branded generics businesses or consumer portfolios, arguing that this enables them to better meet changing customer needs and smooth risk for shareholders.

Most companies continued to pursue their existing strategies in 2011, with some continuing to diversify and others pursuing a focused strategy. There were, however, exceptions with examples of companies shedding diversified assets. Key trends included efforts to improve R&D productivity, expansion of geographic scope, especially in Emerging Markets and Japan, and the pursuit of operational efficiency. Industry consolidation continued with both merger activity and acquisitions of specific assets and capabilities.

#### **Growth drivers**

#### **Expanding patient populations**

The world population is estimated to have passed seven billion in 2011, increasing from six billion in 1998, and is expected to reach nine billion by 2050. In addition, the number of people who can access healthcare continues to increase, particularly among the elderly. Globally, it is estimated that the number of people over 65 will be almost one billion by 2030, double what it was in 2005.

Faster-developing economies, such as China, India and Brazil, offer new opportunities for the pharmaceutical industry to help an expanding number of patients who can benefit from innovative medicines. Emerging Markets now represent approximately 85% of the world population. In addition, pharmaceutical revenues in those markets grew significantly faster than those in Established Markets in 2011 and, as the Estimated pharmaceutical market growth 2010-2015 figure overleaf shows, it is estimated that this trend will continue.

#### **Unmet medical need**

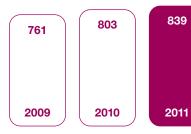
In most established markets, ageing populations and certain lifestyle choices such as smoking, a poor diet and lack of exercise drive an increased incidence of chronic diseases such as cancer, cardiovascular/metabolic and respiratory diseases which require long-term management. The prevalence of chronic disease is increasing in middle income countries and is also beginning to have an impact in low income countries. For example, there are 36 million deaths every year from non-communicable diseases and, of those, 80% are in lower and middle income countries. It is estimated that nearly 33% of the world's diabetes patients will come from India and China by 2030, by which date its prevalence in Brazil is expected to have increased by two-thirds.

#### Strategy and Performance

#### World pharmaceutical markets

#### World

Sales (\$bn)



Growth in 2011

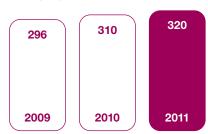
**74.5**%

Market value in 2011

100%

#### US

Sales (\$bn)



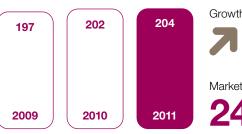
Growth in 2011

**73.4**%

Market value in 2011 **38.1%** 

#### **Western Europe**

Sales (\$bn)



Growth in 2011

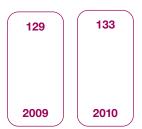
**70.8%** 

Market value in 2011

24.3%

#### **Established ROW**

Sales (\$bn)



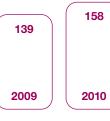
Growth in 2011 73.8%

Market value in 2011

16.5%

#### **Emerging ROW**

Sales (\$bn)



177

2011

Growth in 2011 712.0%

Market value in 2011

21.1%

Data based on world market sales using AstraZeneca's market definitions as set out in the Market definitions table on page 209. Source: IMS Health, IMS Midas Quantum Q3 2011.

2011

#### 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 with the increasing use of generic medication. 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 new types of therapy.

With advances in the technologies for the design and testing of novel compounds, new opportunities exist for the use of innovative small molecules as new medicines. The use of large molecules, or biologics, has also become an important source of innovation, with biologics among the most commercially successful new products. Forecasts for 2016 predict that of the world's top 100 pharmaceutical products, 45% of sales will come from biologics. This compares with only 33% in 2010 and 15% in 2002. Most pharmaceutical companies now pursue both small molecules and biologics R&D.

#### The challenges

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

Improving R&D productivity is a critical challenge for the pharmaceutical industry. Global investment in pharmaceutical R&D by the top 500 pharmaceutical and biotech companies reached an estimated \$133 billion in 2011, a 93% increase from \$69 billion in 2002. Over the same period, the number of new drug launches per year in the US stayed broadly the same, with an annual average of 25. Increasing investment has not yet resulted in a sustained increase in output, although the FDA approved 30 new drugs in 2011. At the same time, there appears to be a shift away from regulatory submissions for broad primary care medicines to more specialist drugs treating, for example, more complex diseases, together with orphan drugs for rare medical conditions.

To ensure it delivers a sustainable return on its R&D investment, the industry is working to increase its probability of success in developing commercially viable new drugs and moving to a lower, more flexible cost base. It does so at a time when regulators and payers are demanding more and better evidence of comparative effectiveness of compounds, which lengthens development times and increases development costs.

Using the full range of innovative technologies, the industry is focused on two critical milestones: Proof of Concept, which delivers candidate drugs with supporting data demonstrating that the drug results in a clinical change with an acceptable endpoint or surrogate in patients with the disease, and, secondly, product approval.

Organisationally, companies are addressing productivity challenges in a variety of ways. These include:

- > focusing on a defined set of therapeutic areas, and exiting those where success has been poor
- > restructuring R&D organisations to create clearer accountabilities and smaller, more entrepreneurial units
- > revamping decision making and governance, so that unsuccessful compounds are identified early, before significant costs have been incurred
- > reducing costs and improving process efficiency, using Lean business improvement tools such as Six Sigma and outsourcing
- > a collaboration-centric business model that includes academic collaborations and co-development agreements that provide for the sharing of development risks and costs with third parties
- > looking externally for high quality science, technologies, targets, drug candidates, and/or entire drug pipelines.

#### **Regulatory requirements**

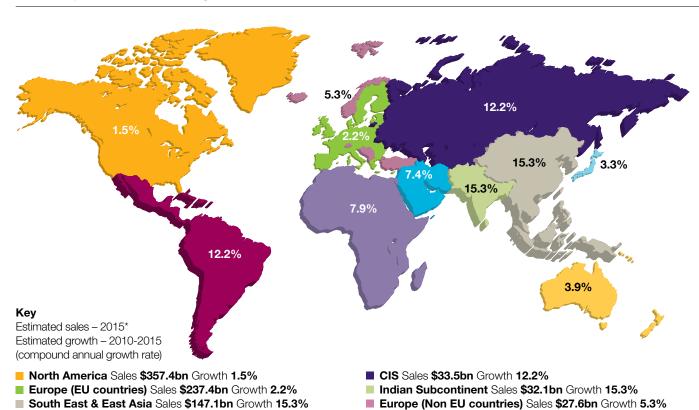
Our industry continues to be one of the most heavily regulated. This reflects public interest in ensuring access to safe, effective and high quality medicines that are responsibly promoted. Given the nature and geographic scope of our business, we maintain important relationships with health authorities worldwide, including the FDA in the US, the EMA in the EU, the Japan Pharmaceuticals and Medical Device Agency and the SFDA in China.

Efforts to harmonise regulations globally are ongoing, yet the number of regulations and their impact continue to multiply. This is particularly evident in the conduct of clinical trials. In order to support the registration of our products in a given regulatory jurisdiction, programmes providing foreign clinical trial data must meet each individual health authority's requirements to ensure relevance to their population. Regulators also continue to redefine their patient safety assessment processes. This includes the management of known and emerging risks, both before and after product approval. In certain markets, additional safety initiatives are developing locally which operate independently of already established international standards. further increasing the complexity and disharmony of drug safety monitoring and reporting. In addition, the growing complexity and globalisation, of both clinical studies and the manufacturing supply chain, has led to an increase in cross-regional health authority collaborations and inspections in these areas.

Public demand for access to data, especially clinical data, to understand how health authorities arrive at their regulatory decisions, has resulted in numerous transparency proposals worldwide. In some instances, policies have been implemented without guidelines that define personal, private and proprietary information. Thus there can be no assurance that the data will be safeguarded against public disclosure.

There is mounting pressure from both health technology assessors and payers to assess not only the safety of our products but also their relative effectiveness and value. Consequently there is a heightened interest by health authorities in both the comparative clinical effectiveness and the ongoing benefit/risk assessment of pharmaceuticals after approval. The regulatory landscape is evolving with an increased focus on incorporating validated health outcome quality measures into clinical trials and developing clinical comparative evidence.

#### Estimated pharmaceutical market growth 2010-2015



Source: IMS Health, IMS Market Prognosis 2011-2015.

Japan Sales \$120.6bn Growth 3.3%

Ex-manufacturer prices at CER.

Africa Sales \$25.0bn Growth 7.9%

Oceania Sales \$16.7bn Growth 3.9%

Latin America Sales \$100.9bn Growth 12.2%

#### **Strategy and Performance**

In spite of the challenges, regulators are approving drugs that address unmet medical needs when supported by strong data and compelling benefit/risk propositions. In addition, health authorities are increasing their collaboration with external stakeholders to drive innovation, define and clarify approval requirements for personalised healthcare and drug-diagnostic combinations, and to accelerate the development of treatments that address public health priorities.

#### **Pricing pressure**

Most pharmaceutical sales continue to be generated in highly regulated markets where governments and private payers, such as insurance companies, exert various levels of control on pricing and reimbursement. Cost containment in healthcare, including containment of pharmaceutical spending, continues to be a focus and the global economic downturn has enhanced this trend. As a consequence, the pricing and reimbursement environments in many markets continue to be highly dynamic. It is increasingly important for companies to work with governments to promote innovation, while ensuring they achieve adequate commercial returns.

Pricing pressures have arisen in the pharmaceutical industry in a number of ways in recent years, particularly through the implementation of a variety of regulatory drug price control mechanisms and other reforms. For example, in Europe, mandatory discounts have been applied in Italy. In Germany, Europe's largest pharmaceutical market, there have been freezes on permitted pharmaceutical prices. In addition, recent German healthcare reforms have transformed the way in which new patent protected drugs are assessed. There is no longer a free market for the pricing and reimbursement for such drugs. Instead the law in Germany now requires manufacturers to prove the additional benefit of their drugs over existing alternatives and demonstrate their value to regulators and payers. Only by showing additional benefit can the drug avoid being transferred to the German reference pricing system, where, for each drug group, a single reimbursement level or reference price is set.

China has experienced 26 rounds of cuts to the maximum permitted retail drug prices in the last seven years and in Japan and South Korea biennial cuts are expected to continue. We are also seeing the introduction of fixed hospital tariffs, which can act as a method of controlling drug costs by incentivising hospitals to choose cheaper generic alternatives.

Elsewhere, such as in Canada and the UK, increasing use is being made of risk sharing agreements, the most common forms of which allow health bodies and payers to seek a refund if a drug fails to meet certain expectations, with other markets expected to follow. Finally, in markets such as France, Mexico and South Korea, price/volume negotiations are becoming prevalent.

In the US, the Affordable Care Act (Act) has already had a direct impact on healthcare activities despite the fact that many of the healthcare coverage expansion provisions of the Act do not take effect until 2014. For example, there has been an increase in drug rebates and discounts. The pharmaceutical industry, including AstraZeneca, has continued to show its commitment to expanding access to government healthcare programmes through, for example, helping to close the coverage gap in the Medicare Part D prescription drug programme and by paying an annual industry fee. The industry is working with policymakers and regulators during the implementation 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 August, as part of the bipartisan agreement to raise the federal debt ceiling, the US Congress created the Joint Select Committee on Deficit Reduction (Committee). The Committee was empowered to recommend a package of \$1.2 trillion in cost savings with the requirement that, if the Committee failed to reach an agreement, the savings would be achieved through across the board spending cuts (sequestration). The Committee discussions ended without reaching

an agreement and, barring future action by Congress, sequestration will take effect on 2 January 2013 and will impact most federal government healthcare programmes, other than Medicaid, with broad reductions in federal government spending. As federal financial pressures continue, we anticipate that some policymakers will look to the pharmaceutical industry for further cost savings in much the same way that they did during deficit reduction discussions.

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 130. The principal aspects of price regulation in our major markets are described further in the Geographical Review from page 77.

#### Patent expiries and genericisation

Over the next few years some of the biggest selling drugs the industry has ever produced face patent expiry. As a consequence, payers, physicians and patients in Established Markets will have low price, generic alternatives in many important classes of primary care drugs. For example, in the US, generics constitute 80% of the market by volume today and are expected to be the single largest driver of value growth up to 2015.

Patents only protect pharmaceutical products for a finite period and the expiry or early loss of patents may lead to the availability of generics. Generic versions of drugs are very competitive with significantly lower pricing than the innovator equivalents. This is partly due to lower investment by generic manufacturers in R&D and market development which generic manufacturers do not need to recover. While generic competition has traditionally occurred when patents expire, it can also occur where the validity of patents is disputed or successfully challenged before expiry. Such early challenges by generics have increased with generic companies increasingly willing to launch products 'at risk', for example, prior to resolution of the relevant patent litigation. This trend is likely to continue, resulting in significant market presence for the generic version during the period in which litigation remains unresolved, even though the courts may subsequently rule that the innovative product is properly protected by a valid patent. The unpredictable nature of 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 this type of settlement agreement.

Biologics have, to date, sustained longer life-cycles than traditional pharmaceuticals and have faced less generic competition. This is due to a more complex manufacturing process for biologics compared with small molecule medicines and the inherent difficulties in producing a copy of a biologic, or 'biosimilar', which is sufficiently similar to the innovator to meet regulatory requirements. However, with regulatory authorities in Europe and the US continuing to implement abbreviated approvals processes for 'biosimilar' versions, biologics are becoming subject to competition from biosimilars and other follow-on biologics.

#### **Building trust**

The pharmaceutical industry faces a challenge in building and maintaining trust, particularly with governments and regulators. The last 10 years have seen a significant increase in the number of settlements between innovator companies and governmental and regulatory authorities for violations of a variety of laws. These include breaches of sales and marketing practices, inducements of physicians to administer a company's products and breaches of anti-trust legislation. For some audiences, there is a perception that pharmaceutical companies place their commercial goals above the interests of patients, physicians and payers. Companies are taking steps to change this perception, by embedding a culture of ethics and integrity, adopting higher standards of governance and improving relationships with employees, shareholders and other stakeholders. For more information about some of the measures we are taking, see the Responsible Business section from page 47.

## **Our strategy**

#### **Mission**

to make the most meaningful difference to health through great medicines that bring benefit for patients and add value for our stakeholders and society

#### **Strategy**

to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business. Our priorities are to drive:

- > World class productivity in R&D
- > Increased external collaboration
- > Our global orientation, reflecting the growth in Emerging Markets
- > Stronger customer orientation, particularly towards payers
- > Operational efficiency with a flexible cost base

#### Strategic pillars

#### **Pipeline**

discovery and development of innovative, differentiated and commercially attractive medicines

#### **Deliver the business**

sales and marketing activities undertaken in the right way and focused on the needs of our customers: patients, physicians, and payers

#### **Business shape**

a reliable supply and manufacturing operation, and Lean organisational infrastructure that ensure our medicines are where they need to be when they are needed

#### **People**

a talented and diverse workforce with the right capabilities operating in a high performance culture

#### Responsible business

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

#### **Values**

principles that define who we are and what is important to us as an organisation, that underpin our mission and our strategy, that demonstrate integrity and enhance trust:

- > Integrity and high ethical standards
- > Respect for the individual and diversity
- > Openness, honesty, trust and support for each other
- > Leadership by example at all levels

Our mission is to make the most meaningful difference to health through great medicines that bring benefit for patients and add value for our stakeholders and society.

The diagram above illustrates the strategic framework which defines the direction and shape of the Group to deliver this. We believe that the most value-creating strategy for AstraZeneca is to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business:

- > biopharmaceutical in that we will develop both chemical (small molecule) and biological (large molecule) medicines
- > focused in that we will continue to be selective about those areas of the pharmaceutical 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 continuing to work 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 continue to be 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. For us, this is the core of our commitment to our stakeholders and society. Successful pharmaceutical innovation, delivered responsibly, brings benefits to patients, creates sustainable value for shareholders and contributes to the economic and social welfare of the communities we serve.

#### **Values**

Building strong relationships is a critical element of our business success. We need to connect with our stakeholders, including patients, doctors, regulators, governments and payers, if we are to understand their needs and challenges, and deliver on our commitment to improving patient health. We also need to earn and maintain the trust of our customers, partners and others. This requires us to behave in accordance with our core values.

## Our business model

Our business model is driven by our strategy and is based on using the best innovative science and technology to invent or acquire, produce and distribute innovative, patent-protected medicines that make a meaningful difference to people's health around the world.

We also commercialise medicines that do not have patent protection where we can obtain prices that reflect the quality and value of our brand. To pursue our strategy, we invest in those projects and products where we believe medical innovation or brand equity will enable us to make acceptable levels of return for our shareholders.

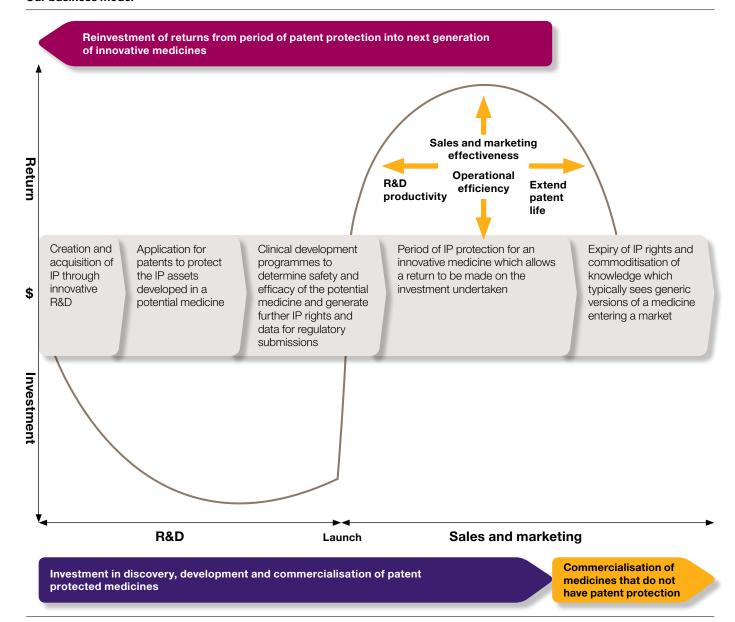
The Life-cycle of a medicine overview on page 10 illustrates the process we use to develop new drugs. It starts with the identification of an unmet medical need and market opportunity and the search for a potential medicine, and moves through clinical trials and drug development, regulatory submission, a medicine's launch and management of its life-cycle.

An inherent element of our business model is the creation and protection of our underlying IP assets. As the diagram below shows, the development of a new medicine requires a significant investment of resources over a period of 10 or more years before product launch, with no guarantee of success. For this to be a viable investment, the resulting new medicine must be safeguarded from being copied with a reasonable amount of certainty for a reasonable period of time. This allows time to generate the revenue we need to reinvest in new pharmaceutical innovation. In addition to establishing and defending our IP assets (see the Intellectual Property section from page 34) and, as illustrated in the diagram, we can also influence the return we make on our investment by improving our:

- > R&D productivity (see from page 30)
- > Sales and marketing effectiveness (see from page 36)
- > Operational efficiency (see from page 38).

A key goal for our planning process is to ensure that we 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 business model



## Our strategic priorities to 2014

Our goal is to create sustainable value for shareholders by being one of the best-performing biopharmaceutical companies. To achieve that goal, the pace of change across AstraZeneca needs to accelerate and we need to deliver on the following medium-term strategic priorities.

#### **Pipeline**

We are transforming our R&D organisation. We have streamlined and refocused our product portfolio, introduced a new operating model, and simplified our site footprint. We continue to focus on improving the quantity and quality of R&D output, by building industry-leading capabilities in critical areas and a more outward-looking organisation, which accesses the best science, regardless of origin.

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 sustain acceptable returns to shareholders. We are therefore accelerating our R&D strategy. We are pioneering innovative ways of conducting research. Neuroscience is a challenging field of medical science with high unmet need, and one that a number of our competitors have chosen to exit. To reinvigorate our efforts in this therapeutic area, we plan to create a virtual innovative medicines unit (iMed) in which a small group of scientists discover and develop a full pipeline of medicines, working with external partners and collaborators. They would replace our current scientific and laboratory resources. Alongside this, we plan to create a simpler, leaner, more flexible organisation through a variety of steps, which better support a more focused portfolio.

#### **Deliver the business**

At a time when many companies are exiting primary care, AstraZeneca is distinctive for combining a broad portfolio of primary and specialty care products with a global reach. We will continue to build on our leading positions in Established Markets and to introduce innovative ways of serving our customers, using digital and telephone channels, service teams, and desk-based medical support. We will invest in growth opportunities, including brands such as Crestor and Brilinta/Brilique and markets such as Japan and China. We will drive sales of our leading products which no longer benefit from patent protection where we retain brand equity and can command prices which reflect the quality and value of our brand. In addition, we will pursue further growth in Emerging Markets by expanding the population we serve, supplementing our patented innovative products with branded generic products sourced externally and marketed under the AstraZeneca brand. To further strengthen revenues, we will accelerate our efforts to secure late-stage/on-market product licensing, acquisition, and peer collaboration opportunities.

Across the Group, we are investing in our ability to meet the needs of those who pay for our medicines. In R&D, our new payer evidence group is ensuring that, as we develop our medicines, we gather not only the clinical data required for regulatory approval, but also the health economics, cost/benefit information and 'value-in-use' data required by payers. Our HealthCore and IMS collaborations will gather real world evidence about the comparative effectiveness of our products. This capability helps us to gain global reimbursement, broad market access and optimal pricing for our medicines.

#### **Business shape**

Given the pressures in the external environment, we will continue to simplify the business. Simplification means not only cost reduction, but also streamlining processes and shifting to a more flexible cost base. In our Commercial organisation, we are simplifying our operating model. We are consolidating the business into three regions: the Americas, EMEA, and Asia-Pacific, running the global and regional organisations from three sites (Wilmington, US, London, UK, and Shanghai, China), and changing our Established Markets footprint in line with declining sales. Following the success of our Nordic and Central American clusters, we are creating further country clusters, to share resources and expertise more effectively. Across our Supply and Manufacturing function, we continue to drive efficiencies through our business improvement programmes, and to use outsourcing and partnering to increase flexibility. We are also consolidating many of our support services into shared services, driving Lean process improvements, investing in automation and new global systems. We are outsourcing selected activities to specialist third party providers in low cost locations.

#### **People**

Talented, motivated and capable people are critical to the successful achievement of our strategic ambitions. We are focused on four key people priorities, as we lead through significant change in the business:

- > acquiring and retaining key capabilities and talent
- > further developing leadership and management capabilities
- > improving the strength and diversity of the talent pipeline
- > improving employee engagement.

#### Responsible business

We reviewed and reshaped our corporate responsibility priority action plan during the year, taking into account our strategy, insights gained from dialogue with stakeholders, and our internal risk assessment. Our new Responsible Business Plan, launched in April 2011, reflects our commitment to enhancing the sustainability of our business by operating responsibly. It underpins our work and provides the framework for applying integrity and high ethical standards across all our activities.

The Responsible Business Plan's objectives are closely aligned to our business strategy. We have given the highest priority to those areas most impacted by our strategic priorities, including sales and marketing practices, access to healthcare, research ethics (including animal welfare), human rights, and supplier management. At the same time we have not lost sight of other significant aspects of our corporate responsibility, such as patient safety and the environment. The Responsible Business Plan is overseen by a Responsible Business Council of senior leaders from within our organisation.

#### Strategy and Performance

#### Restructuring

Since 2007, we have undertaken significant efforts to restructure and reshape our business to improve long-term competitiveness. The first phase is complete. It comprised total restructuring costs of \$2.5 billion and delivered \$2.4 billion in annual benefits by the end of 2010, with a gross headcount reduction of 12,600.

The second phase, which featured a significant change programme in R&D, began in 2010 and was largely completed during 2011. The cost phase of this programme totalled \$2.1 billion and is expected to deliver total annual benefits of \$1.9 billion by the end of 2014, of which \$1 billion had been achieved by the end of 2011. Gross headcount reductions associated with this second phase will be around 9,000.

Both restructuring programmes delivered their targeted benefits to date. We have invested some of the savings to drive future growth and value, such as in our Emerging Markets commercial infrastructure and an expansion of our research capabilities in biologics. At the same time, we have also improved Core pre-R&D and operating margins over the period.

When completed, the next phase of restructuring, announced in February 2012, is expected to deliver a further \$1.6 billion in annual benefits by the end of 2014. Total programme costs are estimated to be \$2.1 billion (approximately \$1.7 billion in cash costs), of which \$261 million were charged in 2011, and the total number of positions expected to be impacted for this phase is estimated to be approximately 7,300. Final estimates for programme costs, benefits and headcount impact in all functions are subject to completion of the requisite consultation processes in accordance with relevant local requirements and labour laws.

#### 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 and February 2012. We continue to plan on the basis that revenue will be in the range of \$28 billion to \$34 billion per annum over the 2010-14 period. However, given increased government price intervention, currency movements and the divestment of Astra Tech, we now expect the centre of gravity for revenue for the remainder of the period is likely to be in the lower half of the range. Using our latest assessment, including the Complete Response Letter received in January 2012 for dapagliflozin in the US, we have lowered our risk adjusted view of the potential revenue contribution in 2014 from recently launched and pipeline products to between \$2 billion and \$4 billion.

Based on continued productivity improvements (including successful completion of restructuring initiatives), our planning assumption remains that Core operating margin, before investment in R&D (Core pre-R&D operating margin) will be in the range of 48% to 54% of revenue. We expect that 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.

The planning assumptions described above depend in turn on assumptions and expectations regarding the development of our business, the industry and macro-economic factors. See the Financial Review from page 82 for a discussion of our high-level planning assumptions. These and other assumptions underlying our expected future results are subject to risks and uncertainties and actual results may differ significantly from our current expectations. See the Principal risks and uncertainties section from page 130.

#### Non-core businesses

We have actively considered potential shareholder value creation from our non-core businesses and, in November 2010, formally initiated a review of strategic options for Astra Tech, a global leader in dental and healthcare (urological and surgical) products, services and support. Our review concluded with the sale of the Astra Tech business to DENTSPLY International Inc. for approximately \$1.8 billion in cash in a transaction that closed on 31 August 2011. Proceeds from the sale are being returned to shareholders through share repurchases.

As of 31 January 2012, we had signed binding agreements with four of the five hospital-based outpatient cancer centres managed by Aptium Oncology, Inc. (Aptium Oncology). Under the terms of these agreements, each hospital has acquired Aptium Oncology's interest in the assets used in connection with the operation of the cancer centres. Transactions with three of the five hospitals had closed by 31 December 2011, a fourth closed in January 2012. We expect the final transaction to be signed during the first quarter and close during the second quarter of 2012. IT transitional services support will be provided to each cancer centre during 2012.

## Our performance in 2011

#### Our performance

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. In setting our objectives we ensure that they are aligned with our medium-term planning assumptions and strategic priorities.

Regular reviews are undertaken in order to monitor and assess progress against business and budget targets. During the year we also seek to manage the business appropriately, both to optimise our opportunities and to assess key risks and mitigating actions. Quarterly reports provide the SET and the Board with insight into progress against current year objectives and milestones for longer-term strategic goals. We assess performance using quantitative, comparative market, operational and financial measures, and qualitative analysis.

We have developed KPIs by which we measure our success in delivering our strategy. A description of our KPIs and how we performed against them in 2011 is shown below and overleaf.

#### **Financial**

Met or exceeded targets as a result of solid business performance plus Astra Tech sale and lower effective tax rate<sup>1</sup>

#### Revenue

Sustain annual revenues of \$28-34 billion

#### 2011:

\$33,591m

2010: \$33,269 million

#### Met target

#### Reinvestment rate

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

#### 2011:

40%

2010: 37%

**Met target** 

### Core pre-R&D operating profit/margin

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

#### 2011:

**54.2**%

2010: 53.5%

#### **Exceeded target**

#### **Total shareholder distribution**

Provide strong cash returns to shareholders via progressive dividends and periodic share repurchases

#### 2011:

\$2.80 \$5.6bn

Full-year dividend \$2.80 Net share repurchases \$5.6 billion

2010: Full-year dividend \$2.55 Net share repurchases \$2.1 billion

Met target

#### <sup>1</sup> See Financial Review from page 82 for more information.

#### **Core EPS**

Achieve Core EPS for 2011 in the range \$7.20-\$7.40

#### 2011:

**\$7.28** 

2010: \$6.71

**Met target** 

## Our performance in 2011 continued

#### **Pipeline**

Major market approvals for *Brilinta*, *Caprelsa*, *Axanum* and Komboglyze™; *Nexium* and *Faslodex* 500mg approved in Japan; mixed results for dapagliflozin submission and disappointments on other pipeline products²

#### **Product approvals**

One-two first major market approvals per year that support revenue target for 2014 of \$3-53 billion from recent launches, pipeline and in-licensing

2011: *Brilinta* approved in the US and Canada; *Caprelsa* (vandetanib) approved in the US and positive CHMP opinion in the EU; *Axanum* approved in the EU, Komboglyze™ approved in the EU, *Fluenz* approved in the EU

2010: Vimovo approved in the US and the EU; Brilique approved in the EU with Complete Response Letter received for Brilinta in the US; Kombiglyze  $XR^{TM}$  approved in the US; additional indications approved for Crestor in the US and the EU and for Seroquel XR in the EU

2014 target reduced

#### **Regulatory submissions**

Major market submissions to support first approvals and line extensions for each new product, and continued marketing applications (first local authorisation and local line extensions) in additional countries to drive growth

2011: *Nexium* and *Faslodex* 500mg approved in Japan; dapagliflozin MAA validated by EMA; Complete Response Letter received from the FDA in the US requesting additional clinical data

2010: Dapagliflozin and vandetanib NDAs submitted in the US and the EU; *Zinforo* and *Axanum* MAAs submitted in the EU

On target

#### Phase III investment decisions

Phase III investment decisions that support value targets for new products<sup>3</sup>

#### 2011: Phase III trials started for NKTR-118 and initiation of Phase III programme for CAZ AVI

2010: Phase III trials started for fostamatinib and TC-5214

2014 target reduced

#### Licensing deals/acquisitions

40% of our pipeline sourced from outside our laboratories

#### 2011:

6 out of 9 Phase III/Registration projects (67%) sourced externally 12 out of 24 Phase II projects (50%) sourced externally

2010

6 out of 9 Phase III/Registration projects (67%) sourced externally 11 out of 32 Phase II projects (34%) sourced externally

Met target

#### **Deliver the business**

Global revenue reduction of 2% included 10% increase in Emerging Markets<sup>4</sup>

#### **Growth of key brands**

Drive revenue growth of key brands that retain exclusivity

#### 2011:

Crestor +13%, Symbicort +11%, Seroquel XR +27%

2010.

Crestor +24%, Symbicort +20%, Seroquel XR +67%

**Met target** 

#### Revenue from new product launches

Revenue in 2014 in the range of \$3-53 billion from recent launches, pipeline and in-licensing

2011:

\$274m

Combined revenue from Onglyza™, Vimovo, Brilinta/Brilique, Caprelsa and Axanum

2010: \$74 million

Combined revenue from Onglyza<sup>TM</sup> and Vimovo

2014 target reduced

#### **Emerging Market sales**

25% of revenue in 2014 from Emerging Markets business

2011:

17%

#### 17% of revenue from Emerging Markets

2010: 16% of revenue from Emerging Markets

On target

 $<sup>^{\</sup>rm 2}$  See Research and Development section from page 30 for more information.

<sup>&</sup>lt;sup>3</sup> Target revised to \$2-4 billion in February 2012. See Medium-term planning assumptions section on page 22.

<sup>&</sup>lt;sup>4</sup> See Financial Review from page 82 and Therapy Area Review from page 56 for more information.

#### **Business shape**

Met targets with continued efficiencies across the organisation⁵

#### **Gross margin**

Maintain gross margin in excess of 80%

2011:

82,2%

2010: 81.2%

Met target

#### **Core SG&A costs**

Improve cost efficiencies and flexibility in SG&A costs

2011:

**1.5%** 

#### 1.5% reduction in Core SG&A costs

2010: 2% reduction in Core SG&A costs

Met target

#### **Procurement savings**

Procurement savings across all functions

2011:

\$487m

#### Savings of \$487 million

2010: Savings of \$541 million

**Met target** 

#### **R&D** cost efficiency

Reduced function costs across R&D to support focused R&D portfolio

2011:

\$5.0bn

### Achieved Core R&D efficiency savings with spend of \$5.0 billion<sup>6</sup>

2010: Achieved Core R&D efficiency savings with spend of \$4.2 billion

**Met target** 

#### **People**

Improvement in employee engagement and senior leader communications<sup>7</sup>

#### **Employee engagement**

Achieve global high performing norm rating for employee engagement by 2014

2011

84%

2010: 83% score

On target

#### Leadership communications

Further developing our leadership and management capabilities

2011

65%

2010: 63% score

Met target

#### Work-life balance

Achieve an improvement in the work-life balance of our employees

2011

67%

2010: 65% score

Met target

<sup>7</sup> See People section from page 40 for more information. All percentages are the result of our global employee survey (FOCUS); percentage scores are measured on a like-for-like basis using comparable questions from the FOCUS survey.

#### Responsible business

Achieved highest ever assessment score for Dow Jones Sustainability World and European Indexes<sup>8</sup>

#### **DJSI** ranking

Maintain position within the DJSI World Index comprising the top 10% of the largest 2,500 companies

2011

**Top 7%** 

2010: Top 8%

**Met target** 

## Confirmed breaches of external sales and marketing codes or regulations

Report confirmed breaches of external codes arising from external scrutiny and voluntary disclosure by AstraZeneca

2011: 17 confirmed breaches of external sales and marketing regulations or codes globally

2010: 11 confirmed breaches of external sales and marketing regulations or codes globally

Met target

#### **Number of audits conducted**

Expand risk-based programme of responsible procurement audits, across all supplier categories and geographies

2011:

**751** 

751 audits of 727 suppliers

2010: 48 audits of 42 suppliers

**Met target** 

<sup>&</sup>lt;sup>5</sup> See Financial Review from page 82 for more information.

<sup>&</sup>lt;sup>6</sup> See Research and Development section from page 30 for more information

 $<sup>^{\</sup>mbox{\scriptsize 8}}$  See Responsible Business section from page 47 for more information.





- > Following the acquisition of Novexel in 2010, we are collaborating with Forest on the co-development and commercialisation of two late stage antibiotic development programmes. In 2011, we announced that one of these, ceftazidime/avibactam (CAZ AVI), is entering Phase III trials to investigate its efficacy in treating patients with complicated intra-abdominal and urinary tract infections.
- > AstraZeneca is one of four companies to have signed up to partner with TB Alliance and the World Health Organization in a six-way alliance through which the companies will share information about the tuberculosis (TB) compounds in their pipelines to quickly identify and collaborate to develop the most promising TB drug regimen, regardless of sponsor. Formed under the Critical Path to TB Drug Regimens (CPTR) initiative, the partnership facilitates a more collaborative approach to TB drug development. It aims dramatically to speed up the development of shorter, safer and more effective multi-drug treatments which are urgently needed to control the global TB pandemic.

We have a long-standing culture of collaboration and 57,200 people worldwide dedicated to working with each other and with our stakeholders to improve healthcare.



# Our strategy is to be a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business

## We need the following resources, skills and capabilities to deliver our strategy:

- > An R&D function with world class productivity. See page 30
- > Cost effective sales and marketing activities focused on our customers' and patients' needs. See page 36
- > A reliable supply and manufacturing operation that ensures our medicines are where they need to be when they are needed. See page 38
- > A talented and diverse workforce with the right capabilities operating in a high performance culture. See page 40

#### These resources need to be underpinned by:

- > A well-functioning system of IP rights. See page 34
- > High quality and flexible support services, including high value information technology and systems. See page 39
- > Employees acting with integrity. See page 40
- > A commitment to acting responsibly and to the sustainable development of our business. See page 47

#### And at the heart of what we do is the need to:

- > Deliver value through innovation. See page 12
- > Find solutions through collaboration. See page 26
- > Earn trust through integrity. See page 44

#### **Business Review**

This section includes information that fulfils the requirements of a business review under the Companies Act 2006. The Strategy and Performance, Corporate Governance, Development Pipeline, Shareholder Information and Corporate Information sections from pages 15, 99, 199, 203 and 208, 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 130.

Many of our products are subject to litigation. Information about material legal proceedings can be found in Note 25 to the Financial Statements from page 184.

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.

## Research and Development We are focused on delivering innovative and valued medicines



I am passionate about making a difference to patients through great medicines. To create value, we aim to unlock the best science available from our own labs and through partnerships"



Martin Mackay President, Global R&D

86

86 pipeline projects of which 79 are in the clinical phase of development and a further seven are approved or launched

9

Nine projects in late stage clinical development, either in Phase III or under regulatory review

18

18 out of 33 projects in Phase II, III or under regulatory review sourced externally

We are committed to deploying 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 at the core of our R&D strategy and continues to drive our focus to create valuable medicines for patients that recognise the needs of healthcare practitioners, governments, payers and external stakeholders throughout the healthcare system.

Our R&D organisation continues to evolve to meet the challenges facing our industry by investing in high quality science and harnessing the innovation of our people. We are continuously improving our understanding of mechanisms and targets that will become the foundation for developing and delivering tomorrow's new medicines. These efforts are undertaken with the highest ethical standards, as we are committed to delivering innovative medicines responsibly. More information about our Responsible Business Plan can be found from page 47.

#### Focused R&D portfolio

We continue to prioritise our resources and focus discovery activities on those diseases within our existing therapy areas where we believe there is the greatest potential to meet patient need through the application of novel science. This continual process of prioritisation is designed to ensure that the projects we have in our pipeline constitute the programmes which we believe are most likely to deliver technical and commercial success.

In 2011, we continued our core research focus on six therapy areas: Cardiovascular, Gastrointestinal, Neuroscience, Infection, Oncology and Respiratory & Inflammation. Our R&D efforts are supported by nine innovative medicine units (iMeds) across small molecule and biologics projects. Eight iMeds focus on defined disease areas, with a ninth targeting New Opportunities. Our iMeds are responsible for discovery and development up to and including Phase II testing and delivery of molecules to our Global Medicines Development (GMD) organisation for Phase III and registration activities. Our GMD organisation provides a single, global platform dedicated to conducting trials for small molecules and biologics and is accountable for delivering the regulatory packages to support launches of new medicines that are commercially attractive and reimbursable. In addition to our defined disease areas, we continuously assess opportunities to acquire, through purchase or partnership, development and commercialisation rights to compounds, targets and technologies outside our core therapeutic expertise.

#### **Development projects**



#### Clinical

- Phase I
   Phase II
   Line Extensions
- <sup>1</sup> Includes seven life-cycle management projects reintroduced from Brazil, Russia, India, China, Mexico, Turkey and Japan.
- <sup>2</sup> Includes seven projects that are approved or launched.

#### **Development projects**

Our pipeline includes 79 projects in the clinical phase of development. As shown in the Development projects chart above, we now have a total of 29 projects in Phase I, 24 projects in Phase II, 10 projects in late stage development, either in Phase III or under regulatory review, and we are running 23 significant life-cycle management projects. During 2011, across the clinical portfolio, 25 projects have successfully progressed to their next phase (including five projects entering first human testing) and 21 projects have been withdrawn. Further details are set out in the Therapy Area Review from page 56 and in the Development Pipeline table from page 199.

#### Portfolio quality

In 2011, we undertook a thorough assessment of our early portfolio projects, resulting in the termination of a number of early projects. Going forward, our focus will be on identifying key candidate medicines that have the highest potential to deliver technical and commercial success. By continuing to apply a rigorous quality approach to our candidate selection process, we expect to increase the likelihood that our most promising medicines progress into Phase III development.

Our Portfolio Investment Board (PIB) plays an important role in maintaining portfolio quality through its continued evaluation of our projects, designed to ensure that we are maximising the value of our R&D investments. More detail relating to the PIB's responsibilities can be found in the Corporate Governance Report from page 99.

#### Pipeline delivery

Several milestones for products currently in development were passed in 2011. These are shown in the table overleaf and more information about these can be found in the Therapy Area Review from page 56.

Of the 21 projects withdrawn in 2011, two were withdrawn following failure to obtain the required regulatory or marketing approvals for the product candidate or the facilities in which it is manufactured and 15 were withdrawn following poorer than anticipated safety or efficacy results. The remaining projects were withdrawn following assessment of the projects against other product pipeline risk factors such as those detailed in the Principal risks and uncertainties section from page 130.

#### Integrated R&D approach

As demonstrated by the Life-cycle of a medicine section on page 10, our R&D activities span the entire life-cycle of a medicine. Our approach brings together drug discoverers and developers within each iMed to focus and collaborate in specific disease areas, while continuing to leverage our expertise in late stage development, product registration and life-cycle management. This new model is designed to increase accountability and enhance scientific knowledge-sharing within therapeutic areas. In addition, our single R&D strategy enables more effective and efficient delivery of our research objectives across the therapeutic portfolio, regardless of geography, disease area or stage of development.

#### **Delivering our strategy**

Milestone	Product	2011 Achievement
Key pipeline progressions	CAZ AVI	Initiation of Phase III programme for CAZ AVI (a combination of ceftazidime and avibactam, formerly known as CAZ-104) for the treatment of complicated intra- abdominal and complicated urinary tract infections
	NKTR-118	Initiation of Phase III programme for treatment of opioid-induced constipation
	Dapagliflozin	FDA acceptance of NDA file for treatment of adult patients with Type 2 diabetes; Complete Response Letter received from the FDA in January 2012 requesting additional clinical data
Komboglyze <sup>TM</sup> (saxagliptin/metformin HCl)	Brilinta/Brilique (ticagrelor)	Regulatory approvals in US, Canada and 64 countries in total for the prevention of cardiovascular events in patients with acute coronary syndromes
	Caprelsa (vandetanib)	FDA approval for treatment of symptomatic and progressive medullary thyroid cancel in patients with unresectable locally advanced or metastatic disease. Positive opinion received from CHMP regarding MAA for <i>Caprelsa</i>
	Axanum (esomeprazole/ASA)	Approval by 23 EU member states as a treatment to prevent CV events in high-risk CV patients in need of low dose ASA who are at risk of gastric ulcers
	0, ( 0,	European Commission approval as a treatment for adults with Type 2 diabetes
	Fluenz (live attenuated, intranasal influenza vaccine)	EU marketing authorisation granted for the treatment of seasonal influenza for children from 24 months to less than 18 years
	Nexium (esomeprazole)	Approval in Japan for acid-related conditions including NERD, reflux esophagitis, and PUD
	Faslodex (fulvestrant) 500mg	Approval in Japan for the treatment of post-menopausal women with hormone receptor-positive metastatic breast cancer which has recurred or progressed following prior endocrine therapy

Our collaboration efforts have resulted in a combination of internally and externally sourced compounds throughout our portfolio, with various development partnerships with biotechnology firms, research institutions and other pharmaceutical companies. We previously announced our intention to source up to 40% of our pipeline from outside our laboratories by 2014 and we are on track to deliver that commitment. Collaborating externally enables us to build the value of our internally-sourced products and identify external sources of cutting-edge science that will enhance and amend our own portfolio of compounds. External partnerships announced in 2011 include:

- > Tremelimumab, a late stage CTLA-4 MAb in oncology which AstraZeneca in-licensed from Pfizer for the potential treatment of a number of oncology indications.
- > A collaboration with the UK Medical Research Council (MRC) in which UK academic researchers are provided with access to over 20 compounds developed by AstraZeneca, for investigation as potential new treatments across a spectrum of diseases.
- > AMG-108, a novel MAb targeting the IL-1 pathway with potential for treating certain inflammatory diseases, which AstraZeneca licensed from Amgen Inc.
- > A strategic collaboration with the Sarah Cannon Research Institute (SCRI), an international leader in advancing therapies for cancer patients through clinical research, under which SCRI will lead the clinical development of a novel targeted oncology compound from AstraZeneca.
- > A collaborative research agreement with Galderma Pharma S.A., a global specialty pharmaceutical company to develop AstraZeneca compounds into new treatments for a range of skin conditions including psoriasis, acne and atopic dermatitis.

- > A collaboration with Manchester University and GSK to establish the Manchester Collaborative Centre for Inflammation Research (MCCIR), a translational science centre that will bring together industry researchers and academia in an alliance to study chronic inflammatory diseases.
- > AZD4694, a late stage radiopharmaceutical imaging candidate, out-licensed to Neoprobe Corporation. AZD4694 is a fluorine-18 labelled radiotracer discovered by AstraZeneca to support development of potential treatments for Alzheimer's disease.
- > Our biologics capabilities signed its first oncology research agreement in China with the Shanghai Chest Hospital. The goal of this collaboration is to build a database of small and non-small cell lung cancer cases.

We continue to search actively for opportunities to advance science and public health through research collaborations and partnerships. This is demonstrated by our ongoing efforts with organisations such as the European Innovative Medicines Initiative (IMI) aimed at improving tools, technologies, methodologies and knowledge management and additional collaborations with the UK MRC and the World Intellectual Property Organisation (WIPO). We have made a significant commitment to the field of neglected tropical diseases (NTDs) R&D via our founder membership of WIPO's 'WIPO Re:Search' consortium. This consortium promotes the formation of research partnerships aimed at driving the identification of solutions to NTDs which are less commercially attractive disease targets, but have particularly severe effects in the world's least developed countries. Our commitment to WIPO Re:Search includes the promise to contribute a range of resources, technology and IP.

#### Investing in capabilities

A core component of our R&D strategy is strengthening four core capabilities. In 2010, we announced an investment of more than \$200 million over five years to develop capabilities in the areas of payer partnering, personalised healthcare, predictive science and clinical design. We are making steady progress in building these skills both internally and through external collaborations. Examples of our efforts in 2011 include:

- > Payer partnering a new payer evidence function has been established to support both our Commercial and R&D organisations in addressing the evidence needs of payers at every stage of the product life-cycle. A key part of this support comes from new capabilities in analysing observational data. We have entered a unique collaboration with HealthCore, the health outcomes research subsidiary of Wellpoint, Inc., to conduct real world studies, designed to determine how to most effectively and economically treat diseases. This provides access to the largest commercially insured population data environment in the US and is fully operational, supporting both development projects and marketed brands. Building on this, in January 2012, we signed a three-year collaboration agreement with IMS Health Inc., providing AstraZeneca with access to pre-existing anonymised health records. This information will provide a degree of insight into how medicines that are already on the market are working in real-world settings across Europe, and will help inform our discovery and clinical development programmes.
- > Personalised healthcare our personalised healthcare capability is focused on identifying patients that are most likely to benefit from our medicines. The proportion of our development portfolio utilising or investigating personalised healthcare approaches such as the use of biomarkers has increased from 25% at the end of 2010 to over 50%, including 10 projects that involve a companion diagnostic to target therapy. Our recently formed personalised healthcare group continues to support *Iressa* with initiatives to improve the speed and quality of diagnostic testing, contributing to *Iressa*'s increase in sales.
- > **Predictive science** we are integrating modelling and simulation into many different aspects of R&D. We recruited 25 external experts from the global modelling and simulation community to accelerate the development of our predictive science capability. Modelling and simulation is now used in the areas of biology, chemistry, formulation development, preclinical and clinical safety assessment, pharmacokinetic and pharmacodynamic evaluation and clinical trial simulation.
- > Clinical design we implemented a range of innovative changes to drive consistency and excellence in the critically important capability of clinical trial design and interpretation. Almost 90% of our R&D teams have incorporated the changes and are starting to utilise a new design and interpretation framework.

#### **Our resources**

At the end of 2011, our R&D organisation comprised approximately 11,300 people at 14 principal centres in eight countries.

Our R&D transformation that began in 2010 has been largely completed, resulting in the closure of several of our R&D facilities and a net reduction of 1,400 positions. The exit of R&D personnel and activities from the Charnwood site in the UK and the Lund site in Sweden was completed in 2011 and the facilities will be closed in early 2012. Our approach to implementing such change is outlined in the Managing change in our organisation section on page 42.

In February 2012, we announced the next phase of restructuring. Further details are set out in the Our strategic priorities to 2014 section from page 21.

Our R&D geographic footprint includes four main small molecule facilities in: the UK (Alderley Park and Macclesfield); Sweden (Mölndal); and the US (Waltham, Massachusetts). Other sites with a focus on research are in Sweden (Södertälje), Canada (Montreal, Quebec) and France (Reims). We also 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 in the UK (Cambridge). Our Wilmington, Delaware site in the US now focuses on late stage development across the portfolio. Finally, our strategic expansion in Emerging Markets continues and includes the growth of our 'Innovation Centre China' research facility in Shanghai, China as well as our research facility in Bangalore, India.

In 2011, there was Core R&D expenditure¹ of \$5.0 billion in our R&D organisation (2010: \$4.2 billion; 2009: \$4.3 billion). In addition, \$189 million was spent on acquiring product rights (such as in-licensing) (2010: \$1,017 million; 2009: \$764 million) and we invested approximately \$468 million on the implementation of our R&D restructuring strategy. The allocations of 2009-2011 spend by early and late activities are presented below.

R&D spend analysis	2011	2010	2009
iMeds (%) (Discovery and early development)	56%	73%	70%
GMD (%) (Late stage development)	44%	27%	30%
Core R&D costs (\$m)	5,033	4,219	4,334

<sup>&</sup>lt;sup>1</sup> Reported expenditure in our R&D organisation was \$5.5 billion (2010: \$5.3 billion; 2009: \$4.4 billion).

#### **Delivering our strategy**

## Intellectual Property We protect the ownership of our inventions



We seek to protect the value of our products and our Company, while safeguarding our reputation"



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 well-functioning 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. Patent rights are limited by territory and duration, yet a significant period of this time can be spent on R&D of our products and before product launch. We therefore commit significant resources to establishing and defending our patent and related IP protections for these inventions.

#### **Patent process**

We file applications for patent protection for our inventions to safeguard the large subsequent investment required to obtain approval of potential new drugs 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 which assess whether our inventions meet the strict legal requirements for a patent to be granted. 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 184.

The basic term of a patent is 20 years from filing of the patent application with the relevant government patent office. However, the product protected by a pharmaceutical patent may not be marketed for several years after patent filing due to the time required for clinical trials and the regulatory approval process necessary to obtain marketing approval for the product. Patent Term Extensions (PTE) are available in certain major markets including the EU and US to compensate for these delays. The term of the PTE can vary from zero to five years depending on the time taken to obtain any marketing approval. The maximum patent term, including any PTE, is however capped at 15 years (EU) or 14 years (US) from the first marketing approval. The average effective patent term on the market is frequently several years less than these maximum terms for reasons including unpredictable regulatory timings and the time taken for any required pricing negotiations.

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 result of patent challenges experienced by our competitors' products may lead to the availability of generics in the same product class as patented products we currently supply, which may materially impact our business. We are 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 130.

#### Patent expiries for our key marketed products

		US	revenue (\$m)	
Key marketed products*#	US Patent expiry	2011	2010	2009
Nexium	2015 <sup>1</sup>	2,397	2,695	2,835
Crestor	2016	3,074	2,640	2,100
Toprol-XL/Seloken	Expired	404	689	964
Atacand	2012	182	216	263
Symbicort	2014 (combination), 2023 (formulation), 2026 (pMDI device)	846	721	488
Zoladex	Expired	39	46	54
Seroquel IR	2012	3,344	3,107	3,074
Seroquel XR	2017 (formulation) <sup>2</sup>	779	640	342
Synagis	2015 (composition), 2023 (formulation)	570	646	782
Prilosec/Losec	Expired	38	47	64

				EU, Canada a	nd Japan revenu	e (\$m)3
Key marketed products*#	EU Patent expiry 4	Canadian Patent expiry	Japanese Patent expiry	2011	2010	2009
Nexium	2014	2014	2020 <sup>5</sup>	1,042	1,422	1,395
Crestor	2017	2012	2017	2,534	2,201	1,782
Toprol-XL/Seloken	Expired	Expired	Expired	163	169	181
Atacand	2012	Expired	N/A	799	837	808
Symbicort	2018 (formulation) 2019 (Turbuhaler device)	2012 (combination) 2018 (formulation) 2019 (Turbuhaler device)	2017 (combination) 2018 (formulation) 2019 (Turbuhaler device)	1,822	1,621	1,459
Zoladex	Expired	Expired	Expired	733	718	744
Seroquel IR	2012	Expired	2012	651	705	792
Seroquel XR	2017 (formulation)	2017 (formulation)	N/A	562	401	301
Synagis	2015 (composition)	2015 (composition)	2015 (composition)	405	392	300
Prilosec/Losec	Expired	Expired	Expired	660	660	641

- \* 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 130. 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 184
- \* 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.

  Licence agreements with Handa and Accord allow each to launch a generic version in the US from 1 November 2016 or earlier upon certain circumstances, subject to regulatory approval.
- Aggregate revenue for the EU, Canada and Japan.
- Expiry in major EU markets.
- <sup>5</sup> PTE application pending.

#### **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 PTE and Paediatric Exclusivity periods.

#### **Data exclusivity**

In addition to patent protection, Regulatory Data Protection (RDP or 'data exclusivity') is an important IP 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.

The period of RDP starts from the date of the first marketing approval from the relevant health authority and runs in parallel to any pending patent protection. RDP would generally be expected to expire prior to patent expiry in all major markets. If a product takes an unusually long time to secure marketing approval or if patent protection has not been secured, expired or lost, then RDP may be the sole IP right protecting a product from copying as generics should not be approved and marketed until RDP has expired.

#### **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 Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (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.

# Sales and Marketing We focus on brands and activities that make a difference



We will lead the industry in commercial innovation that brings value to customers on their terms and improves patient health"



**Tony Zook**Executive Vice-President, Global Commercial Operations

# **Double digit**

Double digit sales growth for Crestor, Seroquel XR and Symbicort

\$5.8bn

Emerging Markets revenue totalled \$5.8 billion, 17% of the total revenue

**\$274m** 

Revenue of \$274 million from recent launches, pipeline and in-licensing

Our global sales and marketing organisation is active in over 100 countries and, at the end of 2011, comprised approximately 32,300 employees. As well as building on our leading positions in the US and Other Established Markets, we continue to increase our strength in Emerging Markets including China, Brazil, Mexico and Russia. See the Market definitions table on page 209 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. This extensive network is supported by a single Commercial organisation that develops global product strategies and drives commercial excellence, ensuring a strong customer focus and commercial direction in the management of our pipeline and marketed products. All our efforts are underpinned by a commitment to conducting our sales and marketing activity in accordance with our values and driving commercial success responsibly.

#### **Driving commercial success**

Delivering commercial success requires us to maximise the value of our portfolio across the whole life-cycle of a medicine. For an overview of this process see the Life-cycle of a medicine section on page 10. We do so by connecting our science with our customers' needs. From an early stage in the medicine discovery process we embed customer insights into our R&D strategy based on our interactions with healthcare providers, patients, regulators and payers. We build on this with our local market expertise and knowledge. This approach helps us to prioritise resources and optimise our portfolio, thereby delivering medicines which customers value and which meet their needs.

Activities in 2011 focused on ensuring continued commercial excellence of key products, such as *Crestor*, *Seroquel XR* and *Symbicort*, driving growth in new markets and accelerating the commercialisation of recently launched products. Recently launched products include Onglyza<sup>TM</sup>, *Brilinta/Brilique*, *Vimovo* and *Caprelsa*. *Brilinta/Brilique* has been approved in 64 countries and, while launches have occurred in 37 markets, due to the time needed to secure reimbursement, formulary approval and protocol adoption, full patient access at the end of 2011 was limited to an estimated 12% of the acute coronary syndromes market.

#### Global strategies tailored to meet local needs

We focus on developing global strategies tailored to meet local needs, and recognise that our commercial capability must evolve to meet future market requirements. The pace and degree of change in global economies, and intensifying regulatory and access challenges have led us to look at ways of better and more efficiently addressing the changing needs and preferences of payers, prescribers and patients.

As part of this effort, in November we announced our consolidation into three regions: (the Americas; EMEA; and Asia-Pacific), running the regional sales and marketing organisation from three sites: (Wilmington, Delaware, US; London, UK; and Shanghai, China), and we are changing

our Established Markets footprint in line with declining sales. Our approach to implementing such consolidation is outlined in the Managing change in our organisation section on page 42.

All our markets have a role to play in delivering our commercial strategy. We continue to prioritise investment and allocate our resources in the most cost effective way. This allows us to identify those markets of major significance to us, those that will become more important drivers of our business in the future and highlight those Established Markets where we need to refocus our approach to deliver sustained success.

#### Creating new commercial sales models

In most countries, our sales are made through wholly-owned local marketing companies. In other countries, we sell through distributors or local representative offices. Our products are marketed primarily to primary care and specialist doctors. Our efforts are directed towards explaining the therapeutic as well as the economic benefits of our products to doctors, governments and others who pay for healthcare.

Face-to-face contact is our traditional marketing method and we are committed to making this channel as effective and efficient as possible. We continue to focus on our customer needs and having learnt from successful approaches implemented in North America and Europe, we are accelerating the adoption of our new commercial sales model which is now live in all our regions; including office-based sales teams, dedicated customer service staff and digital channels.

Our rapid growth in Emerging Markets is driving demand for central commercial support, particularly in respect of sales force effectiveness. We have adopted and rolled out core sales and marketing training programmes in local environments. The main focus of these programmes is to embed core commercial skills and to strengthen sales managers' coaching and planning skills while also reflecting local market needs and conditions.

#### **Pricing our medicines**

Our challenge is to deliver innovative medicines that improve health for patients, bring benefits to society and provide an appropriate return on our investment. Our global pricing policy provides the framework to ensure appropriate patient access while optimising the profitability of all our products in a sustainable way. 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. We also pursue a flexible approach to the pricing of our medicines. For example, we support the concept of differential pricing, provided that appropriate 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.

#### **Delivering value for payers**

Our medicines play an important role in treating unmet medical need. 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.

As outlined in the Pricing pressure section on page 18, there is continued downward pressure on drug pricing and, in the current difficult economic environment, payers expect us to be able to define the value our medicines create. We are acutely aware of the challenges facing those who pay for healthcare and are committed to delivering value which will allow us to bring our valuable medicines to the patients that need them. We therefore work with payers and healthcare providers to understand their priorities and requirements, and generate evidence regarding how our products offer value and support cost effective healthcare delivery.

#### **Broadening affordability**

Sales of medicines in our Established Markets enable us to generate the revenue we need to provide our shareholders with a return, invest in continued innovation and pursue other opportunities to expand the availability of our medicines. At the same time, we recognise that Emerging Markets will contribute around 70% of pharmaceutical industry growth in the five years to 2014. Our programme of investment in these markets continues, both in the large faster growing markets such as China, Mexico, Brazil and Russia, as well as in high-growth, medium-sized and smaller markets.

As we expand our business in these markets, we are exploring broad market strategies to reach new patients, in particular the emerging middle income populations who are increasingly able to access healthcare systems and for whom our medicines are becoming affordable. In some cases, where it is appropriate, we are looking at ways of making our medicines more affordable. For example, our 'Broad Market Strategy' in China means we are expanding our marketing activity and broadening affordability of our medicines to reach an increasing number of physicians and hospitals in communities outside the most affluent cities who do not currently have regular access to healthcare and high quality medicines.

In Brazil, our 'Faz Bem' (Wellbeing) programme provides discounts to the cost of our medicines to patients across all socio-economic groups. The programme also provides additional incentives for those patients who adhere to their treatment regimens which helps improve health outcomes and benefit our business. Like the Faz Bem programme, initiatives in Romania and other Central and Eastern European countries attempt to provide similar incentive schemes to patients that are unable to complete treatment regimens as a result of affordability constraints.

These approaches are part of our overall Access to healthcare strategy which can be found in the Responsible Business section from page 47.

#### A broader portfolio

To support our growth in Emerging Markets, we are broadening our portfolio through the launch of branded genericised medicines. This range will comprise a portfolio of products which are complementary to our patented original medicines in markets where we already have a developed commercial infrastructure, existing relationships with healthcare professionals and a strong reputation.

In the second half of 2011, we continued our programme of generic launches, with three branded generic products being launched in the Philippines. We also launched a generic anti-infective medicine in Thailand in December. Against the backdrop of a challenging competitive environment, we have re-evaluated our portfolio and are now focusing on approximately 70 generic products aligned to our wider portfolio which allows us to adopt an integrated selling model. We plan to market these generic products under the AstraZeneca brand in 20 targeted Emerging Markets.

In December, we announced we had entered into an agreement to acquire Guangdong BeiKang Pharmaceutical Company Limited, a generics manufacturing company, based in Guangdong province, China. This agreement, which remains subject to regulatory approval in China, expected in the first quarter of 2012, will give us access to a portfolio of injectable medicines used to treat infections. It underscores our intention to serve the health needs of Chinese patients through our innovative medicines and, increasingly, high quality branded generic treatments that are locally produced to global standards.

#### Sales and marketing ethics

The pharmaceutical sector is subject to increased oversight by regulatory and governmental 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 2011 performance in the Responsible Business section from page 47.

# Supply and Manufacturing We ensure our medicines are where they need to be when they are needed



Crucial to the delivery of a reliable supply of high quality medicines in a cost effective way is a culture that drives continuous improvement and change"



**David Smith**Executive Vice-President, Global Operations & Information Services

80%

Sustained gross margin in excess of 80%

\$487m

\$487 million in procurement savings

\$388m

Capital expenditure on supply and manufacturing facilities totalled \$388 million

Our strategy is to balance innovative and efficient in-house manufacturing capabilities with external manufacturing resources, particularly in relation to the early stages of our production process. 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 built on the commitment and engagement of our employees and a commitment to minimise the impact on the environment. We focus on what adds value to our customers and patients, as well as waste elimination. This programme has delivered significant benefits in recent years, including reduced manufacturing lead times and lower average stock levels, both of which improve our ability to respond to customer needs and reduce inventory costs. All improvements are designed to ensure we maintain product quality, safety and customer service.

We have applied Lean production business improvement tools and ways of working to improve the efficiency of our manufacturing plants for a number of years, and have now applied them to the whole of our supply chain. This has led to improvements in quality, lead times and overall equipment effectiveness. In 2011, we continued to establish more efficient processes, with experts from our global supply chain organisation providing cross-functional support throughout the business. In October, we launched an online Supply Chain Academy, providing ongoing internal training to drive further improvements across our end-to-end supply chain. Alongside this we ran an internal leadership programme to reinforce the cultural aspects of more efficient supply chain processes.

In October, we announced an investment of \$200 million to build a manufacturing facility in China Medical City in Taizhou, Jiangsu province, China to meet growing local demand for our products and expand availability of our products to people in urban and rural communities. This will be our first manufacturing site to be built using Lean principles from the outset. These principles are being applied from the planning stage to the whole facility, including operators, products, components and equipment. We are designing equipment to meet varying demand, enabling fast, reliable changeover. We also seek to identify where processes could fail, designing systems to minimise these risks.

#### **Product quality**

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

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 improvements to facilities and processes, halt production and impose conditions that must be satisfied before production can resume. Regulatory standards are not harmonised globally and evolve over time.

We hosted 27 independent inspections from 19 different regulatory authorities in 2011. All observations from such inspections are reviewed along with the outcomes of internal inspections and subsequent improvement actions are put in place as required to ensure ongoing compliance. The knowledge obtained from all inspections is shared across the Group.

We are actively involved in providing input into new product manufacturing regulations, both at national and international levels, through our membership of industry associations. For example, in the EU we provided input into the Falsified Medicines Directive, while in the US we contributed to debates concerning drug shortages and security of supply.

#### **Our resources**

Capital expenditure on supply and manufacturing facilities totalled approximately \$388 million in 2011 (2010: \$333 million; 2009: \$360 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 also have a programme in place to provide appropriate supply capabilities for our new products.

At the end of 2011, approximately 9,600 people at 23 sites in 16 countries were working on the manufacturing and supply of our products. In addition to our planned investment in Taizhou, China, 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). We currently 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. We also have major formulation sites for the global supply of parenteral and/or inhalation products in Sweden, France and the UK.

Some 650 permanent and an additional 140 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 capabilities are scalable, which enables efficient management of our combined small molecule and biologics pipeline.

#### Managing sourcing risk

Given our strategy to outsource all API manufacturing, we place particular importance on our global procurement policies and integrated risk management processes to ensure uninterrupted supply of high quality raw materials. Supplies are purchased from a range of suppliers. We factor in a wide range of potential 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, 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 47.

#### **Information Technology**

Effective and flexible IT support services are critical to delivering our strategy. In 2011, we terminated our existing outsource relationship for IS infrastructure services and transitioned to a new multi-sourced operating model. This includes bringing critical strategic and control activities back into AstraZeneca.

# People We are further developing a talented and diverse workforce in a high performance culture

66

Engaged employees, who are true to our core values, supported by accountable and empowered leaders driving performance, underpin the continued success of our business"

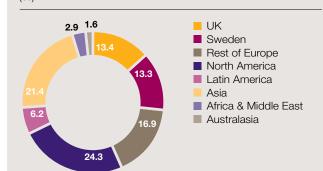


**Lynn Tetrault**Executive Vice-President, Human Resources & Corporate Affairs

84%

Employee engagement FOCUS score rose to 84%

#### Employees by geographical area



With approximately 57,200 people in over 100 countries worldwide, we value the talents, skills and capabilities that a global workforce brings to our business. Our people strategy, which defines our approach to managing our workforce and supports the delivery of our business strategy, is built around four key priorities which we believe are critical: acquiring and retaining key capabilities and talent; further developing leadership and management capabilities; improving the strength and diversity of the talent pipeline; and improving employee engagement while building a high performance culture. Managing significant change in the organisation's workforce is also something to which considerable management attention is directed. We use a range of metrics to track progress against these priorities, which are reported quarterly to the SET.

#### Acquiring and retaining key capabilities and talent

During 2011, we hired approximately 6,400 permanent employees to replace leavers, to fuel the expansion of our business in Emerging Markets and to build the new capabilities required to implement our strategy successfully. With 1,400 of the new hires having joined AstraZeneca in China and 400 in Russia, we have developed a range of innovative approaches to ensure that we have an attractive employer brand globally and to help us achieve our ambitious growth plans in these markets. During the course of the year, we have also successfully attracted key talent to supplement critical capabilities across the business, including in payer excellence and personalised healthcare, and to refresh our leadership pipeline in key areas.

In parallel, we have invested significant management time over the last 12 months to better understand the key drivers influencing employees' decisions to leave across the business, particularly in markets where conditions are most volatile. We have implemented a range of initiatives to minimise the risks to the business from such attrition.

#### Further developing leadership and management capabilities

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

We have 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 our employees.

Alongside judicious hiring of new leaders into critical senior roles, such as recently into our R&D organisation, the development of an internal pipeline of future global leaders is a high priority. 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 we have extended during 2011, addressing people management, change management and other critical capabilities.

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.

#### Improving the strength and diversity of the talent pipeline

Our global workforce provides a diversity of skills, capabilities and creativity and we value the benefits that such diversity brings 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 continue to reshape our organisation and geographic footprint, our ongoing 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.

We have made progress on our evolving global diversity and inclusion strategy following research carried out in 2010 to better understand the barriers to women progressing into more senior roles in the organisation. Under the leadership of a global steering group chaired by our CEO and made up of senior leaders from across the business, we are driving change in three key areas: 'Leadership & Management Capability'; 'Transparency in Talent Management & Career Progression'; and 'Work Life Challenges'. We track gender representation at different levels of the organisation and the country of origin of our senior leaders to measure progress over the medium term.

#### Improving employee engagement

We use a variety of global leadership communications channels to engage employees in our business strategy. These include face-to-face meetings, video conferencing and Yammer (a social media tool) to encourage two way dialogue to take place. For the second year in a row our annual global employee survey (FOCUS) included an open text feedback mechanism, with around 19,000 comments made on a variety of topics.

We measure levels of engagement, the effectiveness of our communications and other areas critical to the performance of our business, such as leadership and management capabilities, through our FOCUS survey. The results are communicated to all employees. Ninety one percent of our people participated in 2011. Our employee engagement score increased by one percentage point from 2010, restoring it to 2009 levels. The leadership category score improved by two percentage points and the leadership communication score, which was identified as a priority after last year's survey, improved by four percentage points. In 2012, we will build on this further, with particular emphasis on clarity of direction and prioritisation from leadership teams.

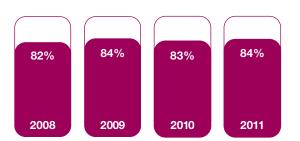
A further area of attention in 2011 was work-life balance, given scores in this area had declined between 2008 and 2010. A set of global work-life balance principles was agreed and communicated in April 2011, initiating a range of activities across the business including manager dialogues, better use of virtual meeting technologies, and health and wellbeing initiatives. Work-life balance category scores improved by two percentage points this year, and we intend to maintain momentum in this area during 2012.

A key element 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, and ongoing coaching and feedback, we strive to 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 on page 104). 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 to 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 113 and also in Note 24 to the Financial Statements from page 176.

#### **FOCUS** engagement scores



#### **Delivering our strategy**

#### Managing change in our organisation

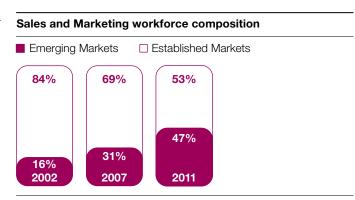
The composition of our global workforce continues to evolve. Our strategic focus on business growth in Emerging Markets has meant the workforce in these areas has grown substantially (as shown in the Sales and Marketing workforce composition figures below). This increase has been accompanied by headcount reductions as a result of our continuing strategic drive to improve efficiency and effectiveness. Reductions have come about through restructuring in R&D, supply and manufacturing, support functions and our sales and marketing workforce in Established Markets, together with the disposal of our Astra Tech business. The net effect of these changes since the end of 2006 has been to reduce our total headcount by some 9,600 from 66,800 to 57,200. This decrease includes a reduction of 2,600 positions in 2010 and a further 5,000 in 2011 which resulted from our business change plans announced in 2010.

In 2011, the most significant business change was the implementation of the R&D strategy announced in 2010, which also involved a number of site changes. While the net impact by the end of 2011 was a reduction of approximately 1,400 roles, almost all R&D employees worldwide were impacted in some way by this change. In order to mitigate further job losses, over 750 employees were redeployed where appropriate skills and capabilities allowed. We were committed to ensuring that AstraZeneca's core values, robust people policies, consultation infrastructure and prior experience were integrated into this multi-faceted business transformation. Trade unions and employee representative groups were involved throughout the restructuring process. With significant investment in outplacement support, high levels of success have been achieved in finding employees alternative opportunities outside AstraZeneca.

In addition, there were reductions in the number of roles in several areas of our sales and marketing organisation in 2011, which were incremental to the ongoing restructuring programme announced in 2010. The most substantial reduction was in the US, where we announced in December that the sales force would be reduced by approximately 1,150 leadership positions and sales representative roles by the end of February 2012.

In February 2012, we announced the next phase of restructuring. Further details are set out in the Our strategic priorities to 2014 section from page 21.

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.



# Compliance We ensure a culture of ethics and integrity



Our task is to ensure that we operate in step with the evolving compliance environment globally and in a way that is consistent with our values"



Katarina Ageborg Chief Compliance Officer

We work to promote best practice in compliance within AstraZeneca in the rapidly changing external environment in which we operate. This is critical to ensuring the trust of our stakeholders and the patients we serve.

Our Global Compliance function has been established to drive and embed a culture of ethics and integrity within our organisation. The addition of Global Compliance to the SET reflects the growing importance of compliance to our business operations.

Our key compliance priorities include:

- > focusing our efforts on important compliance risk areas
- > communicating clear policies to employees
- > improving compliance behaviours through effective training and support
- > ensuring employees can raise concerns and that those concerns will be properly addressed
- > ensuring fair and objective investigations of possible policy breaches
- > monitoring and auditing compliance with policies and working with GIA
- > providing key stakeholders with assurance and effective reporting of material issues.

These priorities are closely aligned to the Group's strategic priorities and reflect our drive to strengthen our efforts for oversight at all levels of our business, including risk management relating to third parties, anti-bribery and anti-corruption. GIA and Global Compliance work closely with one another and both separately provide assurance reporting to the Audit Committee. Our Global Compliance function also works together with a range of specialist compliance functions throughout our organisation to ensure ongoing legal and regulatory compliance. When a potential compliance breach is identified, an internal investigation is undertaken by appropriate staff from our Global Compliance, Human Resources and/or Legal teams. When appropriate, external advisers are engaged to conduct and/or advise on investigations. Should the investigation conclude that an actual compliance breach has occurred, management, in consultation with our Legal function will consider whether the Company needs to make a disclosure and/or to report the findings to a regulatory or governmental authority. More information on GIA and our overall risk management and control framework can be found in the Corporate Governance Report from page 103.

#### **Code of Conduct**

Our Code of Conduct (the Code) is at the core of our compliance programme and applies to all our employees at every level and in every country in which we operate. It has been translated into over 40 languages and each employee has a copy in his/her local language. It provides clear direction as to how our commitment to honesty and integrity is to be translated into consistent actions across all areas of the business. Every employee receives training on the Code and compliance with it is mandatory. Similarly, every employee is required to comply with local laws and regulations, as well as applicable national and international codes. We always seek to operate at the highest of these various standards, whether this is our Code, national legislation or other applicable codes. The Code is regularly reviewed and updated to take account of our changing legal and regulatory obligations.

The Code includes information on how to report possible violations of the Code, including through the AZethics telephone lines and the global website, AZethics.com. Anyone who raises a possible breach in good faith is fully supported by management. We take all alleged compliance breaches and concerns extremely seriously and investigate and report them to the Audit Committee, as appropriate.

In 2011, 222 reports of alleged compliance breaches or other ethical concerns were made via telephone, the AZethics.com website, or the Global Compliance email or postal addresses described in the Code. In 2010, the number of reports through equivalent channels was 368. This decrease is in the context of a significant increase in management self-reporting of compliance incidents, which can be seen as an indication that employees are more comfortable in raising their concerns with line managers, local Human Resources, Legal or Compliance, as recommended in the Code and reinforced in the 2011 annual Code training.

As with the Code, our global policies apply to all members of our Group. They 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. We report on the operation of our Global Policy on External Interactions on page 51.



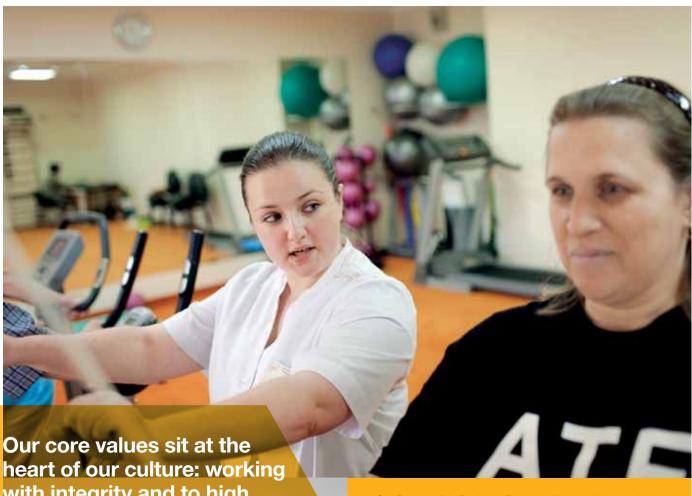


We are dedicated to the research, development and marketing of medicines that make a difference in healthcare. We consider this to be at the core of our responsibility to our stakeholders and society.

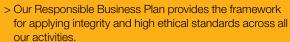
Successful biopharmaceutical innovation brings benefit for patients, creates value for our stakeholders and contributes to the social and economic development of the communities we serve.

Our responsibility also extends to making sure that we deliver success in the right way to bring sustainable benefit through both what we do and how we do it.

The trust of our stakeholders and our continued licence to do business depend on it.



heart of our culture: working with integrity and to high ethical standards; showing respect for the individual and diversity; being open and honest in all our interactions; and leading by example at all levels.



- > Our commitment to the highest standards of sales and marketing practice was underpinned in 2011 by our new Global External Interactions Policy which describes what is required to operate with the highest level of integrity in our interactions with public officials, healthcare professionals and community organisations. Among other things, it places a ban on providing gifts, other than low monetary value cultural items or educational items for the benefit of patients.
- > A Responsible Business Council comprising senior leaders and reporting to the Senior Executive Team has been established. The Council will agree the Responsible Business strategy and oversee its implementation as measured by long-term and annual objectives, targets and KPIs established by the relevant business functions and published in the Responsible Business Plan.





#### For more information:

> See the Responsible Business section which follows

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



Our continuing commitment to enhancing the sustainability of our business was demonstrated by the launch of our Responsible Business Plan and the creation of our Responsible Business Council"



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

In this section we describe how we are working to deliver business success responsibly, including summary information about our commitment and performance in certain 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 sustainable value for shareholders and contributes to the economic development of the communities we serve.

Previous sections have described our strategic business priorities and how we are enhancing our R&D, expanding our footprint in Emerging Markets, continuing 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.

All of these efforts are 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. Our new Responsible Business Plan, published in April 2011, provides our framework for delivering business success responsibly. It puts at the top of our agenda those areas most impacted by our strategic priorities and which are therefore key enablers of our business strategy.

This means a specific focus on:

- > Clinical trials and animal research underpinning our drive for innovation with sound ethical R&D practice worldwide
- > Sales and marketing practices driving consistently high ethical standards to promote our medicines responsibly worldwide
- > Access to healthcare exploring ways of increasing access to healthcare for underserved patient populations in a sustainable way
- > Human rights making sure that we continue to develop and drive a consistent approach across all our activities
- > Diversity and inclusion ensuring that diversity, in its broadest sense, is appropriately represented in our leadership, our workforce and our thinking. See the People section from page 40 for more information
- > Suppliers working only with organisations who embrace ethical standards that are consistent with our own.

#### **Delivering our strategy**

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

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

A summary of these areas of focus is provided in this section. The full Responsible Business Plan is available on our website, astrazeneca.com/responsibility.

#### 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.

The SET and senior managers throughout the Group are accountable for operating responsibly within their areas 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 has a responsibility to integrate sustainability considerations into their day-to-day decision making, actions and behaviours.

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

#### Responsible business governance

During 2011, we established the Responsible Business Council (the Council) – a cross functional team of senior leaders, chaired by our EVP, HR and Corporate Affairs. The Council will meet twice a year and their agenda is focused on driving long-term value creation by agreeing, among other things:

- > Responsible Business priorities for the Group in line with strategic business objectives
- > Strategy and overseeing performance as measured by short- and long-term objectives, targets and key performance indicators recorded in the Responsible Business Plan
- > Appropriate policy positions to support AstraZeneca's business objectives and reputation management.

The Council is supported by a newly established Responsible Business Working Group (the Working Group) of SET area representatives and our CR Team, chaired by the Head of Corporate Affairs Strategy, Brand and CR. Among other things, the Working Group continuously reviews external issues with the potential to impact AstraZeneca and, as appropriate, prepares management and measurement proposals for the Council's consideration. The Working Group will meet four times a year.

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

Stakeholder dialogue was critical in the development of our Responsible Business Plan and we continue to engage with our stakeholders to ensure that our strategy development and risk management take account of their feedback.

During 2011, we developed a global framework for multi-stakeholder engagement to provide a consistent, best practice-based approach across AstraZeneca and to improve how we capture feedback from around the world.

We held a number of multi-stakeholder events throughout the year. These included an event specifically for key Socially Responsible Investor (SRI) contacts. The agenda reflected areas of interest expressed by the SRI community and focused on growth in Emerging Markets, sustaining innovation in R&D and managing environmental impact. Feedback following the event was generally positive and the opportunity to interact with senior AstraZeneca leaders was particularly welcomed by the participants. Discussion centred on how we are managing the potential challenges to sustainability as we expand our business and drive R&D productivity. The SRIs also highlighted that they wanted more information on our access to healthcare strategy.

We also hosted a discussion on global product security during the year. This brought together representatives from diverse organisations, geographies and perspectives to gain insights into what our stakeholders expect from us in the area of product security, and to gain new perspectives on how we can reduce the threat that counterfeiting and illegal trade pose to global health. Attendees included NGOs, supply chain partners, academics and enforcement professionals from both the developed and developing world. The discussion focused mainly on the critical need for collaboration between all the key players in this area, including the role that AstraZeneca can play, working with other manufacturers and influencing broader stakeholders regarding policy and regulation, enforcement and activities to influence patient understanding and behaviour. Product security is an inherent part of our commitment to patient safety, which continues to be a fundamental consideration.

In addition, we use the insights we gain from external surveys to develop our approach in line with global best practice. A member of the Dow Jones Sustainability Index since 2001, AstraZeneca achieved its highest ever placing in the 2011 World Index. We also retained our listing on the DJSI STOXX – European index (the top 20% of the 600 largest European companies) for the fourth year running (one of only four pharmaceutical companies to do so out of 14 assessed). We achieved a total score of 85% (2010: 81%) compared with a sector best score of 87% (2010: 87%). We increased individual scores for 14 out of 23 criteria for 2011 (compared to nine out of 23 criteria in 2010) including corporate governance, R&D, environmental policy and supplier standards. While these scores are encouraging, we lost ground in some areas including marketing practices and health outcomes contribution. 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 2012.

#### **External assurance**

Bureau Veritas has provided external assurance on the responsible business information contained within this Responsible Business section of this Annual Report and of the detailed content of the Responsibility section of our website. Bureau Veritas has found the responsible business 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.



#### **Delivering our strategy**

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

We want to be recognised for our high quality science and for the impact we can make on serious diseases, and to be trusted for the way we work. Our standards of R&D ethics are global and apply to all AstraZeneca research activity, in all locations, whether conducted by us or on our behalf by external contract research organisations (CROs). We continue to work to ensure that these standards are applied, particularly as we expand our activity in countries such as China and Russia.

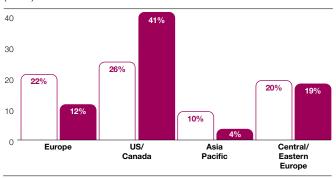
#### **Clinical trials**

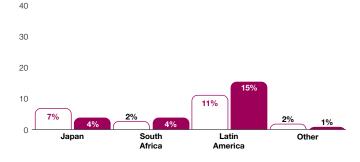
We conduct clinical trials at multiple sites in several different countries. A broad geographic span helps us to ensure that those taking part in our studies reflect the diversity of patients around the world for whom the new medicine is intended. This approach also helps to identify the types of people 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). Protecting participants throughout the trial process is a core priority and we have strict procedures in place to ensure that they are not exposed to any unnecessary risks.

#### Patients in global AstraZeneca studies by geographic region (2011)





☐ Small molecule studies■ Biologics studies

We recognise that situations may exist where continued provision of a non-approved clinical study drug to patients is both appropriate and necessary following the completion of a clinical study. During 2011, we introduced a new standard to provide global guidance in this area. Factors we take into account include the severity of the disease, the availability of alternative treatments, the individual patient response to the medicine, and the overall benefit/risk profile of the medicine based on completed and ongoing studies. If we continue to provide a clinical study drug after the original study is completed, we ensure that appropriate oversight measures are in place, such as dispensing treatment in the context of a clinical study or a compassionate use programme.

All our clinical studies are conceptually designed and finally interpreted in-house but a percentage of them are run for us by CROs. In 2011, around 39% of patients in our small molecule studies and around 66% of patients in our biologics studies were monitored by CROs on our behalf. We contractually require CROs to work to our global standards and we conduct risk-based audits to monitor compliance.

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 2011, we had registered over 1,370 trials and published the results of more than 1,150.

#### **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 preclinical 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 regulatory requirements. We believe that, without our active commitment to the 3Rs, our animal use would be much greater. In 2011, we used approximately 381,400 animals in-house (2010: 408,000). In addition, approximately 16,600 animals were used by external CROs on our behalf (2010: 21,000).

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 peer reviews of our internal animal research facilities conducted by our own qualified staff. External CROs that conduct animal studies on our behalf are required to comply with our global standards and we undertake audits to ensure our expectations are being met.

#### **Protests**

AstraZeneca acknowledges the right of every individual to express their views on the use of animals in research but we condemn the use of violence and other illegal acts. We firmly reject any harassment, intimidation or harming of our employees and their families, our suppliers and our other stakeholders as totally unacceptable.

#### Sales and marketing ethics

Delivering consistently high standards of sales and marketing practice continues to be one of our top priorities and is at the core of our commitment to driving commercial success responsibly. Our activities centre on ensuring that the appropriate information is provided to those who need it to support the safe and effective use of our medicines and enhance patient care.

We have always had a range of sales and marketing policies and standards in place but, following a review in 2010, we further strengthened the requirements and consolidated the range to form a single new Global Policy on External Interactions (the Policy). Launched in April 2011, the new Policy provides a single common, principle-based approach to all our interactions worldwide. Everyone in AstraZeneca, wherever they are located, is required to work to our global standards of ethical sales and marketing practice. We believe this is especially important as we grow our business in Emerging Markets, such as China and Russia, alongside our continued efforts in Established Markets, including the US and Japan.

The diversity of business cultures around the world means that putting a global approach into practice at a local level is a challenge. Nevertheless, we are committed to making it work. During 2011, we continued to provide targeted training for our people to ensure expectations and accountabilities were clear and understood as well as where to obtain further advice and support if needed. We are also talking to our customers and other stakeholders to explain the changes they are seeing to the way we are working with them.

We have comprehensive processes in place for monitoring compliance with our Code of Conduct and global policies, including dedicated compliance professionals who support our line managers locally in monitoring their staff activities. We also have a nominated signatory network that works to ensure that our promotional materials meet all applicable requirements.

Instances of potential non-compliance are collected through our compliance incident management processes and reviewed by senior management in local and/or regional compliance committees. Serious breaches are reviewed by the Audit Committee and, if appropriate, the Board. More information about our compliance and risk assurance processes is contained in the Managing risk section from page 129.

We take all breaches very seriously and act to prevent repeat occurrences. In 2011, we identified a total of 17 confirmed breaches of external sales and marketing regulations or codes globally (2010: 11; 2009: 24). Excluding the confirmed external breaches, there were 1,275 instances of failure to comply with our Code of Conduct and global policies in our Commercial organisation, including contract staff. In relation to all these breaches we removed 214 people from their role, formally warned 570 people, and provided further guidance or coaching on our policies for 971 people. It is important to note that a single breach can involve more than one employee failing to meet the standards required.

We believe that the increase in identified breaches is due in part to our enhanced management oversight of compliance and heightened awareness of policy requirements through targeted training, alongside improved data capture mechanisms. However, we acknowledge that our numbers are likely to continue to vary as we reshape our business and geographic footprint. We will continue to focus our compliance efforts appropriately.

#### Global KPI: Breaches of external sales and marketing codes and regulations ruled by external bodies



#### Disciplinary actions: Breaches of Code of Conduct by our Commercial organisation including contract staff

	Number of pe	eople
Action taken	2011	2010
Removed from role*	214	117
Formal warning	570	740
Guidance and coaching	971	768
Total	1,755	1,625

<sup>\*</sup> In the majority of cases, this means dismissal from the Company/contract termination, but it can include resignations and demotions.

#### **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.

#### Access to healthcare

Providing sustainable access to healthcare for all those who need it is a significant global challenge. The complexities surrounding the issue mean that there is no 'one size fits all' solution. Factors affecting access range from the affordability of medicines to the availability of healthcare systems and the resources to make them effective. We believe it will take a combined global effort involving all related stakeholders to drive sustainable progress in increasing access to healthcare worldwide and we know that, as a global biopharmaceutical company, we can make a meaningful contribution to that effort.

Our strategy takes account of the different barriers to healthcare in different parts of the world and, because access to healthcare can also vary within a country, our approach is tailored locally to meet the needs of different patient populations. We are pursuing a range of different initiatives across these populations to understand what works best and in what context. We believe we will be able to make the biggest contribution to improving health where we are able to adopt a commercial approach. Our goal is always to improve health for patients and add value for our stakeholders and our business.

> Our mainstream business will continue to focus on those people for whom healthcare is readily available and who can afford our medicines. The selling of these medicines in our Established Markets helps enable us to generate the revenue we need to provide our shareholders with a return, invest in continued innovation and pursue other opportunities to increase the availability of our medicines.

#### **Delivering our strategy**

- > As we expand our business in new geographies, we are exploring broad market strategies to reach new patients, in particular the emerging middle income populations who are increasingly able to access healthcare systems and for whom our medicines are becoming affordable. You can read more about our efforts to broaden access to our medicines in the Sales and Marketing section from page 36.
- > The availability of medicines is not always the primary challenge. Access to healthcare also depends on having a functioning healthcare system and the right allocation of resources to make sure that medicines are used appropriately as part of overall health management. For people in communities with limited healthcare infrastructure we partner with others to help strengthen healthcare frameworks and capabilities.

We have defined some common criteria to guide our commitment and ensure that all our partnerships centre on delivering meaningful and enduring benefit. The key principles are that our partnerships:

- > lead to positive, measurable outcomes in underserved communities
- > can be scaled up and potentially replicated to improve outcomes for a greater number of people
- > deliver a sustainable framework that can ultimately be owned and managed locally, without the need for our support.

Such partnerships can also contribute to our business development, by enabling us to understand better the health needs of, and build important relationships in, markets of the future. An example is our Phakamisa initiative in South Africa (see page 55 for further information).

We also partner with NGOs who are experienced at tackling disease at a community level. For example, we have been supporting the British Red Cross since 2002 in their work to tackle TB and TB/HIV in Kyrgyzstan, Turkmenistan and Kazakhstan and, more recently, in South Africa and Lesotho. To date, over 16,000 people have been directly supported in completing their TB treatment across all our partnership countries and TB mortality and morbidity rates continue to fall in our partnership countries in central Asia. Our partnership with the African Medical and Research Foundation (AMREF), created in 2007, centres on strengthening healthcare systems and integrating the management of malaria, HIV/AIDS and TB (MAT) programmes in Uganda, where there is a high burden of all three diseases. Progress to date includes six laboratories upgraded to Ministry of Health standards to support improved diagnosis and over one million patient visits recorded in the Health Management Information System as having received MAT diagnostic, treatment and other services.

Our most recent community investment, the AstraZeneca Young Health Programme (YHP) is designed to help young people in need around the world deal with the health issues they face so they can improve their chances of living a better life. We are working with expert partners, Plan International and Johns Hopkins Bloomberg 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. Adolescent health remains an underserved part of the healthcare agenda and this global investment initiative aims to make a measurable and sustainable difference. YHP initiatives are now in place in nine countries and our target is 15 by the end of 2012. By 2015, YHP will reach 500,000 young people between the ages of 10 and 24 directly and will touch an additional 500,000 lives indirectly.

- > On a broader basis, we collaborate at a global level to increase understanding of fast-emerging and existing health threats in the developing world, and to lend our skills and resources to addressing these. For example:
  - > In partnership with the IFPMA, AstraZeneca is undertaking policy research to understand practical steps to overcome the barriers to treatment and care for non-communicable diseases (NCDs) which are fast overtaking communicable diseases as a developing world health threat. The challenges that NCDs present are not new to us. We have many decades of experience in NCD treatment, with a strong product portfolio and pipeline of new medicines targeting these areas. The majority of our research investment continues to centre on NCDs.
  - > Alongside the rising challenge of NCDs, the battle against TB and neglected tropical diseases (NTDs) is far from over. Scientists at our dedicated research facility in Bangalore, India are focused on finding a new treatment for TB. For further information about this, see the Infection section from page 64. As outlined in the Research and Development section from page 30, during 2011, we joined the World Intellectual Property Organization's (WIPO) Re:Search initiative. This unprecedented collaboration between the private sector and public partners will make publicly available a searchable database of available IP assets and resources for use in NTD research to speed the discovery and development of new potential treatments.

More information about our Access to healthcare strategy and the associated initiatives is available on our website, astrazeneca.com/responsibility.

#### **Human rights**

As we reshape our organisation, grow our business and increase our outsourcing, we are working to make sure that human rights continue to be appropriately integrated into our policies and processes.

AstraZeneca is a signatory 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 long-standing principles for AstraZeneca (as described in our Code of Conduct and global policies) but being part of the UNGC reinforces how seriously we take these principles. It also gives us the framework for further developing our approach.

In recent years, we participated 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 Tool. The first pharmaceutical industry version of the tool was launched in November 2010 and we used it to conduct a labour review in 11 of our marketing companies, including some countries where national labour standards are inconsistent with global best practice. The review focused on International Labour Organization core areas (freedom of association and collective bargaining, forced and bonded labour, child labour, discrimination and working time and wages).

Building on the experience of this review, we adapted and simplified the employment section of the assessment tool and, during the remainder of 2011, used it to conduct a labour review in every country where AstraZeneca has employees.

The results of all our 2011 reviews are currently being collated and analysed to identify what we are doing well and where we may need to improve. Any areas identified for improvement will be included in our local people strategies in the relevant countries.

Also in 2011, the DIHR in collaboration with AstraZeneca, GSK, Novartis and Merck established the Human Rights Assessment Tool for Pharmaceuticals Companies Forum (the Forum). The Forum is a means of sharing information, experience and best practice, helping members to better understand what it means to integrate human rights into daily business practice and to further clarify human rights responsibilities for pharmaceutical companies.

#### **Working with suppliers**

Our ongoing drive to support increased efficiency through our procurement activity continues to be underpinned by our work to make sure that our purchasing is directed only to those organisations which embrace ethical standards consistent with our own.

Our Global Responsible Procurement Standard (the Standard) defines one of the key business processes for integrating our ethical standards into our procurement activity and decision making worldwide. It includes detailed expectations of suppliers. In addition, responsible procurement clauses that include audit requirements are incorporated in supplier contracts. We continue to review the Standard to ensure it appropriately reflects our commitment and during 2011, revised it to strengthen the anti-bribery and anti-corruption (ABAC) requirements in line with our ABAC policy and the requirements of the UK Bribery Act.

The process outlined in our Standard applies to suppliers of goods and services globally and is focused on ensuring that our responsible business expectations are being met. Specific expectations of suppliers such as healthcare professionals or CROs are managed within the relevant functions using specific assessment and monitoring processes.

Our Responsible Procurement 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, focused assessments are then made, relevant to the service provided. Full details of the process are available on our website, astrazeneca.com/responsibility.

By the end of 2011, we had completed 3,342 responsible procurement risk assessments accounting for 71% of our third party spend.

We categorise suppliers as high, medium or low risk. We focus our auditing efforts on high and medium risk rated suppliers but we also audit some suppliers that we consider to be lower risk, to confirm our performance expectations across all suppliers we do business with. In 2011, we worked with our suppliers to substantially increase our audit activity. 727 suppliers across 55 countries have participated in 751 audits undertaken this year (48 audits and 42 suppliers in 2010).

Forty five percent of supplier sites audited demonstrated standards that met our expectations with a further 51% implementing improvements to address non-compliances. We monitor progress across all corrective actions and 4% of suppliers audited this year will require significant follow up to confirm they will make the improvements we require. We will not use suppliers who are unable or unwilling to meet our expectations in a timely way.

Our audits are conducted through a combination of internal resources and external independent auditors. Our assessment programmes reflect best practice from other industry sectors as well as the principles of the Pharmaceutical Supply Chain Initiative.

#### **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 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 our products. As experts in their field, TCS continues to drive 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.

#### **Environmental sustainability**

Managing our environmental impact is a core commitment. In January 2011, we implemented our new SHE strategy and associated objectives and targets for 2011-2015 which are closely aligned with our business objectives and provide the framework for driving our environmental sustainability going forward. This section includes summary information about certain key areas of the framework. Full details of our strategy, objectives and targets are available on our website, astrazeneca.com/responsibility.

We aim to minimise our environmental impact by reducing the carbon footprint and natural resource demands of our business activities, and improve the environmental profile of our products. We believe we are on track to deliver our 2015 targets.

We work to reduce our  $CO_2$  emissions by, among other things, improving our energy efficiency and pursuing lower-carbon alternatives to fossil fuels at our sites, and making sure that our travel and transport activities are as efficient as possible. Our carbon footprint is also affected by some of our respiratory therapies, specifically our

#### **Delivering our strategy**

pressurised metered-dose inhalers that rely on hydrofluoroalkane (HFA) propellants 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. Our target is to reduce our operational greenhouse gas footprint (excluding emissions from patient use of our inhaler therapies) by 20% by 2015. In 2011, our greenhouse gas emissions (from all sources) totalled 1.17 million tonnes (35 tonnes/\$m indexed to Group revenue).

The management of waste is another key aspect of our commitment and we have a 2015 target of a 15% reduction in hazardous and non-hazardous waste. Our primary focus is waste prevention, but where this is not practical, we concentrate on waste minimisation and appropriate treatment or disposal to maximise the reuse and recycling of materials and minimise disposal to landfill. In 2011, our total waste was 45.9 thousand tonnes (excluding our biologics capabilities) with a tonnes/\$m index of 1.41.

We recognise the need to use water responsibly and where possible to minimise the use of water in our facilities. To support the delivery of our target to reduce water use by 25% by 2015, we now have water conservation plans at our largest sites. In 2011, our water use was 4.4 million m³ with a m³/\$m index of 130.

Alongside these efforts, we are also working to ensure that we measure and report the impact of our external manufacturing activity on the environment, and that our suppliers have appropriate environmental improvement targets.

Our continued commitment to product stewardship is underpinned by our ongoing work to integrate environmental considerations into a medicine's complete life-cycle, from discovery and development, through manufacturing, marketing, use and, ultimately, disposal. Further information is available on our website, astrazeneca.com/responsibility, including environmental risk assessment data for our medicines.

#### Employee safety, health and wellbeing

Providing a safe workplace and promoting the health and wellbeing of all our people remains a core consideration. We 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.

In January 2011, we implemented our new SHE strategy and a complementary Health and Wellbeing strategy, 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 and our focus is on promoting driver safety among our sales forces, collectively the single largest group of employees who drive on company business. 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. Driver safety targets are included in regional and local scorecards. Performance is monitored centrally to assess progress and identify areas for improvement.

We regret that during 2011 one of our employees was killed in a road traffic accident while driving on AstraZeneca business. A detailed investigation was carried out, including an audit of the implementation of the Drive Success programme. An action plan was drawn up to respond to the findings of the investigation which include further enhancements to the Drive Success programme and increased communications to drivers. These actions are being tracked and learning will be shared widely across the business.

In 2011, we achieved a 23% improvement in the lost time injury/illness rate compared to the baseline year (2010), exceeding our annual improvement target. This puts us well on track to achieve our 2015 target of a 25% reduction in the lost time injury/illness rate.

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 operates worldwide, we aim to make a positive contribution to our local communities through partnerships, charitable donations and other initiatives that help to make a sustainable difference. Our investment is focused on improving health and promoting science skills.

In 2011, we spent a total of \$1.27 billion (2010: \$1.41 billion) on community sponsorships, partnerships and charitable donations worldwide, including our product donation and patient assistance programmes which make our medicines available free of charge or at reduced prices. Through our three patient assistance programmes in the US we donated products valued at an average wholesale price of over \$938 million (2010: \$1.38 billion). We also donated products worth \$8.2 million, valued at average wholesale price, to the charitable organisations: Americares and Direct Relief International.

#### **Disaster relief**

During 2011, we made a number of contributions to disaster relief efforts, including donations from our Charities Aid Foundation (CAF) account. We also developed an enhanced protocol for working with the British Red Cross, our global disaster relief partner, to improve our internal coordination and enable us to respond in a timely, consistent and effective way to emergencies as and when they arise. This protocol was used to inform the following contributions to disaster relief efforts during the year.

- > In February 2011, we donated £10,000 (approximately \$16,000) from our CAF account to the British Red Cross New Zealand Earthquake Appeal. In March 2011, we donated £100,000 (approximately \$162,000) from our CAF account to the British Red Cross Libya and Region Appeal to help support those who had fled to neighbouring countries to escape the violence in Libya.
- > Following the earthquake in Japan, we donated 51 million Yen (approximately \$640,000) as part of an overall pledge of 100 million Yen (approximately \$1.3 million) to Ashinaga Ikueikai in support of their ongoing relief and rebuilding effort. In addition, employee donations from AstraZeneca in Japan totalling 25.5 million Yen (approximately \$320,000) were matched by the Company. We donated \$25,000 to AMREF to support their local networks in North East Kenya, where the Horn of Africa drought was having a devastating impact.



# healthcollaboration Raising breast cancer awareness and improving treatment

Named after the Zulu word for 'rise' or 'uplifting', our Phakamisa partnership brings together different organisations to help raise breast cancer awareness, increase early diagnosis, and improve access to treatment and effective support networks in communities across South Africa.



## **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 31 December 2011 table on page 57 and the Development Pipeline table from page 199. For details of patent expiries of our key marketed products, see the Patent expiries section on page 35.

Many of our products are subject to litigation. Information about material legal proceedings can be found in Note 25 to the Financial Statements from page 184. Details of relevant risks are set out in the Principal risks and uncertainties section from page 130.

References to months in this section refer to months in 2011, unless otherwise stated.

#### **Sales by Therapy Area**

		2011			2010		2009
	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m
Cardiovascular	10,212	9	5	9,403	12	11	8,376
Gastrointestinal	5,536	(9)	(11)	6,088	1	_	6,011
Infection and other*	1,856	(15)	(15)	2,176	(17)	(18)	2,631
Neuroscience	7,204	7	5	6,704	7	7	6,237
Oncology	3,705	(8)	(12)	4,045	(10)	(12)	4,518
Respiratory & Inflammation	4,468	9	6	4,099	(1)	(1)	4,132
Other businesses**	610	(19)	(22)	754	(16)	(15)	899
Total	33,591	1	(2)	33,269	1	_	32,804

Represents all other pharmaceutical product sales that are not in our six Therapy Areas.

Represents sales by Astra Tech of \$386m (2010: \$535m) and Aptium Oncology of \$224m (2010: \$219m). Astra Tech was sold to DENTSPLY International Inc. on 31 August 2011. Further details on these two businesses are included on page 22.

#### Pipeline by Therapy Area at 31 December 2011

	Phase I	Phase II	Phase III/ Registration	Line Extensions
Cardiovascular	> AZD2820# <b>*</b>	> AZD2927 <b>*</b> > AZD4017 <b>+</b>	> Brilinta/Brilique ◆ > dapagliflozin# ▶	> Axanum ◆ > Brilinta/Brilique PEGASUS-TIMI ▲ (elevated CRP) dapagliflozin/ detormin FDC*  > dapagliflozin/ metformin FDC*  > dapagliflozin/ (diabetes – add on to insulin and add on to metformin LT data)  > dapagliflozin/ metformin FDC*  > dapagliflozin/  > dapagliflozin/  > dapagliflozin/  > dapagliflozin/   > dapagliflozin/   > dapagliflozin/
Gastrointestinal	> tralokinumab * (CAT-354)			> Entocort ❖ > Nexium ▲ (peptic ulcer bleeding) > Nexium (GERD) ◆
Infection	> AZD5099 ❖ > AZD5847 ▲ > MEDI-534 ▲ > MEDI-550 ▲ > MEDI-557 ▲ > MEDI-559 ▲	> AZD9773# ▲ > CXL# ▲ (CEF104)	> CAZ AVI* + (CAZ104) > Q-LAIV Flu Vac ▶ (MEDI-3250) > Zinforo* ▶ (ceftaroline)	> FluMist/Fluenz +
Neuroscience	> AZD1446* ◆ > AZD3241 ▲ > AZD3839* ◆ > AZD5213 ▲ > MEDI-578 ▲	> AZD2423 ▲ > AZD3480# ▲ > AZD6765 ▲ > TC-5214# ▲ (monotherapy)	> NKTR-118# <b>+</b> > TC-5214# ▲ (adjunct)	> Diprivan* ▲ > EMLA* <b>+</b>
Oncology	> AZD1480 ▲	> AZD4547 <b>+</b> > AZD8931 <b>△</b> > fostamatinib** <b>→</b> > MEDI-575* <b>△</b> > selumetinib* <b>△</b> (AZD6244) (ARRY-142886) > tremelimumab* <b>♦</b>	> Caprelsa ◆ (vandetanib) > Ranmark™# ❖ (denosumab)	> Faslodex ◆ (high dose (500mg) 2nd line advanced breast cancer) > Faslodex ◆ (1st line EGFR mut+ NSCLC) > Iressa ◆ (treatment beyond progression)
Respiratory & Inflammation	> AZD2115 <b>*</b> > MEDI-546 <sup>#</sup> <b>△</b> > MEDI-551 <sup>#</sup> <b>△</b> > MEDI-570 <sup>#</sup> <b>△</b>	> AZD1981 ▲ > AZD2423 ▲ > AZD5069 ▲ > AZD5423 ▲ > AZD5423 ▲ > AZD8683 ▲ > benralizumab# ▲ (MED1-563) > mavrilimumab# ▲ (CAM-3001) > MED1-8968# ◆ > sifalimumab# ▲ (MED1-545) > tralokinumab ▲ (CAT-354)	> fostamatinib <sup>#</sup> ▲	> Oxis > Symbicort * (asthma/COPD) > Symbicort > (COPD) > Symbicort > (SMART)

**Key** – showing movements since 27 January 2011

\* Addition

+ Progression

- New filing
- ▲ No change ◆ Launched
  - Reclassified
- # Partnered product.
   \* Kombiglyze XR™ in the US; Komboglyze™ FDC in the EU.
   \*\* Added to pipeline table after starting Phase II in January 2012.

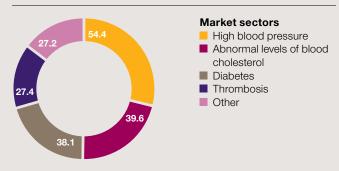
### Cardiovascular

#### In brief

- > Crestor sales up 13% to \$6.62 billion.
- > Results from the SATURN study published in November did not demonstrate a statistically significant greater reduction in favour of *Crestor* versus atorvastatin for the reduction of atherosclerotic plaque (percent atheroma volume) on the primary endpoint even though the reduction was numerically greater. For the secondary efficacy measure of normalised total atheroma volume, *Crestor* demonstrated a statistically significant reduction compared with atorvastatin. Statistically significant differences were observed in favour of *Crestor* for key lipid parameters, and, once again, the study demonstrated that *Crestor* helps to reduce plaque build-up in the arteries.
- > In April 2011 and July, AstraZeneca reached settlements in Canada with Mylan Pharmaceuticals Inc., and Ranbaxy Pharmaceuticals Canada Inc. respectively, resolving litigation relating to the *Crestor* substance patent. The settlement early entry date is 2 April 2012.
- > Several defendants appealed the 2010 decision in the US District Court for the District of Delaware finding in favour of AstraZeneca that the substance patent covering the active ingredient in *Crestor* tablets is valid, enforceable and infringed. The parties await the decision of the US Court of Appeals for the Federal Circuit.
- > Atacand sales down 6% to \$1.45 billion.
- > In July, the FDA approved Brilinta (ticagrelor) to reduce the rate of heart attack (myocardial infarction) and cardiovascular (CV) death in adult patients with acute coronary syndromes (ACS), compared to clopidogrel. In the previous month Health Canada approved Brilinta for the secondary prevention of atherothrombotic events in patients with ACS. In May, we announced new health economics data from a sub-study of the PLATO trial that showed treating a broad spectrum of ACS patients with Brilinta was more cost effective than treatment with generic clopidogrel.
- > In October, *Brilique* (the trade name for ticagrelor in Europe) received final guidance recommendation from The National Institute for Health and Clinical Excellence in the UK, for reimbursement in patients with ACS who have suffered a heart attack or an episode of unstable angina. In December, *Brilique* received a positive final medical benefit assessment in Germany from the Federal Joint Committee as part of the new AMNOG (Arzneimittelmarkt-Neuordnungsgesetz) review process.
- > In January 2011, the EMA validated a MAA for dapagliflozin as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes.
- > In March 2011, the FDA accepted for review the NDA filed by AstraZeneca and BMS for dapagliflozin as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes. Following an FDA Advisory Committee meeting in July requesting additional data, in January 2012, we received a Complete Response Letter from the FDA requesting further clinical data to allow a better assessment of the benefit/risk profile for dapagliflozin.
- > In March 2011, Onglyza™ (saxagliptin) became the first dipeptidyl peptidase IV (DPP-IV) inhibitor available for use in Europe in the treatment of adults with Type 2 diabetes who have moderate or severe renal impairment.
- > In November, AstraZeneca and BMS received approval from the European Commission for the marketing authorisation for Komboglyze<sup>™</sup>, an immediate release fixed dose combination of saxagliptin and metformin HCl as a treatment for adults with Type 2 diabetes.
- > In August, Axanum received positive agreement for approval in 23 European member states and in Norway. Axanum is indicated for prevention of CV events in high-risk CV patients in need of daily low-dose acetylsalicylic acid treatment and who are at risk of gastric ulcers.

#### Therapy area world market

(MAT/Q3/11) (\$bn)



# \$186.7bn

Cardiovascular is the single largest therapy area in the global healthcare market. Worldwide market value of \$186.7 billion.

#### Our marketed products

#### Cardiovascular diseases

- > Crestor¹ (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.
- > **Plendil** (felodipine) is a calcium antagonist used for the treatment of hypertension and angina.
- > 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.
- > **Brilinta/Brilique** (ticagrelor) is an oral antiplatelet for the treatment of acute coronary syndromes (ACS).
- > Axanum (acetylsalicylic acid (ASA) and esomeprazole) is a fixed dose combination indicated for prevention of CV events in high-risk CV patients in need of daily low-dose ASA treatment and who are at risk of gastric ulcers.

#### **Diabetes**

- > Komboglyze<sup>TM4</sup> (saxagliptin and metformin HCI) is an immediate release fixed dose combination indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients with Type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets.
- > **Kombiglyze XR<sup>TM-4</sup>** (saxagliptin and metformin XR) is an extended release fixed dose combination indicated as an adjunct to diet and exercise to improve glycaemic control in adults with Type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.
- Onglyza<sup>TM4</sup> (saxagliptin) is a DPP-IV inhibitor used for the treatment of Type 2 diabetes.

<sup>&</sup>lt;sup>1</sup> Licensed from Shionogi & Co. Ltd.

<sup>&</sup>lt;sup>2</sup> Licensed from Takeda Chemicals Industries Ltd.

<sup>&</sup>lt;sup>3</sup> Licensed from Merck.

<sup>&</sup>lt;sup>4</sup> Co-developed and co-commercialised with BMS.

#### Our financial performance

		World		U	s	We	stern Euro	pe	Esta	ablished R0	wc	Eme	rging Mark	cets	Prior year
2011	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	6,622	16	13	3,074	16	1,225	10	5	1,662	25	15	661	9	8	5,691
Atacand	1,450	(2)	(6)	182	(16)	731	(1)	(6)	213	(5)	(13)	324	6	7	1,483
Seloken/	986	(19)	(20)	404	(41)	85	(7)	(12)	38	(3)	(13)	459	17	15	1,210
Toprol-XL															
Tenormin	270	(2)	(8)	11	(15)	59	(3)	(8)	125	(2)	(10)	75	-	(1)	276
Plendil	256	_	(4)	8	(47)	23	(15)	(19)	14	-	(7)	211	6	2	255
Zestril	144	(8)	(11)	10	_	71	(12)	(16)	14	(18)	(24)	49	_	(2)	157
Onglyza™	211	206	206	156	189	34	240	240	7	250	250	14	367	367	69
Brilinta/Brilique	21	n/m	n/m	11	n/m	9	n/m	n/m	_	-	_	1	n/m	n/m	_
Others	252	(4)	(7)	_	(100)	119	5	_	25	(4)	(15)	108	-	_	262
Total	10,212	9	5	3,856	6	2,356	6	1	2,098	18	9	1,902	9	8	9,403

2010															
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

#### 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, obesity 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 Established Markets and Emerging Markets) as a consequence of the spread of a westernised lifestyle.

In addition to our small-molecule CV research, we are developing potential new therapies using a variety of biologic approaches, including antibodies, peptides and proteins, to address unmet medical needs in the treatment of obesity, diabetes and heart disease.

#### 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. Lipid-modifying 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, with 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. A competitor to *Crestor*, atorvastatin (Lipitor™), was available in generic form in the US from late 2011.

Fewer than half 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 doctors' 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, and has again been shown to reduce atherosclerotic plaque in the recently published SATURN study.

Brilinta/Brilique (ticagrelor) is an oral antiplatelet treatment for ACS in a new chemical class called cyclo-pentyl-triazolo-pyrimidines which are selective adenosine diphospate (ADP) receptor antagonists that act on the P2Y12 ADP-receptor. Brilinta was approved by the FDA in July to reduce the rate of heart attack (myocardial infarction) and CV death in adult patients with ACS, compared to clopidogrel. The FDA approval is based upon data from the PLATO study, a superiority trial that compared treatment with Brilinta to clopidogrel, when added to aspirin, in 18,624 ACS patients worldwide. 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 without increasing major or fatal bleeding. The study provided the basis for regulatory filings worldwide.

In September, *Brilique* (the trade name for ticagrelor in Europe) received final guidance from The National Institute for Health and Clinical Excellence (NICE) in the UK, for reimbursement in patients with ACS who have suffered a heart attack or an episode of unstable angina. In October, the final positive Technology Appraisal Guidance (TAG) from NICE was published. In December, *Brilique* received a positive final medical benefit assessment for the majority of ACS patients in Germany from the Federal Joint Committee as part of the new AMNOG (Arzneimittelmarkt-Neuordnungsgesetz) review process.

#### **Therapy Area Review**

In September, we announced the European Society of Cardiology (ESC) included *Brilique* on their non-ST elevation myocardial infarction (NSTEMI) guidelines in a 1st line position ahead of clopidogrel. This supports its earlier inclusion in the ESC/EACTS revascularisation guidelines in 2010.

In November, *Brilinta* received a Class I recommendation in the updated percutaneous coronary intervention (PCI) guidelines from the American Heart Association (AHA), the American College of Cardiology Foundation (ACCF) and the Society for Cardiovascular Angiography and Interventions (SCAI). That month *Brilinta* was also added to the updated AHA/ACCF Coronary Artery Bypass Graft (CABG) and Secondary Prevention & Risk Reduction Guidelines.

*Brilinta/Brilique* remains under regulatory review in 39 countries. It has been approved in 64 countries, including in the US, Canada and Brazil under the trade name *Brilinta* and in the EU, Iceland and Norway, under the trade name *Brilique*. Additional marketing authorisations and regulatory submissions are planned for 2012.

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 125 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 anti-hypertensive therapy. Atacand Plus is approved in 98 countries.

Axanum is a single capsule of low-dose ASA and esomeprazole (the active ingredient in Nexium). It is indicated for prevention of CV events in high-risk CV patients in need of daily low-dose ASA treatment and who are at risk of gastric ulcers. 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. Up to 30% of patients with upper gastrointestinal 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.

In May, AstraZeneca received a Complete Response Letter from the FDA for the NDA for *Axanum*. AstraZeneca has worked with the FDA and provided additional information. Due to the time delay caused by the Complete Response Letter and the additional review, AstraZeneca has decided to withdraw the NDA for *Axanum*.

In August, *Axanum* received positive agreement for approval in 23 European member states and in Norway. *Axanum* has been approved in 13 of these countries and its first market launch occurred in Germany in November.

#### Clinical studies of our key marketed products

GALAXY, our long-term global clinical research programme for *Crestor*, investigates links between optimal lipid control, atherosclerosis and CV morbidity and mortality. The programme has completed a number of studies involving over 65,000 patients in over 55 countries, some of which are referred to below.

The SATURN study was designed to measure the impact of *Crestor* 40mg and atorvastatin (Lipitor<sup>TM</sup>) 80mg on the progression of atherosclerosis in high-risk patients. Results from the SATURN study published in November did not demonstrate a statistically significant greater reduction in favour of *Crestor* versus atorvastatin (Lipitor<sup>TM</sup>) on the primary endpoint of percent atheroma volume, even though the reduction was numerically greater. For the secondary efficacy

measure of normalised total atheroma volume (TAV), *Crestor* demonstrated a statistically significant reduction compared with atorvastatin (Lipitor<sup>TM</sup>). Statistically significant differences were observed in favour of *Crestor* for key lipid parameters, and, once again, the study demonstrated that *Crestor* helps to reduce plaque build-up in the arteries.

In October 2010, AstraZeneca initiated PEGASUS TIMI-54, a 21,000 patient study in over 30 countries. The study examines the ability of *Brilinta/Brilique* 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 2010 and is ongoing.

The ATLANTIC trial started recruitment in September and is designed to examine the efficacy of pre-hospital (eg ambulance) versus in-hospital administration of *Brilinta/Brilique* co-administered with aspirin in approximately 1,770 patients presenting with one type of heart attack called ST-elevated myocardial infarction (STEMI). The aim of this study is to determine whether initiation of *Brilinta/Brilique* as early as possible can lead to improved outcomes for these patients.

#### **Diabetes**

Type 2 diabetes is a chronic progressive disease and patients often require multiple medications to control their condition. The disease continues to grow as a consequence of western lifestyles and it increasingly affects people at a younger age. 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

AstraZeneca continues its strong worldwide¹ collaboration with BMS to develop and commercialise two compounds discovered by BMS (Onglyza™ (saxagliptin) and dapagliflozin) for the treatment of Type 2 diabetes.

Onglyza<sup>TM</sup> has been submitted for regulatory review in more than 90 countries and approved in 68, including the US, Canada, Mexico, 30 European countries, India, Brazil and China. In March 2011, Onglyza<sup>TM</sup> became the first DPP-IV inhibitor available for use in Europe in Type 2 diabetes patients with moderate or severe renal impairment. This followed the European Commission's approval of a label update for Onglyza<sup>TM</sup> in the treatment of adults with Type 2 diabetes who have moderate or severe renal impairment. The approved dosage for this patient group is a once-daily 2.5mg dose.

In November, AstraZeneca and BMS were granted approval from the European Commission for the marketing authorisation for Komboglyze<sup>TM</sup> (a fixed dose combination of Onglyza<sup>TM</sup> and metformin immediate release tablets) as a treatment for adults with Type 2 diabetes. The decision applies to the 27 member states of the EU. This followed FDA approval in November 2010 for Kombiglyze XR<sup>TM</sup>, a fixed dose combination of Onglyza<sup>TM</sup> plus metformin hydrochloride extended-release tablets. Kombiglyze XR<sup>TM</sup> 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. Kombiglyze XR<sup>TM</sup> was launched in January 2011 in the US.

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

#### In the pipeline

Dapagliflozin, an investigational compound, is a potential first-in-class SGLT2 inhibitor under joint development with BMS as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes. In March 2011, the FDA accepted for review the NDA filed by AstraZeneca and BMS for dapagliflozin as a once-daily oral therapy for the treatment of adult patients with Type 2 diabetes. In June, AstraZeneca and BMS announced the results of two Phase III trials that showed that dapagliflozin treatment was effective in lowering blood glucose and body weight as initial combination therapy with metformin in drug-naïve Type 2 diabetes patients with poor glycemic control. In addition, long-term (102 week) data from double-blind extensions of two Phase III studies in Type 2 diabetes patients showed that improvements in blood glucose lowering and weight loss were maintained over two years for dapagliflozin added to metformin. In July, AstraZeneca and BMS reported the outcome of the FDA Advisory Committee meeting on the NDA. On the question 'Do the efficacy and safety data provide substantial evidence to support approval of dapagliflozin as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus?', the committee voted against recommending approval by nine 'no' votes to six 'yes'. AstraZeneca and BMS subsequently submitted additional clinical data to support the FDA's review of dapagliflozin. This submission represented a major amendment to the NDA and resulted in a three-month extension to the PDUFA action date to January 2012.

In January 2012, AstraZeneca and BMS received a Complete Response Letter from the FDA requesting additional clinical data to allow a better assessment of the benefit/risk profile for dapagliflozin. This includes clinical trial data from ongoing studies and may require information from new clinical trials. AstraZeneca and BMS will work closely with the FDA to determine the appropriate next steps for the dapagliflozin application and remain committed to its development.

In November, AstraZeneca and BMS announced results from a pre-specified meta-analysis of CV safety data from 14 Phase IIb/III trials in adult patients with Type 2 diabetes. These showed that dapagliflozin was not associated with an unacceptable increase in CV risk relative to all comparators pooled in the clinical programme.

The review of the MAA for dapagliflozin in the EU is in progress with a decision expected by the second quarter of 2012.

Our activities in the glucokinase activator area were discontinued during 2011 based on Phase IIb data not showing results supporting the intended target product profile (TPP). In addition, during 2011, we discontinued AZD8329 and AZD7687 due to clinical results not supporting the intended TPP. In 2011, AZD2820 was initiated in clinical testing for the treatment of obesity.

#### **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 primarily in preclinical development, with AZD2927 recently entering Phase II.

#### Financial performance 2011/2010

#### Performance 2011

#### Reported performance

CV sales grew by 9% to \$10,212 million, up from \$9,403 million in 2010, driven by the continuing growth in *Crestor*.

#### Performance - CER growth rates

CV sales increased by 5%.

Global sales of *Crestor* increased by 13% to \$6,622 million. US *Crestor* sales increased by 16% to \$3,074 million. A competitor to *Crestor*, atorvastatin (Lipitor $^{\text{TM}}$ ), was available in generic form in the US from late 2011.

Crestor sales outside the US increased by 10% to \$3,548 million. Volume growth for Crestor in these markets continues to significantly exceed the growth in the overall statin market. Sales in Western Europe increased by 5%, largely due to double digit growth in France and Spain. Sales in Established ROW increased by 15%. Sales in Emerging Markets increased by 8%, where good growth in China was partially offset by generic erosion in Brazil.

US sales of the *Toprol-XL* product range, which includes sales of the authorised generic, decreased by 41% to \$404 million, due to declining prescription volume and lower prices. An additional generic product received regulatory approval in December.

Sales of *Seloken* in other markets increased by 8% to \$582 million, with a 15% increase in Emerging Markets.

US *Atacand* sales decreased by 16%. Outside the US, *Atacand* sales decreased by 4%.

Alliance revenue from the Onglyza<sup>™</sup> collaboration with BMS totalled \$211 million, with alliance revenue in the US of \$156 million and \$55 million in other markets.

Brilinta/Brilique sales were \$21 million.

#### 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 by 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.

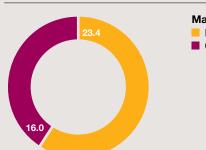
Atacand sales were up 3%, despite US sales being down 18%, as a result of strong growth in Established ROW (8%) and Emerging Markets (17%).

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.

## **Gastrointestinal**



#### Therapy area world market (MAT/Q3/11) (\$bn)



Market sectors

■ PPI ■ Other

\$39.4bn

The gastrointestinal market is valued at \$39.4 billion, with the proton pump inhibitor market accounting for \$23.4 billion.

#### In brief

- > Sales of *Nexium* were \$4.4 billion, down 12% from the previous year.
- > In June and July, the Opposition Division of the European Patent Office revoked European Patent (EP) 1020461 (relating to Nexium) and EP 1020461 (relating to Nexium i.v.). AstraZeneca has appealed these decisions.
- > Losec/Prilosec sales down 11% to \$946 million.
- > In September, AstraZeneca launched Nexium 10mg and 20mg capsules in Japan for the treatment of acid-related conditions including NERD, reflux esophagitis and PUD, following regulatory approval in July. Nexium also received regulatory approval for prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with NSAIDs.

#### 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	rging Mark	ets	Prior year
2011	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	4,429	(11)	(12)	2,397	(11)	762	(37)	(39)	540	19	10	730	18	20	4,969
Losec/Prilosec	946	(4)	(11)	38	(21)	242	(4)	(10)	447	2	(7)	219	(12)	(15)	986
Others	161	21	19	101	33	46	2	(2)	7	17	17	7	17	_	133
Total	5,536	(9)	(11)	2,536	(10)	1,050	(30)	(33)	994	11	2	956	9	10	6,088

2010															
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

#### Our strategic objectives

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

#### **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 GERD. In the US, the EU and other markets Nexium is approved for use in children from the age of one year for the treatment of GERD. In December, the FDA approved Nexium for delayed-release oral suspension for the treatment of erosive esophagitis due to acid-mediated GERD in patients aged one month to less than one year. In the EU, Nexium in combination with antibiotics is also approved for use for the treatment of duodenal ulcers caused by Helicobacter pylori (H. pylori) infection in children from the age of four years. 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.

In September, AstraZeneca launched *Nexium* 10mg and 20mg capsules in Japan for the treatment of acid-related conditions including NERD, reflux esophagitis and PUD, following regulatory approval in July. *Nexium* also received regulatory approval for prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with NSAIDs. AstraZeneca and Daiichi Sankyo will co-promote *Nexium* in Japan under the terms of a 2010 agreement. AstraZeneca will manufacture and develop the product and Daiichi Sankyo will be responsible for its distribution.

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. is approved for use in children from one year in the EU and from age one month in the US.

In May 2010, 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 has worked with the FDA and provided additional information. Due to the time delay caused by the Complete Response Letter and subsequent review, AstraZeneca withdrew the sNDA in the US in May.

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.

#### In the pipeline

Our activities in the field of reflux inhibition and hypersensitivity therapy have been discontinued. We have commenced work with IL-13 inhibition in ulcerative colitis.

#### Financial performance 2011/2010

#### Performance 2011

#### Reported performance

GI sales decreased by 9% to \$5,536 million from \$6,088 million in 2010.

#### Performance - CER growth rates

GI sales decreased by 11%.

Nexium sales in the US decreased 11% to \$2,397 million.

Nexium sales in other markets decreased by 13% to \$2,032 million. Sales in Western Europe decreased by 39% largely due to generic competition, with France accounting for almost half the decline. Sales in Established ROW increased by 10%, as the launch in Japan more than offset the impact of generic competition in Canada. Sales in Emerging Markets increased by 20%.

*Prilosec* sales in the US decreased by 21% to \$38 million. *Losec* sales outside the US decreased by 10% to \$908 million.

#### 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

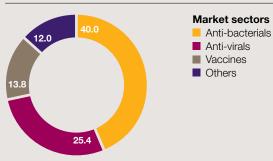
Global GI sales were unchanged. This was due to *Nexium* sales being unchanged from 2009 at \$4,969 million and *Losec/Prilosec* sales showing a small increase of 1% to \$986 million. *Nexium* sales in the US were down 5% to \$2,695 million, although this was offset by sales outside the US which were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

### Infection



#### Therapy area world market

(MAT/Q3/11) (\$bn)



# \$91.2bn

The world infection market is valued at \$91.2 billion, with anti-bacterials accounting for approximately 44%, anti-virals for 28% and vaccines 15%.

#### In brief

- > Synagis sales of \$975 million; in the US \$570 million, down 12%.
- > Merrem/Meronem sales of \$583 million, down 30%.
- > FluMist sales of \$161 million, down 7%.
- > In February 2011, the European Commission granted marketing authorisation for Fluenz, a nasally administered live attenuated influenza vaccine, for the prevention of seasonal influenza for children 24 months to less than 18 years of age. EU launches are planned for the 2012/2013 influenza season.

#### Our marketed products

#### Respiratory syncytial virus (RSV)

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

#### **Serious bacterial infections**

- > **Merrem/Meronem**<sup>1</sup> (meropenem) is a carbapenem antibacterial used for the treatment of serious infections in hospitalised patients.
- > **Cubicin™**<sup>2</sup> (daptomycin) is a cyclic lipopeptide anti-bacterial used for the treatment of serious infections in hospitalised patients.

#### Influenza virus

- > **FluMist/Fluenz** (influenza vaccine live, intranasal) is an intranasal live, attenuated, trivalent influenza vaccine.
- <sup>1</sup> Licensed from Dainippon Sumitomo. <sup>2</sup> Licensed from Cubist Pharmaceuticals, Inc.
- RSV in paediatric patients at high risk of acquiring RSV disease.

#### Our financial performance

		World		US		We	stern Euro	ре	Est	ablished R0	wc	Eme	rging Mark	cets	Prior year
2011	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	975	(6)	(6)	570	(12)	404	3	3	-	-	-	1	_	-	1,038
Merrem/	583	(29)	(30)	41	(68)	179	(45)	(48)	53	(7)	(14)	310	2	_	817
Meronem															
FluMist	161	(7)	(7)	160	(8)	_	_	_	_	_	_	1	_	_	174
Non Seasonal Flu	7	(82)	(82)	7	(82)	_	_	-	_	_	_	-	-	_	39
Others	130	19	17	70	3	10	n/m	n/m	20	_	(25)	30	55	90	108
Total	1,856	(15)	(15)	848	(19)	593	(18)	(19)	73	(5)	(17)	342	5	6	2,176

2010															
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
Meronem															
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

#### 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 pipeline products 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 small molecule and biologics research into novel approaches in areas of unmet medical needs. Complementing our biologics capabilities, we are actively evaluating and integrating small molecule anti-RSV and anti-influenza basic research into our overall anti-viral approach.

#### **Respiratory syncytial virus**

Approximately half of all infants are infected with 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. RSV is the most common virus that causes lung and airway infections in infants and young children. 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 global standard of care for RSV prevention. Approved in 81 countries worldwide, Synagis remains the only immunoprophylaxis in the marketplace indicated for the prevention of RSV in paediatric patients at high risk of RSV. Synagis is administered by intra-muscular injection.

#### In the pipeline

We 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

#### **Serious bacterial infections**

World demand for antibiotics and novel therapeutic approaches 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 a significant number of AstraZeneca's licensed territories in which it is sold, except for the US (36% value share of the carbapenem market). Merrem/Meronem maintains a 6% share of the global intravenous antibiotic market (by value), despite experiencing loss of US market exclusivity in June 2010. Continued generic growth across the carbapenem class is anticipated over the next 12 months following the launches of numerous generics across Europe and the US.

Cubicin™ 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. Cubicin™ was submitted for marketing approval by the SFDA in China in September for the additional indication of complicated skin and skin structure infections.

#### In the pipeline

Zinforo (ceftaroline) is a novel injectable cephalosporin, which is being developed in collaboration with Forest. Zinforo is effective against gram-positive organisms and commonly susceptible gram-negative organisms associated with community-acquired pneumonia (CAP) and complicated skin and soft tissue infections (CSSTI). In particular, Zinforo is active against methicillin-resistant staphylococcus aureus (MRSA). Forest received FDA approval for ceftaroline in October 2010 in the US for the treatment of acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia caused by designated susceptible bacteria. Forest launched in March 2011 under the brand name Teflaro™ (ceftaroline). 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 2010. Further submissions in other jurisdictions continued in 2011.

Following the acquisition of Novexel in 2010 we are working with Forest on future joint global development programmes, including CAZ AVI (a combination of ceftazidime and avibactam, formerly known as CAZ104) and CXL (a combination of ceftaroline and avibactam, formerly known as CXL104/CEF104). The CAZ AVI Phase III programme was initiated in 2011 and includes five trials to confirm the efficacy and tolerability of CAZ AVI in adult patients with complicated intra-abdominal or complicated urinary tract infections. Patients with infections which are resistant to commonly used antibiotics will also be included in the Phase III programme. CXL is in Phase II development for serious infections where coverage against resistant strains is required.

To meet the high and growing need for new and better therapies for resistant bacterial infections we have built an anti-bacterials discovery capability to ensure that AstraZeneca has the resources to create novel mechanism anti-bacterials. Out of this work, a candidate anti-bacterial drug, AZD5099, with a novel mechanism of action involving inhibition of bacterial DNA gyrase, started single ascending dose Phase I studies in healthy volunteers in June. We are also actively evaluating and integrating biologics anti-bacterial modalities (MAbs and vaccines) into our overall approach to dealing with serious bacterial infection challenges.

#### 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.

#### **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 seven countries including the US, Canada and Brazil.

In February 2011, the European Commission granted marketing authorisation to *Fluenz* (the trade name for *FluMist* in the EU), for the prevention of seasonal influenza for children 24 months to less than 18 years of age. The decision is applicable to the 27 EU member states and the European Economic Area. It is expected that the *Fluenz* vaccine will be initially available in select European markets for the 2012/2013 influenza season.

#### **Therapy Area Review**

#### In the pipeline

In April 2011, our biologics capabilities submitted a supplemental Biological License Application for MEDI-3250, a quadrivalent version of *FluMist* containing protection against two A strains and both B lineages of influenza. The PDUFA date is 29 February 2012 and, if approved, launches are anticipated in the US for the 2013-2014 influenza season.

It is anticipated that the MAA and other regulatory submissions for MEDI-3250 will be made from the third quarter of 2012 onwards.

#### **Sepsis**

Sepsis is a life-threatening condition resulting from uncontrolled severe infections. It remains a significant problem in medical management, with approximately three million worldwide incidents annually 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

Our potential treatment for severe sepsis licensed from Protherics Inc. (now part of the BTG plc group) AZD9773 (formerly known as CytoFab<sup>TM</sup>), is an anti-TNF $\alpha$  polyclonal antibody fragment and continues in Phase II development with two studies: a global 300-patient Phase IIb study (still recruiting) and a small Phase II study in Japan for which recruitment is complete. 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.

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. Work ongoing at our research facility in Bangalore, India focuses on finding drugs that will act on multi-resistant strains, will simplify the treatment in (current regimens 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). Bangalore scientists work closely with our infection research centre in Boston, US as well as with academic leaders in the field, and 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. Our discovery collaboration with the Global Alliance for TB Drug Development continues to work towards progressing suitable compounds through to the lead optimisation stage. Research funded by 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, continues. Our most advanced programme, AZD5847 (a novel anti-tubercular oxazolidinone antibiotic), has completed its Phase I programme and is expected to enter Phase IIa trials with support from The National Institute of Allergy and Infectious Diseases in 2012.

#### Financial performance 2011/2010

#### Performance 2011

#### Reported performance

Infection sales decreased by 15% to \$1,856 million from \$2,176 million in 2010.

#### Performance - CER growth rates

Infection sales decreased by 15%.

US Synagis sales decreased by 12% to \$570 million. Outside the US, sales were up 3% to \$405 million.

FluMist sales were \$161 million, a 7% decline from 2010.

Sales of *Merrem/Meronem* decreased by 30% in 2011 as a result of generic competition in the US and Western Europe.

#### 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 2009.

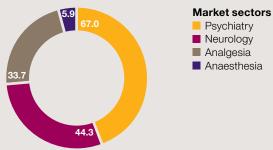
Global *Synagis* sales were down 4%, with sales in the US down 17% to \$646 million being partially offset by strong growth in Western Europe where sales were up 31% to \$392 million.

### **Neuroscience**



#### Therapy area world market

(MAT/Q3/11) (\$bn)



\$150.9bn

The neuroscience world market totals \$150.9 billion.

#### In brief

- > Total Seroquel sales up 8% to \$5.8 billion.
- > In February 2011, the first patients were enrolled in the Phase IIb clinical trial for TC-5214, a neuronal nicotinic receptor modulator being co-developed with Targacept, as a switch monotherapy treatment for major depressive disorder (MDD).
- > In November and December respectively, AstraZeneca announced that the first two Phase III trials for TC-5214 as an adjunct therapy for MDD did not meet their primary endpoints, resulting in a \$150 million impairment charge.
- > In March 2011, the first patients were enrolled in the Phase III clinical programme for NKTR-118, an oral peripherally-acting opioid antagonist being investigated for the treatment of opioid-induced constipation.
- > In September and October respectively, AstraZeneca entered into two settlement agreements regarding its US Seroquel XR patent infringement litigation, first, against Handa and, secondly, against Accord and Intas Pharmaceuticals Ltd. Both settlements were in connection with the companies' proposed generic versions of AstraZeneca's Seroquel XR (quetiapine fumarate) extendedrelease tablets.
- > In September, AstraZeneca filed a Citizen Petition with the FDA in respect of Seroquel XR requesting the FDA withhold approvals of any generic quetiapine drug product which omits from its labelling certain hyperglycemia and suicidality warning language that the FDA required AstraZeneca to include in its Seroquel XR labelling.
- > As of 31 January 2012, AstraZeneca was aware of approximately 25 Seroquel product liability claims that have not been settled in principle. These claims primarily relate to diabetes and/or other related injuries. AstraZeneca has reached agreements in principle on monetary terms with attorneys representing 28,575 claimants.

#### Our marketed products

#### **Psychiatry**

- > 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 generalised anxiety disorder (GAD). Approved use for Seroquel IR and Seroquel XR varies based on territory.

#### Analgesia and anaesthesia

- > **Zomig** (zolmitriptan) is used for the acute treatment of migraines with or without aura and *Zomig Nasal Spray* is indicated for the acute treatment of cluster headache in some territories.
- > Diprivan (propofol) is an intravenous general anaesthetic used in the induction and maintenance of general anaesthesia, for use in intensive care sedation and conscious sedation for surgical as well as diagnostic procedures.
- > Vimovo (naproxen/esomeprazole magnesium) 375/20-500/20mg delayed-release tablets, is a fixed dose combination of enteric-coated naproxen (an NSAID), and immediate release esomeprazole, a proton pump inhibitor (PPI). Vimovo is generally approved for symptomatic relief in the treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis, in patients at risk of developing NSAID-associated gastric and/or duodenal ulcers. Approved use for Vimovo varies based on territory.
- > **Naropin** (ropivacaine) is used as a long-acting local anaesthetic for surgical anaesthesia and acute pain management.
- > Xylocaine (lidocaine) is a widely used short-acting local anaesthetic for topical and regional anaesthesia.
- > EMLA (lidocaine and prilocaine) is used as a local anaesthetic for topical application to prevent pain associated with injections and superficial surgical procedures.

#### **Therapy Area Review**

#### **Our financial performance**

		World		US		We	stern Euro	ре	Est	ablished R	OW	Eme	ets	Prior year	
2011	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
Seroquel IR	4,338	5	3	3,344	8	546	(3)	(8)	228	2	(8)	220	(15)	(17)	4,148
Seroquel XR	1,490	29	27	779	22	490	36	30	89	46	34	132	40	41	1,154
Local Anaesthetics	602	-	(6)	10	(66)	242	(9)	(13)	205	10	-	145	16	13	605
Zomig	413	(4)	(7)	158	(10)	174	1	(4)	68	(1)	(9)	13	18	9	428
Diprivan	294	(9)	(13)	12	(73)	42	(16)	(20)	83	9	1	157	4	(1)	322
Vimovo	34	n/m	n/m	21	n/m	6	n/m	n/m	6	n/m	n/m	1	n/m	n/m	5
Others	33	(21)	(24)	1	_	17	(37)	(41)	3	_	_	12	9	9	42
Total	7,204	7	5	4,325	8	1,517	6	1	682	10	1	680	5	2	6,704
2010															
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

(4)

(19)

(7)

(3)

172

50

27

1.433

(3)

(25)

8

#### Our strategic objectives

428

322

47

6.704

(1)

11

(2)

(2)

8

(4)

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, neuropathic pain control and cognition.

176

45

6

4.003

#### **Psychiatry**

Zomig

Diprivan

Others

Total

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. We continue to pursue projects in clinical development to address current unmet medical needs. While no further internal discovery 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 adult 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. In the US, Seroquel IR is also approved for treatment of acute manic episodes in bipolar disorder in children and adolescents ages 10 to 17 years and for schizophrenia in adolescents ages 13 to 17 years.

To date, *Seroquel XR* has been approved in 76 countries for schizophrenia, 66 countries for bipolar mania, 55 countries for bipolar depression, 41 countries for bipolar maintenance, 42 countries for major depressive disorder (MDD) and six 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.

#### In the pipeline

(2)

(16)

(7)

69

76

3

618

17

29

17

8

20

11

151

11

650

(15)

22

38

20

(23)

17

25

14

In September, the last patient was enrolled in the RENAISSANCE programme for TC-5214, the Phase III trial designed to support an NDA filing in the US planned for the second half of 2012 and an MAA filing in Europe planned for 2015 for TC-5214 as an adjunctive treatment for MDD. TC-5214, a nicotinic modulator, is being co-developed with Targacept. The first two of these Phase III studies did not meet their primary endpoints after eight weeks of treatment with TC-5214 as compared to placebo. Two additional Phase III efficacy and tolerability studies and one long-term safety study are ongoing. Regulatory filing targets for TC-5214 will be reviewed following full results of the remaining studies which are expected in the first half of 2012. In February 2011, the first patients were enrolled in a multinational Phase IIIb clinical trial of TC-5214 as a switch monotherapy treatment for patients with MDD with inadequate response to initial antidepressant therapy.

434

290

48

6,237

AZD6765 has progressed into Phase IIb development to address the needs of patients with severe treatment-resistant depression. Development of AZD2066 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), 375/20-500/20mg delayed-release tablets, co-developed by AstraZeneca and Pozen, is a fixed dose combination of enteric-coated naproxen (an NSAID), and immediate-release esomeprazole, a stomach acid-reducing proton pump inhibitor (PPI). Vimovo is generally approved for symptomatic relief in the treatment of rheumatoid arthritis (RA), osteoarthritis (OA) and ankylosing spondylitis (AS), in patients at risk of developing NSAID-associated gastric and/or duodenal ulcers. The approved use for Vimovo varies based on territory.

Following FDA approval in April 2010, *Vimovo* launched in the US in July 2010. In October, *Vimovo* received positive agreement for approval in 23 European member states. In the EU, *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. We are now pursuing pricing and reimbursement and national approvals in each EU member state. *Vimovo* is now available in every region around the world.

#### In the pipeline

In March 2011, the first patients were enrolled in the Phase III KODIAC programme for NKTR-118, an oral peripherally-acting opioid antagonist being investigated for the treatment of opioid-induced constipation (OIC), a common gastrointestinal side effect of prescription opioids when used for chronic pain management. The Phase III programme is designed to investigate the safety and efficacy of NKTR-118 as a medicine to relieve OIC, and global submissions are anticipated for mid-2013. NKTR-118 is part of the exclusive worldwide licence agreement announced in September 2009, between AstraZeneca and Nektar Therapeutics.

AZD2423 continues in 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 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.

#### In the pipeline

Compounds in Phase II development include products deriving from our relationship with Targacept (AZD3480 and AZD1446). AZD3480, an  $\alpha$ 4ß2 neuronal nicotinic receptor (NNR) agonist, is currently in Phase IIb clinical testing for AD, conducted by Targacept. AZD1446 has completed Phase I and a Phase IIa trial in AD patients is planned in 2012. The option on the Targacept compound, TC-5619 (an  $\alpha$ 7 NNR agonist), was not exercised following the completion of Phase IIa studies, in cognitive disorders in schizophrenia and attention deficit hyperactivity disorder.

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 continues 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. AZD4694, a radioligand currently in Phase II studies, has been out-licensed to Navidea Biopharmaceuticals (formerly Neoprobe Corp.) for Phase III development and commercialisation.

An alliance with the University of Pennsylvania School of Medicine aims to generate new AD drug candidates for the clinical development pipeline. In this collaboration, researchers focus on the protein tau, which is a key component of neurofibrillary tangles that characterise AD.

#### Financial performance 2011/2010

#### Performance 2011

#### Reported performance

Neuroscience sales increased by 7% to \$7,204 million, up from \$6,704 million in 2010.

#### Performance - CER growth rates

Neuroscience sales increased by 5% globally with US sales up 8%.

US sales of *Seroquel* were \$4,123 million, 10% up on 2010. US sales for *Seroquel XR* increased 22% to \$779 million. Total prescriptions for *Seroquel XR* increased by 8%, whilst prescriptions for *Seroquel IR* decreased by 6% compared with 2010.

Seroquel sales outside the US were \$1,705 million in 2011, a 4% increase. Sales of Seroquel XR increased by 32% to \$711 million.

US Vimovo sales were \$21 million. Sales outside the US were \$13 million.

#### Performance 2010

#### Reported performance

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

#### Performance – CER growth rates

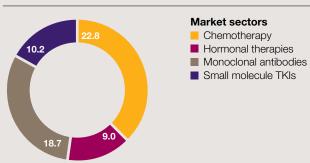
Neuroscience sales were up 7%.

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.

## **Oncology**



#### Therapy area world market (MAT/Q3/11) (\$bn)



# \$60.7bn

The world market value for cancer therapies is \$60.7 billion and continues to grow.

#### In brief

- > Arimidex sales down 53% to \$756 million as a result of patent expiry in the US in 2010 and across the EU.
- > Zoladex sales \$1.2 billion, up 3% from the previous year.
- > Casodex sales \$550 million, down 12%, as a result of continued generic competition across all markets.
- > Faslodex sales \$546 million, up 55%.
- > Iressa sales \$554 million, up 32%.
- > We ended the investigation of zibotentan as a potential treatment for cancer following the results of clinical trials in patients with advanced prostate cancer.
- > In April 2011, vandetanib received FDA approval for the treatment of symptomatic or progressive medullary thyroid cancer (MTC) that cannot be removed by surgery or that has spread to other parts of the body. In August, the FDA approved the trade name Caprelsa for vandetanib. In November, the MAA for Caprelsa (vandetanib) received a positive opinion from the CHMP for the treatment of aggressive and symptomatic MTC in patients with unresectable locally advanced or metastatic disease.
- > In September, AstraZeneca received regulatory approval in Japan for Faslodex (fulvestrant) 500mg for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer which has recurred or progressed following prior endocrine therapy.
- > In December, AstraZeneca announced its decision to discontinue the development of olaparib (AZD2281) for the maintenance treatment of serous ovarian cancer, resulting in a \$285 million impairment charge. This followed a review of an interim analysis of a Phase II study which indicated that the previously reported progression free survival benefit was unlikely to translate into an overall survival benefit, the definitive measure of patient benefit in ovarian cancer.

#### **Our marketed products**

- > Arimidex (anastrozole) is an aromatase inhibitor used for the treatment of 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 non-small cell lung cancer.
- > 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 progressed following treatment with prior endocrine therapy.
- > **Nolvadex** (tamoxifen citrate) remains a widely used breast cancer treatment outside the US.
- > Caprelsa (vandetanib) is a kinase inhibitor indicated for the treatment of symptomatic or progressive MTC in patients with unresectable (non-operable) locally advanced or metastatic disease.

#### Our financial performance

		World		US		We	stern Euro	ре	Esta	ablished R	ow	Eme	cets	Prior year	
2011	Sales \$m	Reported growth %	CER growth %	F 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	756	(50)	(53)	42	(91)	260	(55)	(56)	308	7	(2)	146	(3)	(6)	1,512
Zoladex	1,179	6	3	39	(15)	262	(5)	(9)	494	10	-	384	12	18	1,115
Casodex	550	(5)	(12)	(6)	(138)	80	(29)	(33)	364	5	(5)	112	9	7	579
Iressa	554	41	32	2	(50)	127	159	147	204	12	2	221	40	34	393
Others	666	49	46	276	71	206	53	46	70	15	5	114	28	26	446
Total	3,705	(8)	(12)	353	(51)	935	(19)	(22)	1,440	8	(1)	977	16	16	4,045

2010															
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

#### Our strategic objectives

We aim to build on our position as one of the world leaders in cancer treatment with established brands such as *Zoladex* and *Arimidex* and growing brands such as *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 a 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.

Faslodex 500mg is now approved in many markets including the EU, the US and Japan. It offers an additional, efficacious, hormonal therapy option for patients with hormone-receptor positive advanced breast cancer. It is given by once-monthly injections and is approved for the treatment of hormone-receptor positive advanced breast cancer in post-menopausal women whose disease has progressed following treatment with a prior endocrine therapy. In 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 premenopausal women. In a number of countries, Zoladex is also approved for the adjuvant treatment of early stage pre-menopausal breast cancer as an alternative to and/or in addition to chemotherapy. Zoladex offers proven survival benefits for breast cancer patients with a favourable tolerability profile. Launches of generic goserelin (the active ingredient in Zoladex) are expected in Europe during 2012.

Iressa is approved in 81 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.

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.

Caprelsa (vandetanib) fights cancer through two proven mechanisms: blocking the development of tumour blood supply by inhibition of the vascular endothelial growth factor (VEGF) pathway and by inhibiting the growth and survival of the tumour through epidermal growth factor receptor (EGFR) and rearranged during transfection (RET) pathways. Vandetanib was approved by the FDA in April 2011 for the treatment of symptomatic or progressive medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease with approval for the trade name Caprelsa subsequently granted by the FDA in August. A Risk Evaluation and Mitigation Strategy (REMS) is required for Caprelsa by the FDA due to the risks of QT prolongation, Torsades de pointes and sudden death. In November, the MAA for Caprelsa received a positive opinion from the CHMP for the treatment of aggressive and symptomatic MTC in patients with unresectable locally advanced or metastatic disease. Caprelsa remains under review by other regulatory agencies. There are approximately 30 early-stage studies ongoing that look at cancers in which vandetanib might be effective. These cancers include pancreatic, glioblastoma (brain), biliary tract (liver duct), and thyroid (papillary and follicular).

#### In the pipeline

Cediranib is an anti-angiogenic compound that has been evaluated across a range of tumour types. Study BR 29, a National Cancer Institute of Canada sponsored Phase II/III study, exploring cediranib in combination with carboplatin/paclitaxel in patients with NSCLC was stopped because it did not meet pre-specified efficacy criteria to progress to Phase III. Several ongoing Phase II studies with cediranib will continue to completion, however no further development is planned.

Zibotentan (ZD4054) is a specific endothelin A-receptor antagonist. AstraZeneca has ended the investigation of zibotentan as a potential treatment for cancer following the results of clinical trials in patients with advanced prostate cancer. In February 2011, the Phase III ENTHUSE study 15, which studied zibotentan monotherapy in patients with non-metastatic castrate resistant prostate cancer (CRPC), was stopped following the results of an early efficacy review by the Independent Data Monitoring Committee. This review indicated that zibotentan monotherapy was unlikely to meet its primary efficacy

#### **Therapy Area Review**

endpoints of progression free survival and overall survival and was therefore unlikely to benefit patients with non-metastatic CRPC. In July, the results from the Phase III ENTHUSE study 33, showed that the addition of zibotentan to docetaxel did not improve the overall survival for metastatic CRPC patients. The full data from both of these studies, in addition to the data from the Phase III ENTHUSE study 14 announced in 2010 will be published in due course.

In December, AstraZeneca announced its decision to discontinue the development of olaparib (AZD2281) for the maintenance treatment of serous ovarian cancer. This followed a review of an interim analysis of a Phase II study (study 19) which indicated that the previously reported progression free survival benefit was unlikely to translate into an overall survival benefit, the definitive measure of patient benefit in ovarian cancer.

Our early oncology pipeline includes a range of novel compounds that target signalling pathways believed to be pivotal in cancer cell growth and survival as well as DNA repair mechanisms. AZD8931, a pan-erb kinase inhibitor, continues in Phase II trials in different segments of metastatic breast cancer.

Selumetinib (AZD6244/ARRY-142886) is a potent MEK (mitogen-activated protein kinase 1) inhibitor, licensed from Array BioPharma, Inc. In October, data from a Phase II placebo-controlled study of selumetinib in combination with docetaxel in the 2nd line treatment of lung cancer patients was reported. The study's primary endpoint of overall survival demonstrated a numerically greater increase in survival in favour of selumetinib in combination with docetaxel versus docetaxel alone, but did not reach statistical significance. The secondary endpoints were all demonstrated with statistical significance.

AZD4547 is in Phase II testing for solid tumours. AZD1480, AZD2014, AZD3514 and AZD5363 are all completing Phase I studies while AZD1208 entered Phase I clinical trials in 2011. AZD7762 and AZD2461 were terminated in 2011 while AZD8055, a selective TOR kinase inhibitor, was discontinued and effort focused on a second compound, AZD2014.

We are also developing potential new cancer drugs using a variety of biologics 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).

Tremelimumab is a CTLA-4 MAb and uses certain parts of the immune system to fight diseases, including cancer. Tumours have mechanisms to evade the immune system, and blockade of CTLA-4 with tremelimumab can reactivate the immune system to help fight the cancer. AstraZeneca entered into an in-licensing agreement with Pfizer for tremelimumab in October. Under the terms of this agreement, AstraZeneca will assume global development rights to tremelimumab and Pfizer will retain the rights to use tremelimumab with specified types of combination therapies. We plan to explore tremelimumab in a number of potential cancer indications.

Our biologics pipeline also includes investigational treatments for cancers of the blood as well as for a variety of solid tumours. We currently have two investigational drugs in Phase II trials and five investigational drugs in Phase I clinical trials. Additional drug candidates are expected to progress into Phase I and Phase II trials in 2012.

#### Financial performance 2011/2010

#### Performance 2011

#### Reported performance

Oncology sales decreased by 8% to \$3,705 million, down from \$4.045 million in 2010.

#### Performance - CER growth rates

Oncology sales decreased globally by 12%.

In the US, sales of *Arimidex* decreased by 91% to \$42 million. Generics now account for 97% of anastrozole prescriptions in the US.

Arimidex sales in other markets decreased by 34% to \$714 million. Arimidex retained market exclusivity in the major EU markets until February 2011.

Casodex sales outside the US decreased by 8% to \$556 million.

Iressa sales increased by 32% to \$554 million, with strong growth in Western Europe and Emerging Markets.

Faslodex sales in the US increased by 71% to \$264 million. Sales outside the US reached \$282 million, an increase of 42%, driven by the increased adoption of the new 500mg dosage regimen.

#### 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 2010. *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 of 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.

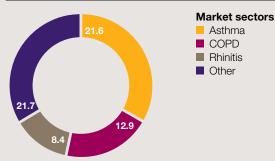
Faslodex sales for the full year increased by 35% in the US and grew by 32% outside the US.

# **Respiratory & Inflammation**



#### Therapy area world market

(MAT/Q3/11) (\$bn)



\$64.6bn

The prescription respiratory world market value is \$64.6 billion.

#### In brief

- > Total Symbicort sales \$3.1 billion, up 11%.
- > Total Pulmicort sales \$892 million, unchanged.
- > In March 2011, the production of *Pulmicort* (budesonide) 100 and 200 µg/dose HFA pMDI (pressurised metered-dose inhaler) was discontinued due to complex manufacturing issues related to technical aspects of the device, which prevented the ongoing manufacture of the product.

#### 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), including chronic bronchitis and emphysema 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 Turbuhaler (budesonide in a dry powder inhaler) 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 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 Turbuhaler (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		U	US		stern Euro	pe	Esta	ablished R	ow .	Eme	cets	Prior year	
2011	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	3,148	15	11	846	17	1,434	5	_	418	46	35	450	21	19	2,746
Pulmicort	892	2	_	279	(9)	189	(12)	(16)	126	11	2	298	25	23	872
Rhinocort	212	(7)	(9)	74	(20)	37	(5)	(10)	20	25	13	81	3	-	227
Others	216	(15)	(19)	8	(80)	109	(8)	(13)	23	5	-	76	4	1	254
Total	4,468	9	6	1,207	4	1,769	2	(3)	587	34	24	905	19	17	4,099

2010															
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

#### Our strategic objectives

We aim to build on our strong position in the respiratory and inflammation field through the growth of key products, 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 such as fostamatinib.

#### **COPD** and asthma

According to WHO, COPD, a serious lung disease that includes chronic bronchitis and/or emphysema, 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 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 2010, 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 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.

In March 2011, the production of *Pulmicort* (budesonide) 100 and 200 µg/dose HFA pMDI (pressurised metered-dose inhaler) was discontinued due to complex manufacturing issues related to technical aspects of the device, which prevented the ongoing manufacture of the product. This issue was not related to the active ingredient, budesonide. The impact of this withdrawal has been minimal, representing less than 3% of total *Pulmicort* sales for 2010. Our other respiratory products, including *Pulmicort Turbuhaler* and *Pulmicort Respules* were not affected as they use different devices or device compounds. Our other pMDI products such as *Symbicort* were also not affected.

#### Clinical studies of our key marketed products

In 2010, the FDA requested all manufacturers of LABA-containing products to conduct a post-marketing safety study to evaluate serious asthma outcomes with marketed pharmaceuticals when added to corticosteroids compared to corticosteroids alone to treat asthma. In December, recruitment began for a randomised, double-blind, 26-week, active-controlled clinical trial comparing *Symbicort* pMDI with budesonide HFA pMDI to evaluate the risk of serious asthma outcomes (hospitalisations, intubation and death) in 11,700 adult and adolescent patients 12 years of age and older with persistent asthma.

#### 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 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 AG), 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. A biological approach, MEDI-8968, a MAb targeting the IL-1 receptor, has also commenced a Phase II trial in COPD.

We are targeting uncontrolled asthma/asthma exacerbations through small molecule approaches such as a CRTh2 receptor antagonist and toll-like receptor 7 agonists (being developed in collaboration with Dainippon Sumitomo) as well as biological approaches such as benralizumab (MEDI-563), a MAb that binds to the interleukin-5 receptor which results in depletion of eosinophils and basophils, and tralokinumab (CAT-354), a MAb that targets interleukin-13.

#### 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 on top of the current revenues of approximately \$10 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 in 2011. 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. Novel oral drugs targeting intra-cellular signalling pathways that provide anti-TNF-like levels of efficacy and potentially more convenient dosing will likely be used both after and ahead of the TNF blockers, especially in patients who currently choose not to take, are anxious about taking or are ineligible to take, injectable biologic agents.

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. Although a disease-modifying agent has been 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 2010. Fostamatinib is at the most advanced stage of development of the oral spleen tyrosine kinase (SYK) inhibitors being evaluated for an RA indication. It is thought to block reversible signalling in multiple cell types involved in inflammation and tissue degradation in RA. The ongoing Phase III programme, called OSKIRA, commenced in September 2010. A further Phase IIb monotherapy study (OSKIRA 4) was initiated in January 2011. This study will provide important information on the profile of fostamatinib, unconfounded by background disease-modifying anti-rheumatic drugs, such as methotrexate. The first anticipated regulatory filings based on the OSKIRA programme are currently anticipated for 2013.

In 2011, we continued to invest in several novel multi-functional MAbs in inflammatory and autoimmune conditions. Sifalimumab (MEDI-545), which targets interferon-alpha, commenced a Phase IIb study in patients with SLE. MEDI-546, which targets the Type I IFN receptor, is initiating a Phase IIb 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 II study evaluating the efficacy and safety in subjects with RA and is being prepared for a Phase IIb study in RA patients.

#### Financial performance 2011/2010

#### Performance 2011

#### Reported performance

Respiratory & Inflammation (R&I) sales increased by 9% to \$4,468 million compared with \$4,099 million in 2010.

#### Performance - CER growth rates

R&I sales increased by 6% globally.

US sales of *Symbicort* were \$846 million, an increase of 17%. *Symbicort* sales in other markets increased to \$2,302 million, 9% ahead of last year, fuelled by strong growth in Japan, up 88% and in Emerging Markets, up 19%.

US *Pulmicort* sales decreased by 9% to \$279 million. Sales of *Pulmicort* outside the US increased by 4% to \$613 million.

#### Performance 2010

#### Reported performance

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.

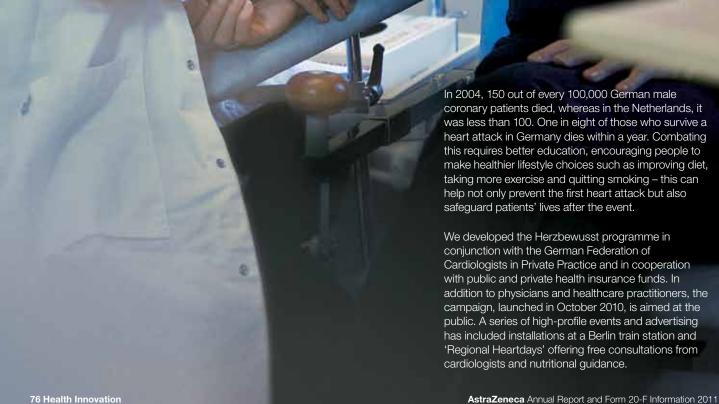
Sales of *Pulmicort* were down 34%, mainly as a result of US sales which decreased by 62% to \$305 million as a result of the launch, under licence from AstraZeneca, of the Teva generic budesonide inhaled suspension product in December 2009. Sales of *Pulmicort* outside the US were up 10% to \$567 million.

<sup>&</sup>lt;sup>1</sup> Decision Resources 2011.



# healthinnovation Reducing the number of heart-related deaths

Germany is proud of its healthcare system yet still has high mortality rates for coronary heart disease. 'Herzbewusst' (heart conscious) is a programme designed to help people help themselves in preventing acute coronary syndromes and, for the first time in Germany, has included a variety of stakeholders from the outset.



# **Geographical Review**

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 56. Details of material legal proceedings can be found in Note 25 to the Financial Statements from page 184 and details of relevant risks are set out in the Principal risks and uncertainties section from page 130.

See the Market definitions table on page 209 for information about AstraZeneca's market definitions.

#### 2011 in brief

- > In the US, sales were down 2% to \$13,426 million (2010: \$13,727 million). The pricing impact from US healthcare reform measures lowered revenue by around 3.3%. Good growth for Crestor, the Seroquel franchise, Symbicort and Onglyza™ broadly offset the impact of generic competition for Arimidex, Toprol-XL and Merrem, and declines in Nexium.
- > Sales in Western Europe were down 11% to \$8,501 million (2010: \$9,168 million), due largely to volume erosion on Nexium, Arimidex and Merrem. This was partially offset by volume growth attributable to Crestor, Seroquel XR, Symbicort, Iressa and Faslodex.
- > Established ROW sales were up 4%, driven by continued growth for Symbicort, Crestor, Nexium and Seroquel. In 2011, AstraZeneca became the largest research-based pharmaceutical company in Canada by sales value.
- > Emerging Markets sales increased by 10% to \$5,763 million (2010: \$5,198 million), with sales growth in China of 15% and Russia of 19%. Sales in Brazil were down as a result of generic competition for Crestor and Seroquel IR.
- > AstraZeneca is the fourth largest pharmaceutical company in the US, with a 6% market share of US prescription pharmaceuticals by sales value and is the sixth largest prescription-based pharmaceutical company in Western Europe, with a 4.4% market share of prescription sales by value.

#### Our financial performance

		2011			2010		2009
	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m
US	13,426	(2)	(2)	13,727	(7)	(7)	14,777
Western Europe	8,501	(7)	(11)	9,168	(1)	2	9,252
Canada	1,604	6	1	1,510	26	14	1,203
Japan	3,064	17	6	2,617	11	4	2,367
Other Established ROW	1,233	18	4	1,049	23	6	853
Established ROW	5,901	14	4	5,176	17	7	4,423
Emerging Europe	1,244	7	7	1,165	7	6	1,091
China	1,261	20	15	1,047	29	28	811
Emerging Asia Pacific	968	9	5	890	14	7	780
Other Emerging ROW	2,290	9	12	2,096	26	20	1,670
Emerging Markets	5,763	11	10	5,198	19	16	4,352
Total	33,591	1	(2)	33,269	1	_	32,804

#### **Geographical Review**

#### US

AstraZeneca is the fourth largest pharmaceutical company in the US, with a 6% market share of US prescription pharmaceuticals by sales value.

Sales in the US decreased by 2% to \$13,426 million (2010: \$13,727 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, *Brilinta*, *Crestor*, Onglyza<sup>™</sup>, *Seroquel*, *Symbicort* and *Faslodex*, were up by 16% to \$8,474 million (2010: \$7,316 million). Increased generic competition for *Arimidex*, and *Toprol-XL* and its authorised generic, resulted in a sales decline in these brands of 62% to \$446 million (2010: \$1,183 million).

Brilinta was approved by the FDA in July to reduce the risk of cardiovascular death and heart attacks in patients with acute coronary syndromes (ACS). Unrestricted managed markets access was 59%, and trial among target interventional cardiologist initiators was 6% at the end of 2011. Crestor achieved sales of \$3,074 million (2010: \$2,640 million) and a total prescription growth of 4.4% within the statin market. This growth outpaced the market almost four-fold. A competitor to Crestor, atorvastatin, was available in generic form in the US beginning in late 2011.

Seroquel continued to be the most prescribed atypical anti-psychotic, with sales up 10% to \$4,123 million (2010: \$3,747 million). Total Seroquel prescriptions declined by 1%, driven by Seroquel IR erosion of 4% due to increased generic and branded competition. Strong Seroquel XR prescription volume growth of 17% partially offset the total Seroquel IR prescription volume decline. Seroquel XR accounts for 18% of total Seroquel prescription volume in the US, up from 16% at the end of 2010.

Symbicort pMDI continued to deliver steady growth in the US, with sales up 17% to \$846 million (2010: \$721 million) and prescription growth of 10%, leading the fixed combination class in total prescription growth. It achieved a 20.3% total prescription share and a 21.5% new prescription share of the inhaled corticosteroid/long-acting beta-agonist market.

Onglyza<sup>TM</sup>/Kombiglyze XR<sup>TM</sup> captured one in four new dipeptidyl peptidase IV (DPP-IV) patient treatment decisions and achieved a 6.5% total prescription market share gain in 2011, ending the year with a total prescription market share of 16.5% of the DPP-IV inhibitor market. Kombiglyze XR<sup>TM</sup> was launched in January 2011 and doctors are now prescribing it to one in 10 new patients. Onglyza<sup>TM</sup> revenues in the US were \$156 million (2010: \$54 million).

Nexium was the fifth most prescribed branded pharmaceutical in the US. In the face of continuing generic, OTC and pricing pressures, Nexium sales declined 11% to \$2,397 million (2010: \$2,695 million). Nexium remains the branded market leader retaining significant market share and volume within the proton pump inhibitor class.

Sales of *Toprol-XL* and its authorised generic (metoprolol succinate extended-release tablets), which is marketed and distributed by Par Pharmaceutical Companies, Inc. (Par) decreased 41% to \$404 million (2010: \$689 million), due to the impact of generic competition from Watson Pharmaceuticals Inc. and Wockhardt Limited, which entered the market in 2010. In December, Mylan Inc. announced that its subsidiary Mylan Pharmaceuticals Inc. (Mylan) received final approval from the FDA for its ANDA for metoprolol succinate extended-release tablets in 25mg, 50mg, 100mg and 200mg doses.

Following multiple generic anastrozole products entering the US market in June 2010, sales of *Arimidex* declined by 91% to \$42 million (2010: \$494 million).

In June, the US District Court ruled that Mylan did not infringe the *Entocort* formulation patent (EC patent no. 5,643,602). Following Mylan's entry of its generic, AstraZeneca launched an authorised generic with marketing and distribution by Par Pharmaceutical, Inc.

In 2011, sales of *Synagis* were down 12% to \$570 million (2010: \$646 million). Sales in the 2010/2011 RSV season started slower than anticipated due to later than forecast seasonal onset, coupled with payer pressure resulting from wider adoption of more restrictive guidelines regarding the use and dosing of *Synagis* by the American Academy of Pediatrics.

Sales for Aptium Oncology increased by 2% to \$224 million (2010: \$219 million) and sales for Astra Tech were down 24% to \$77 million (2010: \$101 million), all recorded in the period prior to its disposal to DENTSPLY International Inc., which completed in August.

In March 2010, the Affordable Care Act came into force. It has had, and is expected to continue to have, a significant impact on our US sales and the US healthcare industry as a whole. For 2010, the impact of higher minimum Medicaid rebates on prescription drugs was a reduction in our pre-tax profit for the period of nearly \$230 million. In 2011, the overall reduction in our profit before tax for the year due to higher minimum Medicaid rebates on prescription drugs, discounts on branded pharmaceutical sales to Medicare Part D beneficiaries and an industry-wide excise fee was \$750 million. These amounts reflect only those effects of the Affordable Care Act that we know have had or will have a direct impact on our financial condition or results of operations and which we are therefore able to quantify based on known and isolatable resulting changes in individual financial items within our financial statements. There are other potential indirect or associated consequences of these legislative developments, which continue to evolve and which cannot be estimated but could have similar impacts. These include broader changes in access to or eligibility for coverage under Medicare, Medicaid or similar governmental programmes, such as the recent proposals to limit Medicare benefits. These could indirectly impact our pricing or sales of prescription products within the private sector. By their nature and the fact that these potentially numerous consequences are not directly linked to a corresponding and quantifiable impact on our financial statements, it is not possible to accurately estimate the financial impact of these potential consequences of the Affordable Care Act or related legislative changes when taken together with the number of other market and industry related factors that can also result in similar impacts. Further details of the potential impact of the Affordable Care Act are contained in the Pricing pressure section from page 18 and the Principal risks and uncertainties section from page 130.

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 2011, 80% 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 2011 was down by only 2% to \$20,165 million (2010: \$19,542 million), despite the continuing challenging economic environment. Combined sales of key products (*Arimidex, Crestor, Nexium, Seroquel* and *Symbicort*) were down 1% with sales of \$10,301 million (2010: \$9,923 million). Emerging Markets delivered particularly strong sales, up 10% with sales of \$5,763 million (2010: \$5,198 million).

#### **Western Europe**

AstraZeneca is the sixth largest prescription-based pharmaceutical company in Western Europe, with a 4.4% market share of prescription sales by value.

Total sales in Western Europe were down 11% to \$8,501 million (2010: \$9,168 million) due largely to volume erosion on *Nexium*, *Arimidex* and *Merrem* following generic entrants and the negative price impact from price reductions primarily related to government interventions. This development was partially offset by volume growth attributable to *Crestor*, *Seroquel XR*, *Symbicort*, *Iressa* and *Faslodex*.

Crestor outperformed the statin class with strong 13% sales growth by volume. Likewise, Seroquel outperformed the atypical anti-psychotics market segment more than twice in value, with strong growth of Seroquel XR, up by 31%, primarily driven by the bipolar indication. Generic versions of Nexium are now available in most markets with overall sales down 39% to \$762 million (2010: \$1,202 million).

*Brilique* was launched in Germany, the UK, Italy, Spain, Norway, Sweden, Denmark, Finland, Austria, Greece and Switzerland, and sales exceeded \$9 million.

The macro-economic situation has deteriorated, leading to increased pressure on healthcare budgets with some European markets beginning to emerge from the crisis and others still facing major issues with the implementation of new austerity measures. Most governments in Europe intervene directly to control the price, volume and reimbursement of 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 delayed and reduced access to medicines for patients in areas of important unmet medical need. These and other measures all contribute to an increasingly difficult environment for branded pharmaceuticals in Europe.

In Germany, sales growth fell by 8% to \$1,189 million (2010: \$1,235 million), as the increased compulsory rebates for *Symbicort* and *Seroquel* were carried over from mid-2010 and reference pricing for *Symbicort* and *Atacand* commenced. However, *Seroquel, Faslodex* and *Iressa* 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 and 2011 which resulted in an overall sales decline of 9% to \$305 million (2010: \$322 million). In the UK, an 18% decrease in sales to \$866 million (2010: \$1,022 million) reflected strong volume erosion on *Nexium* by 56%, *Merrem* by 86% and *Arimidex* by 76% respectively following generic entry which was not offset by the solid performance from *Symbicort* and *Seroquel XR*.

Overall sales in France decreased by 12% to \$1,740 million (2010: \$1,889 million), driven by *Nexium* erosion, down to \$266 million (2010: \$448 million), a 42% fall following generic entry at the end of April 2011, which was not entirely offset by double digit growth of *Crestor* and continued strong growth of *Symbicort*, *Faslodex* and *Iressa* despite significant competition. Sales in Italy were down by 11% to \$1,113 million (2010: \$1,198 million). Our main sales were hit by price cuts on off patent products to align their prices with the EU average price, and by price cuts and prescription controls on *Crestor*. Despite this, we achieved double digit volume growth for *Crestor*, *Seroquel* and *Symbicort*.

#### **Established ROW**

Sales in Established ROW increased by 4%. The key products driving sales growth in 2011 were Crestor, Symbicort, Nexium and Seroquel.

#### Canada

In 2011, AstraZeneca became the largest research-based pharmaceutical company in Canada by sales value. Despite loss of exclusivity for *Atacand* after expiry of the compound patent (Canadian patent no. 2,040,955) and the 'at-risk' launch of a generic version of *Nexium* by a competitor, total Canadian sales increased by 1% to \$1,604 million (2010: \$1,510 million). Combined sales of *Crestor, Nexium, Symbicort* and *Seroquel* were \$1,171 million (2010: \$1,055 million). *Crestor* became the largest prescription product in Canada by sales value, with year-on-year sales growth of 14% to \$716 million (2010: \$600 million).

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. Overall, the trend in Canada indicates that provinces will continue to introduce policy changes that drive cost savings and exert pricing pressure on new and existing medicines (for example, conditional listings, product listing agreements and bulk purchasing), while providing reasonable patient access to innovative medicines.

#### Japar

Sales in Japan increased by 6% to \$3,064 million (2010: \$2,617 million). The Tohoku earthquake and tsunami did not significantly disrupt supply of AstraZeneca medicines and did not have a material impact on financial performance.

Strong volume gains of 7% were driven mainly by the continued growth of primary care brands. Sales of *Crestor*, which is co-promoted with Shionogi & Co. Limited, grew by 16% while sales of *Symbicort Turbuhaler* grew by 88% in its second year in the market. Sales growth of *Losec* slowed by 5%, following the September launch of *Nexium* (co-promoted with Daiichi Sankyo).

Our oncology business remains one of the leaders in Japan based on the performance of established brands including *Iressa*, *Arimidex*, *Zoladex* and *Casodex*. In November, we also completed the launch of *Faslodex*, the approval and launch of an additional indication for *Iressa*, and the signing of an agreement with Daiichi Sankyo to co-promote Ranmark<sup>TM</sup> (denosumab) for the treatment of bone disorders stemming from bone metastasis. Daiichi Sankyo acquired the denosumab rights in 2007 from Amgen Inc. and received approval in January 2012.

#### Other Established ROW

Sales in Other Established ROW showed robust growth of 4% to \$1,233 million (2010: \$1,049 million). Strong volume growth in Australia for our key products was partially offset by the full year impact of price cuts imposed in April 2010 on *Crestor* and *Nexium* and continued price adjustments imposed by the Australian authorities in 2011. *Crestor, Nexium* and *Symbicort* all gained market share in the year, with *Crestor* achieving a 28% volume share in the statin class. *Brilique* has achieved registration in 2011 in both Australia and New Zealand, with Pharmaceutical Benefits Scheme reimbursement in Australia expected in 2012.

#### **Geographical Review**

#### **Emerging Markets**

In the Emerging Markets, sales increased by 10% to \$5,763 million (2010: \$5,198 million), which was principally 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 continued efforts to reduce the cost of prescriptions in line with the systems in Western Europe, Canada and Australia.

#### **Emerging Europe**

Sales in Emerging Europe grew by 7% to \$1,244 million (2010: \$1,165 million) driven by increased sales in Russia and Romania, which more than offset reduced sales in Turkey.

We have continued to build our presence in Russia, where sales increased by 19% to \$284 million (2010: \$232 million) mainly due to increased sales of *Symbicort* by 41%, *Nexium* by 33% and *Crestor* by 25% driven by growth in the retail segment. We have also consolidated our position among the leaders in the hospital and regional reimbursement segments.

In Romania, we delivered a strong performance with sales up 24% to \$154 million (2010: \$119 million), largely as a result of sales of *Atacand* increasing by 63%, *Seroquel* increasing by 43% and *Symbicort* increasing by 86%. In late 2009, the Turkish government imposed unprecedented levels of price reductions on the pharmaceutical industry. As a result, our sales were down in Turkey in 2010, but recovered in 2011, up 7% to \$297 million (2010: \$304 million).

#### China

Our sales in China (excluding Hong Kong) increased by 15% to \$1,261 million (2010: \$1,047 million). The slow down in growth rate versus 2010 was primarily driven by a reduction in overall Chinese market growth which was particularly evident in major cities as well as weaker performance in our gastrointestinal and anaesthesia businesses. Our cardiovascular (CV) and oncology businesses continued to grow ahead of the market due to strong performances by Crestor and Betaloc Zok (Seloken/Toprol-XL), despite delays in activation of reimbursement in Beijing, Shanghai and Guangzhou. We continue to be one of the leading multinational pharmaceutical companies in China and the second largest in the prescription market by sales value. In November, we announced our decision to invest \$200 million in a new manufacturing facility to further strengthen our position in China. In December, we announced we had entered into an agreement to acquire Guangdong BeiKang Pharmaceutical Company Limited, a generics company based in Conghua City, Guangdong province. This agreement, which remains subject to regulatory approval in China, will provide us with access to a portfolio of injectable medicines used to treat infections.

#### **Emerging Asia Pacific**

Sales in Emerging Asia Pacific grew 5% to \$968 million (2010: \$890 million). This was driven by strong sales growth in India, up 21%, Vietnam, up 29%, and Indonesia, up 11%. 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 and the Philippines.

#### **Other Emerging ROW**

Our sales grew by 12% to \$2,290 million (2010: \$2,096 million) largely due to strong sales growth in Venezuela and Argentina. We achieved double digit year-on-year sales growth for most of our key products, *Nexium*, *Seroquel XR*, *Symbicort*, *Zoladex*, *Atacand* and *Seloken*. Excluding Brazil, where generic competitors entered the market for the first time in 2011, *Crestor* sales grew by around 12% across the region.

In Latin America the pharmaceutical market continues to grow strongly, underpinned by a relatively stable political and economic climate. Strong competition from local, non-multinational, companies with branded generic products is increasingly becoming a feature of the region.

Brazilian sales for the year were impacted by loss of exclusivity not only on *Crestor* but also *Atacand* monotherapy and *Seroquel IR*. The Brazilian pharmaceutical market continues to experience double digit growth. Mexican year-on-year sales were flat, mirroring a market that is currently showing low single digit growth.

2011 saw successful launches of *Brilinta* in Brazil, *Vimovo* in a number of countries in Central America and the Caribbean, and Onglyza™ in Colombia.

In the Middle East and Africa, despite political challenges arising from the 'Arab Spring' revolutions, we further accelerated our growth with sales up 12%. Our largest markets were South Africa, Saudi Arabia, the UAE and Algeria where we achieved steady growth. South African growth was mainly driven by *Symbicort* up 12%, *Seroquel* up 14% and *Crestor* up 10%.





Faz Bem reflects our commitment to making the most meaningful difference to patient health by providing access to the growing middle class in Brazil. As well as providing patients with access to medicines for the first time, the programme improves patient health awareness. In doing so, Faz Bem both benefits our business and supports the efforts of the government to improve healthcare in Brazil.

# Expanding access and affordability for our medicines

In Brazil, our 'Faz Bem' (Wellbeing) programme provides discounts to the cost of our medicines. It also provides additional incentives for those who adhere to treatment regimes and so helps improve health outcomes.



Our strong cash flow enabled us to deliver increased net cash distributions of \$9.4 billion to shareholders while continuing to invest to drive future growth and value.

Simon Lowth Chief Financial Officer

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Core operating profit was down 4%. Core R&D expense included a significant increase in intangible impairments compared with last year; without these, Core operating profit would have declined broadly in line with the revenue. Core earnings per share increased by 7%, benefiting from a lower tax rate and fewer shares outstanding as a result of share repurchases.

The actions related to the first two phases of our restructuring programmes are now completed, and are on track to deliver \$4.3 billion in annual benefits by the end of 2014. These programmes have played an integral part in the significant improvement in our Core operating margin since they were launched in early 2007.

A new phase was announced in February 2012, and this programme is expected to deliver a further \$1.6 billion in annual benefits by the end of 2014, at a planned cost of \$2.1 billion.

Our cash generation remains strong, enabling us to invest for future growth and value by funding organic investment in R&D, externalisation and capital expenditures while also providing \$9.4 billion in net cash distributions to shareholders by way of dividends and net share repurchases.



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The purpose of this Financial Review is to provide a balanced and comprehensive analysis of the financial performance of the business during 2011, the financial position as at the end of the year and the main business factors and trends which could affect the future financial performance of the business.

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

#### 2011 Business background and results overview

The business background is covered in The pharmaceutical industry section from page 15, the Therapy Area Review from page 56, and the Geographical Review from page 77 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 is a variety of price and volume control mechanisms and retrospective rebates based on sales levels that are imposed by governments.
- > The risk of generic competition following loss of patent protection or patent expiry or an 'at risk' launch by a competitor, with the potential adverse effects on sales volumes and prices. For example in 2011, our performance was affected by generic competition in the US for *Arimidex* and *Toprol-XL*. Further details of patent expiries for our key marketed products are included in the Patent expiries section on page 35.
- > 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 2011 are:

- > Revenue was down 2% at \$33,591 million (Reported: up 1%).
- > Strong double digit sales growth at CER for Crestor, Seroquel XR and Symbicort.
- > Emerging Markets revenue increased by 10% (Reported: 11%).
- > Revenue performance reflects the loss of nearly \$2 billion of revenue from generic competition, as well as a further \$1 billion lost to the impact of government price interventions.
- > Core operating profit was down 4% (Reported: 3%) to \$13,167 million.
- > Operating profit up 10% (Reported: 11%) to \$12,795 million.
- > The sale of Astra Tech, which resulted in a gain of \$1,483 million and was excluded from Core operating profit.
- > Core operating margin of 39.2% of revenue was down 1.2 percentage points (Reported: 1.6 percentage points), as benefits arising from higher gross margin and lower SG&A spend at CER were more than offset by increased expenditures in R&D and lower Core other income. Reported operating margin was 38.1%.
- > Core EPS increased by 7% (Reported: 9%) to \$7.28. Basic EPS was up 29% (Reported: 31%) to \$7.33. Basic and Core EPS benefited from the lower number of shares outstanding resulting from net share repurchases and a lower effective tax rate compared with last year.
- > Dividends paid increased to \$3,764 million (2010: \$3,361 million). Net share repurchases totalled \$5,606 million.
- > Total restructuring costs associated with the global programme to reshape the cost base of the business were \$1,161 million in 2011. This brings the total restructuring costs charged to 31 December 2011 to \$4,869 million.

#### 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 IFRSs 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 2011 Reconciliation of Reported results to Core results table on page 85 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 2011 Reported operating profit table on page 85.
- > Gross and operating profit margin percentages, and Core pre-R&D operating margin. These measures set out the progression of key performance margins and illustrate the overall quality of the business. Core pre-R&D operating margin 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 85 and 91.
- 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.

As shown in the 2011 Reconciliation of Reported results to Core results table on page 85, 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. This illustrates 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 Core 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 as 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 2011 Reported operating profit table on page 85, our reconciliation of Core financial measures to Reported financial information in the Reconciliation of Reported results to Core results table on page 85, and to the Results of operations – summary analysis of year to 31 December 2010 section from page 91 for our discussion of comparative Reported growth measures that reflect all factors that affect our business. Our determination of non-GAAP measures, and 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.

# Results of operations – summary analysis of year to 31 December 2011 2011 Reported operating profit

			2011	2010	Percer	tage of sales	2011 compare	ed with 2010
	Reported \$m	CER growth \$m	Growth due to exchange effects \$m	Reported \$m	Reported 2011 %	Reported 2010 %	CER growth %	Reported growth %
Revenue	33,591	(601)	923	33,269			(2)	1
Cost of sales	(6,026)	625	(262)	(6,389)	(17.9)	(19.2)	(10)	(6)
Gross margin	27,565	24	661	26,880	82.1	80.8	-	3
Distribution costs	(346)	3	(14)	(335)	(1.0)	(1.0)	(1)	3
Research and development	(5,523)	(15)	(190)	(5,318)	(16.5)	(16.0)	-	4
Selling, general and administrative costs	(11,161)	(409)	(307)	(10,445)	(33.2)	(31.4)	4	7
Profit on disposal of Astra Tech	1,483	1,483	-	-	4.4	-	n/a	n/a
Other operating income and expense	777	59	6	712	2.3	2.1	8	9
Operating profit	12,795	1,145	156	11,494	38.1	34.5	10	11
Net finance expense	(428)			(517)				
Profit before tax	12,367			10,977				
Taxation	(2,351)			(2,896)				
Profit for the period	10,016			8,081				
Basic earnings per share (\$)	7.33			5.60				

#### 2011 Core operating results

			2011	2010	2011 compared	with 2010
	Core \$m	CER growth \$m	Growth due to exchange effects \$m	Core \$m	CER growth %	Total Core growth %
Gross margin	27,619	(63)	658	27,024	-	2
Gross margin %	82.2%			81.2%		
Distribution costs	(346)	3	(14)	(335)	(1)	3
Research and development	(5,033)	(639)	(175)	(4,219)	15	19
Selling, general and administrative costs	(9,918)	160	(301)	(9,777)	(2)	1
Other operating income and expense	845	(71)	6	910	(8)	(7)
Operating profit	13,167	(610)	174	13,603	(4)	(3)
Operating margin %	39.2%			40.8%		
Net finance expense	(428)			(517)		
Profit before tax	12,739			13,086		
Taxation	(2,797)			(3,416)		
Profit for the period	9,942			9,670		
Basic earnings per share (\$)	7.28			6.71		

#### 2011 Reconciliation of Reported results to Core results

			Merck 8	& MedImmune		5.00	
	2011 Reported \$m	Restructuring costs	Amortisation \$m	Intangible impairments \$m	Legal settlements \$m	Profit on sale of Astra Tech \$m	2011 Core \$m
Gross margin	27,565	54	-	-	_	-	27,619
Distribution costs	(346)	) –	_	_	_	_	(346)
Research and development	(5,523)	468	_	22	_	_	(5,033)
Selling, general and administrative costs	(11,161)	639	469	_	135	_	(9,918)
Profit on disposal of Astra Tech	1,483	_	_	_	_	(1,483)	_
Other operating income and expense	777	-	68	_	_	_	845
Operating profit	12,795	1,161	537	22	135	(1,483)	13,167
Add back: Research and development	5,523	(468)	-	(22)	_	-	5,033
Pre-R&D operating margin	18,318	693	537	_	135	(1,483)	18,200
Pre-R&D operating margin %	54.5%						54.2%
Net finance expense	(428)	-	-	-	-	-	(428)
Profit before tax	12,367	1,161	537	22	135	(1,483)	12,739
Taxation	(2,351)	(306)	(98)	(6)	(36)	_	(2,797)
Profit for the period	10,016	855	439	16	99	(1,483)	9,942
Basic earnings per share (\$)	7.33	0.63	0.32	0.01	0.07	(1.08)	7.28

### Results of operations – summary analysis of year to 31 December 2011 continued

Revenue increased by 1% on a Reported basis but decreased by 2% on a CER basis. As in 2010, revenue benefited from strong growth of *Crestor, Symbicort* and *Seroquel* but was offset by lower revenues for *Nexium, Arimidex* and *Seloken/Toprol-XL*. Emerging Markets sales growth of 10% (Reported: 11%) and Established ROW 4% (Reported: 14%) was offset by a decline in US sales of 2% (Reported: 2%) and Western Europe of 11% (Reported: 7%). Further details of our sales performance are contained in the Performance 2011 sections of the Therapy Area Review from page 56 and the Geographical Review from page 77.

Core gross margin of 82.2% increased 1.3 percentage points (Reported: 1.0 percentage points). The year-on-year improvement in the margin was largely due to the impact of the intangible impairment related to lesogaberan on 2010 gross margin and a \$131 million benefit from the settlement of patent disputes with PDL Biopharma Inc. in 2011.

Core R&D expenditure was \$5,033 million, 15% higher than last year (Reported: 19%), driven by higher intangible impairments charged to R&D expenditure in 2011, including \$285 million for olaparib and \$150 million for TC-5214, and late stage project spend.

Core SG&A costs of \$9,918 million were 2% lower than in 2010 (Reported: 1% higher). Investment in Emerging Markets and recently launched brands, as well as the impact of the US healthcare reform excise tax were more than offset by operational efficiencies across Established Markets.

Core other income of \$845 million was \$65 million less than the previous year principally as a result of a higher level of disposal gains in 2010.

Core pre-R&D operating margin was 54.2%, up 1.0 percentage points (Reported: 0.7 percentage points), as the higher gross margin was only slightly offset by lower Core other income and higher SG&A costs as a percentage of revenue.

Core operating profit was \$13,167 million, a decrease of 4% (Reported: 3%). Core operating margin declined by 1.2 percentage points (Reported: 1.6 percentage points) to 39.2% as a result of the higher R&D spend and lower Core other operating income.

Core EPS were \$7.28, up 7% (Reported: 9%), with the lower operating profit offset by a lower effective tax rate, lower net interest as well as the benefit of a lower average number of shares outstanding.

Within Core adjustments, restructuring costs and amortisation were broadly in line with last year's level. Non-core intangible impairments and legal provisions were significantly reduced from 2010. In 2011, Core adjustments also included the profit on the sale of our dental and healthcare subsidiary Astra Tech. Excluded from Core results were:

- > Impairment charges of \$22 million (2010: \$568 million), arising from impairments of assets capitalised as part of the MedImmune acquisition.
- > \$135 million (2010: \$612 million) of legal provision charges in respect of the ongoing *Seroquel* product liability litigation, Average Wholesale Price litigation in the US and the *Toprol-XL* antitrust litigation. 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 184.
- > Restructuring costs totalling \$1,161 million (2010: \$1,202 million), incurred as the Group continues its previously announced efficiency programmes.
- > Amortisation totalling \$537 million (2010: \$518 million) relating to assets capitalised as part of the MedImmune acquisition and the Merck exit arrangements.
- > Profit on sale of our subsidiary Astra Tech of \$1,483 million. On 31 August, we completed the sale of Astra Tech to DENTSPLY International Inc. for a net cash consideration of \$1,772 million. Further details of this disposal are included in Note 22 to the Financial Statements on page 170.

Reported operating profit was up 10% at CER (Reported: 11%) at \$12,795 million, largely as a result of the impact of the profit on the disposal of Astra Tech. Reported EPS were \$7.33, up 29% (Reported: 31%), as a result of the same factors affecting Core EPS along with the profit recognised on the disposal of Astra Tech.

Net finance expense was \$428 million, against \$517 million in 2010, due to reduced interest payable on lower debt balances (\$46 million) and a lower net pension interest expense of \$55 million principally due to increased pension assets held by our defined benefit schemes.

The 2011 taxation charge of \$2,351 million (2010: \$2,896 million) consists of a current tax charge of \$2,578 million (2010: \$3,435 million) and a credit arising from movements on deferred tax of \$227 million (2010: \$539 million).

The current year tax charge includes a prior period current tax credit of \$102 million (2010: charge of \$370 million). The reported effective tax rate for the year was 19.0% (2010: 26.4%). The reported effective tax rate has benefited from the non-taxable gain on the disposal of Astra Tech and an adjustment in respect of prior periods following the announcement in March 2011 that HM Revenue & Customs in the UK and the US Internal Revenue Service (IRS) agreed the terms of an Advance Pricing Agreement regarding transfer pricing arrangements for AstraZeneca's US business for the period from 2002 to the end of 2014 and a related valuation matter as detailed more fully in Note 4 to the Financial Statements from page 152. Excluding these benefits, the effective tax rate for the year was 26.4% on a reported basis. This 26.4% tax rate is applied to the taxable Core adjustments to operating profit, resulting in a Core effective tax rate for the year of 22.0% including the benefit of the Advanced Pricing Agreement and related valuation matter settlement. A description of our tax exposures is set out in Note 25 to the Financial Statements on page 189.

Total comprehensive income for the year increased by \$1,364 million from 2010 to \$9,470 million. This was driven by the increase in profit for the year of \$1,935 million, offset by a decrease of \$571 million in other comprehensive income, principally due to \$741 million of actuarial losses on our defined benefit schemes arising from lower discount rates being applied to our long-term pension obligations reflecting external market conditions.

#### Cash flow and liquidity - 2011

All data in this section is on a Reported basis.

Cash generated from operating activities was \$7,821 million in the year to 31 December 2011, compared with \$10,680 million in 2010. The decrease of \$2,859 million is primarily driven by higher tax payments made this year, including a net amount of \$1.1 billion in relation to the Advance Pricing Agreement between the UK and US governments' tax authorities and the settlement of a related valuation matter, an increase in trade and other receivables and higher contributions made to our UK defined benefit pension fund.

Investment cash inflows of \$577 million include the sale of Astra Tech (\$1,772 million). Cash outflows on the purchase of tangible fixed assets amounted to \$839 million in the year, in line with 2010. Further details of the Astra Tech disposal are included in Note 22 to the Financial Statements from page 170.

Net cash distributions to shareholders increased from \$5,471 million in 2010 to \$9,370 million in 2011 through dividend payments of \$3,764 million and net share repurchases of \$5,606 million, a significant increase on 2010 repurchases of \$2,110 million. This reflects the Board's 2010 stated objective of \$4 billion share repurchases in 2011, with the target increased in 2011 following the Board's decision to use the net proceeds from the Astra Tech sale to increase share repurchases.

#### **Summary cash flows**

	2011 \$m	2010 \$m	2009 \$m
Net funds/(debt) brought forward at 1 January	3,653	535	(7,174)
Earnings before interest, tax, depreciation, amortisation and impairment (EBITDA)	15,345	14,235	13,630
Profit on disposal of Astra Tech	(1,483)	_	_
EBITDA before profit on disposal of Astra Tech	13,862	14,235	13,630
Movement in working capital and provisions	(897)	82	1,329
Tax paid	(3,999)	(2,533)	(2,381)
Interest paid	(548)	(641)	(639)
Other non-cash movements	(597)	(463)	(200)
Net cash available from operating activities	7,821	10,680	11,739
Purchase of intangibles (net)	(458)	(1,180)	(355)
Other capital expenditure (net)	(737)	(708)	(824)
Acquisitions	-	(348)	_
Net cash received on disposal of Astra Tech	1,772	_	_
Investments	577	(2,236)	(1,179)
Dividends	(3,764)	(3,361)	(2,977)
Net share (repurchases)/issues	(5,606)	(2,110)	135
Distributions	(9,370)	(5,471)	(2,842)
Other movements	168	145	(9)
Net funds carried forward at 31 December	2,849	3,653	535

#### **Net funds**

	2011 \$m	2010 \$m	2009 \$m
Cash and cash equivalents	7,571	11,068	9,918
Short-term investments	4,248	1,482	1,484
Net derivative financial instruments	358	325	196
Cash, short-term investments and derivatives	12,177	12,875	11,598
Overdraft and short-term borrowings	(221)	(125)	(136)
Current instalments of loan	(1,769)	_	(1,790)
Loans due after one year	(7,338)	(9,097)	(9,137)
Loans and borrowings	(9,328)	(9,222)	(11,063)
Net funds	2,849	3,653	535

At 31 December 2011, outstanding gross debt (interest-bearing loans and borrowings) was \$9,328 million (2010: \$9,222 million). Of this gross debt, \$1,990 million is due within one year (2010: \$125 million).

Closing net funds include \$3,765 million of US Treasury Bills with a maturity date greater than 90 days. These are included in short-term investments. Net funds of \$2,849 million have decreased by \$804 million during the year as a result of the net cash outflow described above.

#### 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	2011 Total \$m	2010 Total \$m
Bank loans and other borrowings	2,493	1,574	1,684	9,764	15,515	15,964
Operating leases	92	116	62	122	392	506
Contracted capital expenditure	190	-	_	_	190	259
Total	2,775	1,690	1,746	9,886	16,097	16,729

#### Financial position - 2011

All data in this section is on a Reported basis.

#### **Summary statement of financial position**

	2011 \$m	Movement \$m	2010 \$m	Movement \$m	2009 \$m
Property, plant and equipment	6,425	(532)	6,957	(350)	7,307
Goodwill and intangible assets	20,842	(1,187)	22,029	(86)	22,115
Inventories	1,852	170	1,682	(68)	1,750
Trade and other receivables	8,754	907	7,847	138	7,709
Trade and other payables	(9,360)	(326)	(9,034)	(103)	(8,931)
Provisions	(1,862)	76	(1,938)	(252)	(1,686)
Net income tax payable	(2,334)	1,521	(3,855)	(1,002)	(2,853)
Net deferred tax liabilities	(1,221)	449	(1,670)	285	(1,955)
Retirement benefit obligations	(2,674)	(202)	(2,472)	882	(3,354)
Non-current other investments	201	(10)	211	27	184
Net funds	2,849	(804)	3,653	3,118	535
Net assets	23,472	62	23,410	2,589	20,821

In 2011, net assets increased by \$62 million to \$23,472 million. The increase in net assets as a result of the Group profit of \$10,016 million was offset by dividends of \$3,752 million and share repurchases of \$6.015 million.

#### Property, plant and equipment

Property, plant and equipment decreased by \$532 million to \$6,425 million. Additions of \$807 million (2010: \$808 million) were offset by depreciation of \$1,086 million (2010: \$1,076 million) and disposals of \$233 million (2010: \$73 million), including \$151 million of assets on the sale of Astra Tech.

#### Goodwill and intangible assets

Our goodwill of \$9,862 million (2010: \$9,871 million) principally arose on the acquisition of Medlmmune and the restructuring of our US joint venture with Merck in 1998. No goodwill has been capitalised in 2011.

Intangible assets amounted to \$10,980 million at 31 December 2011 (2010: \$12,158 million). Intangible asset additions were \$442 million in 2011 (2010: \$1,791 million), amortisation was \$911 million (2010: \$810 million) and impairments totalled \$553 million (2010: \$833 million). \$113 million of assets were disposed of on the sale of Astra Tech.

Intangible asset impairment charges recorded in 2011 include \$285 million following the termination of development of olaparib for the maintenance treatment of serous ovarian cancer and an impairment of \$150 million reflecting a lower probability of success assessment for TC-5214, based on the results of the first two of four Phase III efficacy and tolerability studies. See pages 72 and 68 respectively of the Therapy Area Review for more information.

Included within our intangible assets are rights we have acquired as a result of our Merck termination arrangements. Further details of these arrangements are included in Note 25 to the Financial Statements from page 181. 2012 is the first year that AstraZeneca may exercise the second (and final) option in relation to these termination arrangements. If the option is exercised in 2012, this will effectively end AstraZeneca's relationships with, and obligations to, Merck (other than some residual manufacturing arrangements).

#### Receivables, payables and provisions

Trade receivables increased by \$383 million to \$6,630 million driven, principally, by higher gross sales in the US in December 2011 and the way calendar working days fell at the 2011 year end. Other receivables increased by \$566 million to \$1,237 million driven by an increase in our Seroquel related settlement funds.

Included within trade receivables is approximately \$650 million of net receivables, representing 10% of our trade receivables, due from customers in eurozone countries that have a sovereign credit rating of A or lower (Spain \$300 million, Italy \$270 million, Portugal \$50 million and Greece \$30 million). Within this balance is approximately \$230 million of overdue government debt. In light of current market conditions, debts within these euro countries have been subject to enhanced monitoring and scrutiny by the Group. Our bad debt provisioning against these debts reflects our current estimate of the recoverability of these balances based on consideration of a number of factors such as the status of current negotiations, past payment history and individual countries' budget constraints. In 2011, our revenue from these four countries was \$1,113 million (Italy), \$709 million (Spain), \$305 million (Greece) and \$223 million (Portugal).

Trade and other payables increased by \$326 million in 2011, driven by increases in accruals of \$177 million and rebates and chargebacks of \$446 million, offset by a decrease in other payables of \$215 million. The increase in rebates and chargebacks arose principally from increased managed-care and group purchasing organisation rebates. Further details of the movements on rebates and chargebacks are included on page 94.

The movement in provisions of \$76 million in 2011 includes \$716 million of additional charges recorded in the year, offset by \$657 million of cash payments. Included within the \$716 million of charges for the year is \$135 million in respect of legal charges and \$450 million for our global restructuring initiative. Cash payments of \$657 million include \$377 million against our ongoing global restructuring initiatives and \$153 million related to legal matters. Further details of the charges made against our provisions are contained in Notes 17 and 25 to the Financial Statements.

#### Tax payable and receivable

Net income tax payable has decreased by \$1,521 million to \$2,334 million, principally due to the payment of a net amount of \$1.1 billion in relation to the Advance Pricing Agreement between the UK and US governments' tax authorities and the settlement of a related valuation matter. Our tax receivable balance of \$1,056 million 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 189). Net deferred tax liabilities reduced by \$449 million in the year.

#### **Retirement benefit obligations**

Net retirement benefit obligations increased by \$202 million, due to an increase in post-retirement scheme obligations of \$954 million driven by a reduction in the discount rate applied to long-term scheme obligations, reflecting present market conditions for corporate bonds, offset by pension fund employer contributions made in the year of \$733 million (2010: \$469 million) as detailed in Note 18 to the Financial Statements from page 165.

In recent years the Group has undertaken several initiatives to reduce its net pension obligation exposure. For the UK defined benefit pension scheme, which represents AstraZeneca's largest defined benefit scheme, these initiatives have included agreeing funding principles for cash contributions to be paid to the UK pension scheme to target a level of assets in excess of the current expected cost of providing benefits, and, in 2010, amendments to the scheme to freeze pensionable pay at 30 June 2010 levels (reducing the pension fund obligation by \$693 million). In addition to the cash contributions to be paid into the UK pension scheme, AstraZeneca makes contributions to an escrow account which is held outside the pension scheme. The escrow account assets are payable to the fund in agreed circumstances, for example, in the event of AstraZeneca and the pension fund trustee agreeing on a change to the current long-term investment strategy.

AstraZeneca has agreed to fund the UK defined benefit scheme shortfall by making lump sum payments totalling  $\mathfrak L715$  million (\$1,103 million) before 30 June 2013. The first of these lump sum payments of  $\mathfrak L180$  million (\$278 million) was paid into the pension scheme from the escrow account in December 2011. A further  $\mathfrak L300$  million (\$463 million) was paid into the pension scheme during January 2012 with the balance payable by 30 June 2013. In 2011,  $\mathfrak L132$  million (\$213 million) was paid into the escrow account and a further  $\mathfrak L230$  million (\$355 million) was paid in during January 2012. At 31 December 2011, \$296 million escrow fund assets are included within other investments (as detailed in Note 10 to the Financial Statements on page 160).

In 2011, approximately 96.7% (2010: 96.5%) of the Group's obligations were concentrated in the UK, the US, Sweden and Germany. Further details of the Group's pension schemes are included in Note 18 to the Financial Statements from page 165.

#### **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 146. The Group also has taxation contingencies. These are described in the Taxation section in the Critical accounting policies and estimates section on page 97 and in Note 25 to the Financial Statements from page 189.

#### 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 181. As detailed in Note 25, payments to our collaboration partners may not become payable due to 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 the Research and Development section from page 30, 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 90 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 business acquisitions and disposals in the past three years are contained in Note 22 to the Financial Statements from page 170. Details of our significant externalisation transactions are given below:

- > In January 2007, AstraZeneca signed an exclusive co-development and co-promotion agreement with BMS for the development and commercialisation of saxagliptin, a dipeptidyl peptidase IV inhibitor (DPP-IV) and dapagliflozin, a selective sodium-glucose cotransporter 2 (SGLT2) inhibitor, both for the treatment of Type 2 diabetes. 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 \$170 million for dapagliflozin and may make future milestone payments of \$230 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 \$120 million in 2011, \$50 million in 2010 and \$150 million
- > 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. 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 further milestone payments linked to worldwide product sales. As detailed in Note 9 to the Financial Statements from page 158, the carrying value of the intangible asset in relation to TC-5214, was impaired by \$150 million in 2011 based on the results of the first two of four Phase III efficacy and tolerability studies of the compound.

The Group determines the above externalisation transactions 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 R&D strategy, the expected total value of development payments under the transaction and its proportion of 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 include, without limitation, new market developments, new territories, new areas of research and strategic implications.

In aggregate, milestones capitalised under the Group's other externalisation arrangements totalled \$123 million in 2011, \$337 million in 2010 and \$306 million in 2009, and the Group recognised other income in respect of other externalisation arrangements totalling \$18 million in 2011, \$82 million in 2010 and \$440 million in 2009.

#### Capitalisation and shareholder return

**Dividend for 2011** 

	\$	Pence	SEK	Payment date
First interim dividend	0.85	51.9	5.33	12 September 2011
Second interim dividend	1.95	123.6	13.21	19 March 2012
Total	2.80	175.5	18.54	

#### **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	3,604	6,208
2011	127.4	6,015	2.80	3,6781	9,693
Total	553.0	26,535	18.425	27,621	54,156

<sup>&</sup>lt;sup>1</sup> Total dividend cost estimated based upon number of shares in issue at 31 December 2011.

#### Capitalisation

The total number of shares in issue at 31 December 2011 was 1,292 million. 10.7 million shares were issued in consideration of share option exercises for a total of \$409 million. Share repurchases amounted to 127.4 million Ordinary Shares at a cost of \$6,015 million. Shareholders' equity increased by a net \$33 million to \$23,246 million at the year end. Non-controlling interests increased to \$226 million (2010: \$197 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 a 5% increase in the second interim dividend to \$1.95 (123.6 pence, 13.21 SEK) to be paid on 19 March 2012. This brings the full year dividend to \$2.80 (175.5 pence per share, 18.54 SEK), an increase of 10%.

In 2010, the Group recommenced its share repurchase programme. The Group completed net share repurchases of \$5,606 million in 2011 (2010: \$2,110 million). The Board has announced that the Group intends to complete net share repurchases in the amount of \$4.5 billion during 2012, subject to market conditions and business needs.

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.

AstraZeneca assumes that the global biopharmaceutical industry can grow at least in line with real GDP over the planning horizon. While downward pressures on revenue from government interventions in the marketplace have intensified, AstraZeneca's assessment remains that, as yet, these do not yet constitute a sustained 'stepchange' in trend. The assumptions going forward 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 is expected that revenue in 2012 will continue to be affected by government interventions on pricing, and ongoing generic competition, including the anticipated loss of market exclusivity for Seroquel IR and Atacand in global markets, as well as for Crestor in Canada.

Over the last several years, the Group has undertaken significant restructuring initiatives aimed at reshaping the cost base to improve long-term competitiveness. The second phase of restructuring, which was announced in January 2010, comprised a significant change programme in R&D as well as additional productivity improvement initiatives in the supply chain and SG&A. The first two phases of the restructuring programme are now largely complete at a cumulative cost of \$4.6 billion. This programme will deliver annual benefits to the Group by 2014. In February 2012, the Group announced the next phase of restructuring. Further details are set out in the Our strategic priorities to 2014 section from page 21.

A planning assumption remains 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 2010 2010 Reported operating profit

			2010	2009	Percentage of sales		2010 compare	ed with 2009
	Reported \$m	CER growth \$m	Growth due to exchange effects	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 margin	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

		2		2009	2010 compared	d 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)
Gross margin %	81.2%			83.0%		
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	_	_
Operating margin %	40.8%			41.5%		
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

		Merck & Medlmmune		Post-			
	2010 Reported \$m	Restructuring costs \$m	Amortisation \$m	Intangible impairments \$m	Legal settlements \$m	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
Pre-R&D operating margin %	50.5%						53.5%
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

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

2010 revenue was unchanged (Reported: up 1%). Revenue in 2010 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 56.

Core gross margin in 2010 of 81.2% declined 1.6 percentage points (Reported: 1.8 percentage points). The impairment of lesogaberan, 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 in 2010 was \$4,219 million, 4% lower than 2009 (Reported: 3%). Increased investment in biologics was more than offset by lower project costs and operational efficiencies. The lower project costs in 2010 were the result of several late stage projects completing their trials, partially offset by the commencement of Phase III programmes for TC-5214 and fostamatinib.

2010 Core SG&A costs of \$9,777 million were 2% lower than 2009 (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 in 2010 was \$16 million less than 2009. 2009 benefited from disposal gains related to Abraxane™ 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% in 2010, 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.

2010 Core operating profit was \$13,603 million, unchanged at CER. 2010 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 EPS were \$6.71 in 2010, 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 in 2010 were broadly in line with 2009, with increased restructuring costs and intangible impairments offset by gains chiefly attributable to changes in the Group's UK pension arrangements. Excluded from Core in 2010 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 2010.
- > \$612 million of legal settlements, of which \$592 million was 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.
- > 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 MedImmune 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.

2010 operating profit was down 1% at CER (Reported: unchanged) at \$11,494 million. Basic EPS were \$5.60, up 7% (Reported: 8%), as a result of the factors affecting Core EPS.

Net finance expense was \$517 million in 2010, versus \$736 million in 2009. Fair value gains of \$5 million were recorded on long-term bonds in 2010, versus fair value losses of \$145 million for 2009. In addition to this, there was 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) consisted 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 2010 current year tax charge included 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 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 2010 was 26.4% (2009: 30.2%, 28.8% excluding the impact of legal provisions).

Total comprehensive income for 2010 increased by \$616 million from 2009. This was driven by the increase in profit 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.

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 was 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.

Investments cash outflows of \$2,236 million in 2010 included 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 2010. 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 2010 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 was due within one year (2009: \$1,926 million). Strong business cash flows improved net funds by \$3,118 million, resulting in net funds of \$3,653 million at 31 December 2010.

#### Financial position - 2010

All data in this section is on a Reported basis.

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 2010 increased net assets by \$494 million.

#### Property, plant and equipment

Property, plant and equipment decreased by \$350 million to \$6,957 million as at 31 December 2010. 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 Medlmmune and on the restructuring of our US joint venture with Merck in 1998. No goodwill was 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 and \$128 million related to our decision to discontinue further development of lesogaberan. The 2010 impairment balance also included \$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

In 2010, 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 included \$1,361 million of additional charges recorded in 2010, offset by \$1,109 million of cash payments. Included within the \$1,361 million of charges in 2010 was \$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. Cash payments of \$1,109 million included \$335 million against our global restructuring initiative and \$709 million related to legal provisions.

#### Tax payable and receivable

Net income tax payable in 2010 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 comprised tax owing to AstraZeneca from certain governments expected to be received on settlements of transfer pricing audits and disputes. Net deferred tax liabilities reduced by \$285 million in 2010. This movement included 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 in 2010, 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.

#### Financial risk management

#### Financial risk management policies

#### Insurance

Our risk management processes are described in the Managing risk section from page 129. 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. 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 171 and in the Risk section from page 129.

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 171.

#### Critical accounting policies and estimates

Our Financial Statements are prepared in accordance with IFRSs 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 146. 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.

#### **Revenue recognition**

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

Rebates, chargebacks and returns in the US When invoicing sales in the US, we estimate the rebates and chargebacks that we expect to pay. 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). They 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 managed-care organisations, long-term care facilities and group purchasing organisations are entitled to rebates depending on specified performance provisions, which vary from contract to contract.

The effects of these deductions on our US pharmaceuticals revenue and the movements on US pharmaceuticals revenue provisions are set out below.

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 made reasonable 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 - US Pharmaceuticals

	2011 \$m	2010 \$m	2009 \$m
Gross sales	23,613	22,909	22,646
Chargebacks	(1,958)	(2,075)	(1,841)
Regulatory – US government and state programmes	(2,293)	(1,949)	(1,357)
Contractual – Managed-care and group purchasing organisation rebates	(5,437)	(4,755)	(4,752)
Cash and other discounts	(452)	(437)	(428)
Customer returns	(72)	(21)	(193)
Other	(276)	(265)	(196)
Net sales	13,125	13,407	13,879

#### Movement in provisions – US Pharmaceuticals

	Brought forward at 1 January 2011 \$m	Provision for current year \$m	Adjustment in respect of prior years	Returns and payments \$m	Carried forward at 31 December 2011 \$m
Chargebacks	523	2,012	(54)	(2,086)	395
Regulatory – US government and state programmes	1,122	2,364	(71)	(2,125)	1,290
Contractual – Managed-care and group purchasing organisation rebates	1,194	5,452	(15)	(5,031)	1,600
Cash and other discounts	41	452	_	(452)	41
Customer returns	133	75	(3)	(84)	121
Other	64	276	_	(260)	80
Total	3,077	10,631	(143)	(10,038)	3,527

#### Movement in provisions - US Pharmaceuticals continued

	Brought forward at 1 January 2010 \$m	Provision for current year \$m	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

The large increase in managed-care and group purchasing organisation rebates in 2011 is principally driven by the impacts of the Affordable Care Act. See page 78 of the Geographical Review for more information.

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. 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 *Toprol-XL/Seloken* 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 generic launch (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 only one dose size in a market of several dose sizes) the likely level of switching from one dose to another. Under our accounting policy, revenue is recognised only when the amount of the revenue can be measured reliably. Our approach in meeting this condition for products facing generic competition will vary from product to product depending on the specific circumstances.

The closing adjustment in respect of prior years benefited 2011 net US pharmaceuticals revenue by 1.1% (2010: increased revenue by 1.1%; 2009: increased revenue by 0.8%). However, taking into account the adjustments affecting both the current and the prior year, 2010 revenue was not impacted by adjustments between years and 2009 revenue benefited by 0.3%.

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 IP 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 from page 146. 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 157. 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 2011 included \$285 million following the termination of development of olaparib for the maintenance treatment of serous ovarian cancer and an impairment of \$150 million reflecting a lower probability of success assessment for TC-5214, based on the results of the first two of four Phase III efficacy and tolerability studies. See pages 72 and 68 respectively of the Therapy Area Review for more information.

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 Medlmmune in 2007 and the payments to partially retire Merck's interests in our products in the US in 2008 and 2010. We are satisfied that the carrying values at 31 December 2011 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 181.

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 158.

#### 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 181.

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.

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. As detailed in Note 18 to the Financial Statements from page 165, the benefits provided by the UK pension plan were also modified during 2010.

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 current liabilities. 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 to the Financial Statements on page 189.

#### Sarbanes-Oxley Act Section 404

As a consequence of our NYSE listing, 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 2011 and the assessment is set out in the Directors' Responsibilities for, and Report on, Internal Control over Financial Reporting on page 140. KPMG Audit Plc has audited the effectiveness of our internal control over financial reporting at 31 December 2011 and, as noted in the Auditor's Reports on the Financial Statements and on Internal Control over Financial Reporting (Sarbanes-Oxley Act Section 404) on page 141, their report is unqualified.



# healthcollaboration Fighting the rise of cardiovascular disease

According to some studies, up to 50% of people in certain Gulf states are affected by high cholesterol. To fight this, we have launched a unique educational programme, called 'Safe @ Heart', designed to bring together all stakeholders to improve awareness and reduce cholesterol levels.

In 2009, a partnership between local cardiac societies and AstraZeneca launched the first large observational study of its kind (CEPHEUS) in the Gulf states and Saudi Arabia. It analysed the current management of cholesterol treatment among more than 5,000 adult patients being treated with statins. Preliminary results showed that 50% of the studied population did not reach their cholesterol treatment goals.

The Safe @ Heart programme is a practical response to this issue, taking a holistic, society-wide approach to driving improvements. The programme includes working with physicians to stress the importance of reaching cholesterol goals and helping them improve cholesterol management. It works with patients, carers and the general public to increase awareness and promote treatment adherence and lifestyle changes. We are also working with health authorities and governments in the fight against the rise of cardiovascular disease in the region.

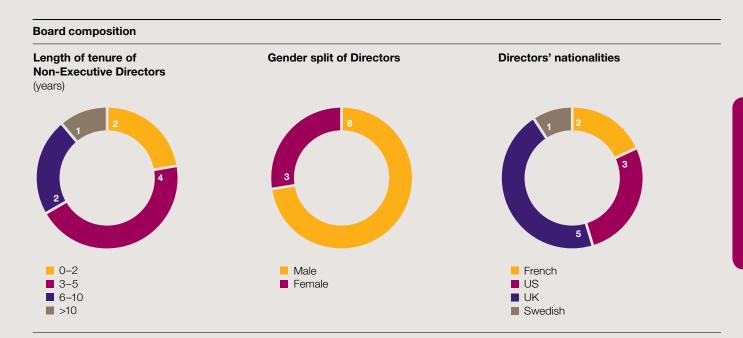
# Board of Directors and Senior Executive Team A diverse team with the skills and experience to lead the business

This section briefly describes how the Group is organised, including the overall structure and principal roles and responsibilities of the Board, its committees and the SET.

#### Board composition, processes and responsibilities

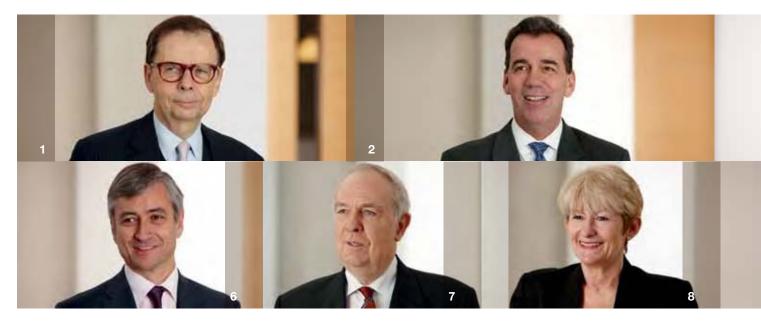
The Board comprises two Executive Directors (the CEO and the CFO) and nine Non-Executive Directors. The membership of the Board at 31 December 2011 and information about individual Directors is contained in the Board of Directors section below and overleaf.

All Directors are collectively responsible for the success of the Group. In addition, the Non-Executive Directors are responsible for exercising independent, objective judgement in respect of Board decisions and for scrutinising and challenging management. The Non-Executive Directors also have various responsibilities concerning the integrity of financial information, internal controls and risk management.



#### **Board of Directors and Senior Executive Team**

# **Board of Directors**



#### 1 Louis Schweitzer (69)

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 (58)

#### **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 (50)

#### **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 Energy where he was Finance Director, a position he left following completion of the sale of the company to Iberdrola S.A. 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 (60)

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 non-executive member of the boards of UnitedHealth Group Inc. and PPG Industries, 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.

#### 5 Bruce Burlington (63)

Non-Executive Director and member of the Science Committee and the Audit Committee

Appointed as a Director in August 2010. 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 Medical 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).

#### 6 Jean-Philippe Courtois (51)

#### Non-Executive Director and member of the Audit Committee

Appointed as a Director in February 2008. Jean-Philippe Courtois has close to 30 years' experience in the global technology industry and is President of Microsoft International, 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 and in 2011 was named as one of 'Tech's Top 25' by The Wall Street Journal Europe.



7 Rudy Markham (65)
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 member of the supervisory board of CSM NV, a Fellow of the Chartered Institute of Management Accountants and a Fellow of the Association of Corporate Treasurers.

#### 8 Dame Nancy Rothwell (56)

Non-Executive Director, Chairman of the Science Committee, member of the Remuneration Committee and the Nomination and Governance Committee

Appointed as a Director in April 2006. Nancy Rothwell 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 and a member of the Prime Minister's Council for Science and Technology. 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.

#### 9 The Right Honourable Baroness Shriti Vadera (49) Non-Executive Director and member of the Audit Committee

Appointed as a Director in January 2011. Shriti Vadera has significant experience of emerging markets, and knowledge of global finance and public policy. She is a Non-Executive Director of BHP Billiton Plc and BHP Billiton Limited. She advises funds, governments and companies and has recently undertaken a number of international assignments including advising the Republic of Korea as Chair of the G20, the government of Dubai on the restructuring of Dubai World, Temasek Holdings, Singapore on strategy and Allied Irish Banks on restructuring and European policy.

She was Minister in the UK government from 2007 to 2009, most latterly in the Cabinet Office and Business Department, working on the government's response to the financial crisis. From 1999 to 2007, she was on the Council of Economic Advisers, HM Treasury focusing on business and international economic issues. Prior to that she spent 14 years in investment banking with S G Warburg/ UBS in banking, project finance and corporate finance specialising in emerging markets.

#### 10 John Varley (55)

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., and Rio Tinto plc and Rio Tinto Limited, Chairman of Business Action on Homelessness and of Marie Curie Cancer Care, 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 (55)

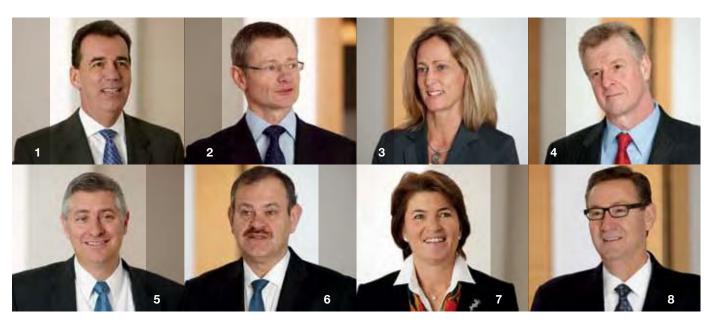
Non-Executive Director and member of the Science Committee

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, Saab AB and LKAB, and a Non-Executive Director of Stora Enso Oyj, Temasek Holdings Limited and the Knut and Alice Wallenberg Foundation.

Other officers of the Company at 31 December included members of the SET, as set out on page 102, and Adrian Kemp, Company Secretary.

#### **Board of Directors and Senior Executive Team**

# **Senior Executive Team**



1 David Brennan Chief Executive Officer

See page 100.

#### 2 Simon Lowth

**Chief Financial Officer** 

See page 100.

#### 3 Katarina Ageborg

**Chief Compliance Officer** 

Katarina Ageborg was appointed Chief Compliance Officer in July and has overall responsibility for the delivery, design and implementation of AstraZeneca's compliance responsibilities. Since joining AstraZeneca in 1998, she has held a series of senior legal roles supporting Commercial and Regulatory and most recently led the Global IP function from 2008 to 2011. Prior to joining AstraZeneca, she established her own law firm in Sweden and worked as a lawyer practising on both civil and criminal cases.

#### **4 Martin Mackay**

#### President, Global R&D

Martin Mackay joined AstraZeneca in July 2010. He leads a global organisation tasked with advancing a portfolio of investigational medicines across a range of disease areas. Prior to joining AstraZeneca, he was the President of PharmaTherapeutics R&D at Pfizer. His career at Pfizer spanned 15 years, where he held various leadership roles, including the President of R&D. He serves on the Scientific and Regulatory Committee of the industry trade group PhRMA and co-chairs the US-India BioPharma & Healthcare Summit Advisory Board. He is a Visiting Professor at the University of Lincoln, UK.

#### **5 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 IP function. He joined AstraZeneca in 1995 and has worked in various litigation roles, where he has had responsibility for IP, 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.

#### 6 David Smith

#### **Executive Vice-President, Operations & 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 IS. 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 Inc. and Timberland LLC in senior supply chain roles. In 2003, he returned to the pharmaceutical sector and joined Novartis in Switzerland.

#### 7 Lynn Tetrault

#### **Executive Vice-President, Human Resources & 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.

### 8 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 MedImmune. 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 Inc. He earned a bachelor's degree in biology from Frostburg University and an associate's degree in chemical engineering from Pennsylvania State University.

# Corporate Governance Report



Louis Schweitzer Chairman and Chairman of the Nomination and Governance Committee

The principles set out in the UK Corporate Governance Code remain the primary standards and guidance for corporate governance within AstraZeneca. The Board, its Committees and individual Directors apply those principles in all aspects of their work.

The Board's Committees play an essential role in good governance. Under the chairmanship of Michele Hooper and John Varley respectively, the Audit Committee and the Remuneration Committee carry significant workloads and discharge their responsibilities on behalf of the Board with rigour and diligence. More information about their work is set out in the report that follows and in the Directors' Remuneration Report. As Chairman of the Nomination and Governance Committee, I believe we have made good progress in recent years in succession planning at Board and senior executive level. Our work includes paying attention to the composition of the Board and its Committees, consideration of both planned and unplanned succession scenarios and recognition of the importance of gender and other diversity in good governance. For reasons of confidentiality, it is often not possible to report in detail on much of this work.

The Board itself is mindful of the need to monitor its own performance and improve it where we can. We approach each annual performance evaluation of the Board and its Committees with an open mind. While reassured by the results of the evaluation in 2011, which was facilitated by external consultants, the report that follows summarises areas for further improvement, which include expanding the role played by the Science Committee in assurance work under the competent and committed chairmanship of Nancy Rothwell.

#### **Louis Schweitzer**

Chairman

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 UK Corporate Governance Code published by the UK Financial Reporting Council (FRC) in May 2010. This Corporate Governance Report (together with other sections of this Annual Report) describes how we apply the main principles of good governance in the UK Corporate

Governance Code. We have complied throughout the accounting period with the provisions of the UK Corporate Governance Code, which is 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 nine 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 runs an annual strategy review process. 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.

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 Non-Executive 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 Non-Executive 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.

#### **Corporate Governance Report**

#### **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.

The Board held seven meetings and its annual strategy review day in 2011. With the exception of two Board meetings in September and the strategy day in the same month, which were held at our site in Wilmington in the US, all the meetings took place in London, UK. The Board is currently scheduled to meet six times and hold a strategy review day in 2012, 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, succession planning and diversity

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 from pages 100 to 101 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 Board recognises, in particular, the importance of the debate about gender diversity, prompted by the publication in the UK in February 2011 of the report by Lord Davies, 'Women on Boards'. Since the formation of AstraZeneca in 1999, the proportion of women Board members has been approximately 25% and the Board intends to continue with its current approach to diversity in all its aspects, while at the same time seeking Board members of the highest calibre and with the necessary experience and skills to meet the needs of the Company and its shareholders. Information about our approach to diversity in the organisation below Board-level can be found in the People section on page 41.

The following changes to the composition of the Board have occurred during the period covered by this Annual Report:

- Shriti Vadera was appointed as a Non-Executive Director and a member of the Audit Committee with effect from 1 January 2011.
- > Jane Henney, a Non-Executive Director, retired from the Board on 28 April 2011.

#### **Independence of the Non-Executive Directors**

During 2011, the Board considered the independence of each Non-Executive Director for the purposes of the UK Corporate Governance Code 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 Code, the test of independence is not appropriate in relation to the Chairman after his appointment.

Marcus Wallenberg was appointed as a Director of Astra in May 1989 and subsequently became a Director of the Company in 1999. Until September 2005, he was a member of the board of directors and the Chief Executive Officer of Investor AB, which has a 4.02% interest in the issued share capital of the Company as at 2 February 2012. 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 Code. However, the Board believes that he has brought, and continues to bring, considerable business experience and makes a valuable contribution to the work of the Board. In April 2010, Marcus Wallenberg was appointed by the Board as a member of the Science Committee, reflecting his interest in innovation and R&D, knowledge of the history of the Company and its scientific heritage and culture, and his broad experience of other industries and businesses in which innovation and R&D are important determinants of success.

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.

#### 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 109 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.

#### **Board and Board Committee meeting attendance in 2011**

Name	Board	Audit	Remuneration	Nomination and Governance
David Brennan	7 (7)*	_	-	_
Bruce Burlington	7 (7)	3 (3)	-	_
Jean-Philippe Courtois	6 (7)	4 (6)	-	_
Jane Henney <sup>1</sup>	1 (2)	3 (3)	_	1 (1)
Michele Hooper	7 (7)	6 (6)	_	4 (4)
Simon Lowth	7 (7)	_	-	_
Rudy Markham	7 (7)	5 (6)	5 (5)	_
Nancy Rothwell	7 (7)	_	5 (5)	3 (3)
Louis Schweitzer	7 (7)	_	5 (5)	4 (4)
Shriti Vadera	7 (7)	6 (6)	-	_
John Varley	7 (7)	_	5 (5)	4 (4)
Marcus Wallenberg	6 (7)	-	_	_

<sup>&</sup>lt;sup>1</sup> Jane Henney retired from the Board on 28 April 2011.

#### **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 and site visits. The Audit Committee section from page 107 contains information about Audit Committee members' visits to our business in Brazil, Russia and China during 2011. In addition, Board or Board Committee meetings were held at our sites in Wilmington, US, Gaithersburg, US, Mölndal, Sweden, and Alderley Park, UK during the year.

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 2011. 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**

During the year, the Board conducted the annual evaluation of its own performance and that of its Committees and individual Directors. The review was facilitated by an external consultancy, Lintstock Ltd (Lintstock), a London-based corporate advisory firm that provides objective and independent counsel to leading European companies. For a number of years, Lintstock has supplied software and services to the Company Secretary's team for the web-based questionnaires used for internal Board performance evaluations, and for the management of insider lists. Other than these limited instances, Lintstock is not a supplier to the Company and was able to act as a robust and independent external facilitator for the Board performance evaluation.

The 2011 evaluation involved a series of web-based questionnaires and individual meetings between Lintstock and each Board member. Lintstock then prepared and discussed with the Chairman and the Company Secretary a draft report of their findings. The final report was circulated to the full Board and discussed at the Board meeting held in December. The evaluation covered a range of topics, including: the composition of the Board; the effectiveness of its strategic oversight; Board members' involvement in the affairs of the Company outside Board meetings; decision making and time management; the nature and quality of the information and general support provided to the Board; its approach to risk management and oversight of internal controls; and succession planning and how effectively it prioritises matters. Separate questionnaires covered the operation and effectiveness of the Board's committees.

The review concluded that the Board operates effectively and in an open manner. Board members have a good level of involvement in matters between Board meetings. The points to be addressed arising from the review include further improvements in the use of the Board's time in terms of Board meeting arrangements and how agenda items are scheduled and approached; further refinement of the composition of the Board over time; consideration of a short strategic update during the year between the annual strategy days in September; minor improvements to the information provided to Board members in terms of content and format; more involvement by the Science Committee in assurance work on behalf of the Board; and continuing the improvements made in 2011 to the review by the Board of SET-level succession plans.

As part of the assessment process, each Director responded to a questionnaire about their individual contribution to the work of the Board and personal development needs, following which they had individual discussions with the Chairman to follow up their responses. Each Director continues to perform effectively and to demonstrate commitment to the role.

<sup>\*</sup> Number in brackets denotes number of meetings during the year which Board members are entitled to attend.

#### **Corporate Governance Report**

The Board's annual performance evaluation was previously externally facilitated in 2008. The Board intends to continue 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 2012. 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 2011, the Directors have continued to review the effectiveness of our system of controls, risk management and our high-level internal control processes. 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 GIA, as well as the external auditor on matters identified in the course of its statutory audit work. The system is designed to manage rather than eliminate the risk of failure to achieve business objectives and can only provide reasonable (not necessarily absolute) assurance of effective operation and compliance with laws and regulations.

Underpinning these reviews is an annual 'letter of assurance' process by which responsible managers confirm the adequacy of their systems of internal financial and non-financial controls, their compliance with Group policies and relevant laws and regulations (including the industry's regulatory requirements), and that they have reported any control weaknesses through our 'continuous assurance' process.

The internal control framework has been in operation throughout 2011 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 deficiencies 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 129, 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 113.

#### **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 shareholders 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. In November, we invited corporate governance representatives from our largest institutional shareholders to a meeting attended by Louis Schweitzer, Chairman of the Board; Michele Hooper, senior independent Non-Executive Director and Chairman of the Audit Committee; John Varley, Chairman of the Remuneration Committee; and Rudy Markham, member of the Remuneration Committee and the Audit Committee. Although the meeting was primarily focused on executive remuneration matters, it provided an opportunity for shareholders to raise any broader corporate governance issues for discussion as well.

#### **Board Committee membership**

Name	Audit		Nomination and Governance	Science	Independent <sup>1</sup>
David Brennan					n/a
Bruce Burlington	✓			✓	<b>✓</b>
Jean-Philippe Courtois	✓				<b>✓</b>
Jane Henney <sup>2</sup>	<b>✓</b>		1	/	<b>✓</b>
Michele Hooper <sup>3</sup>	Chair		1		<b>√</b>
Simon Lowth					n/a
Rudy Markham	✓	✓			<b>✓</b>
Nancy Rothwell		✓	1	Chair	<b>✓</b>
Louis Schweitzer <sup>4</sup>		✓	Chair		n/a
Shriti Vadera	✓				<b>✓</b>
John Varley		Chair	1		<b>√</b>
Marcus Wallenberg				1	×

<sup>&</sup>lt;sup>1</sup> As determined by the Board for UK Corporate Governance Code purposes.

<sup>&</sup>lt;sup>2</sup> Jane Henney retired from the Board on 28 April 2011.

<sup>&</sup>lt;sup>3</sup> Michele Hooper is the senior independent Non-Executive Director.

Louis Schweitzer was considered independent by the Board upon his appointment as Chairman. In accordance with the UK Corporate Governance Code, the test of independence is not appropriate in relation to the Chairman after his appointment.

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.

#### **Audit Committee**

The members of the Audit Committee are Michele Hooper (Chairman of the Audit Committee), Jean-Philippe Courtois, Rudy Markham, Shriti Vadera, Bruce Burlington, and until her retirement at the 2011 AGM, Jane Henney. They are (or in the case of Jane Henney, were) all Non-Executive Directors. The Board considers each member to be independent under the UK Corporate Governance Code and under the general guidance and specific criteria of the Listing Standards concerning the composition of audit committees applicable to non-US companies listed on the NYSE. In April 2011, 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 Code, the Board remains satisfied that at least one member of the Audit Committee has recent and relevant financial experience. At its meeting in December, 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, including the critical estimates and judgements contained in our reporting.
- > Compliance with the Corporate Integrity Agreement (CIA).

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 remit of the Audit 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 Audit 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 Audit Committee in advance. The CFO (supported by the Vice-President, Group Finance) monitors the status of all services being provided by the external auditor. The procedures also deal with placing non-audit work out for tender, where appropriate. Authority to approve work in excess of the pre-agreed fee limits is delegated to the Chairman of the Audit Committee in the first instance. A standing agenda item at Audit Committee meetings covers the operation of the pre-approval procedures and regular reports are provided to the full Audit Committee.

The Audit Committee held six scheduled meetings in 2011. The individual attendance record of members of the Audit Committee is set out in the Board and Board Committee meeting attendance in 2011 table on page 105. Following each Audit Committee meeting, the Chairman of the Audit Committee reported to the Board on the principal matters covered at the meeting and minutes of the meetings were circulated to all Board members. In addition, the Chairman of the Audit Committee held regular scheduled calls between Audit Committee meetings with each of the Vice-President, GIA, the Chief Compliance Officer, the CFO and the lead partner of the external auditor.

During 2011, 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 Audit Committee's work and to provide an opportunity to discuss specific areas of interest. In particular, members of the Audit Committee travelled to our marketing companies in Brazil and Russia as well as to our marketing company, and R&D and manufacturing sites in China to meet senior leaders in these important Emerging Markets. During these visits, Audit Committee members were able to gain a greater understanding of the unique business and cultural dynamics of each of these markets and to hear how our local operations meet the challenges presented by these developing economies within the context of our global compliance framework.

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 following her appointment, the Chief Compliance Officer, which position replaced the Global Compliance Officer), the General Counsel and the lead partner from the Company's external audit firm. The purpose of these meetings was to facilitate free and open discussions between Audit Committee members and those individuals, separately from the main sessions of the Audit Committee, which were also attended by the CEO, the CFO, the General Counsel and the Vice-President, Group Finance.

## **Corporate Governance Report**

During 2011 and January 2012, in addition to the discussions noted above, the Audit Committee also considered and discussed the following matters:

- > The key elements of the financial statements, and estimates and judgements contained in our financial disclosures, which were reviewed and various accounting matters considered.
- > The reports 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 Audit Committee also reviewed quarterly activity reports of audit work carried out by GIA and the status of follow up actions with management as well as reports from the Global Compliance function.
- > The systems and processes that management has developed pertaining to risk identification, classification and mitigation.
- > Compliance with the applicable provisions of the Sarbanes-Oxley Act. In particular, the Audit Committee regularly reviewed the status of compliance with the programme of internal controls over financial reporting implemented pursuant to section 404 of the Sarbanes-Oxley Act. The Audit Committee increased its focus on IS/IT controls in the context of the changes to the Group's IS/IT environment, described below. Further information about this is set out in the Sarbanes-Oxley Act Section 404 section on page 97.
- > Data about reports made by employees via the AZethics telephone and online facilities and other routes regarding potential breaches of the Code of Conduct together with the results of inquiries into these matters.
- > Quarterly reports received from the US Compliance Officer responsible for monitoring the US business's compliance with the CIA (for more information about the obligations imposed on the Board by the CIA, see below).
- > The decision to terminate AstraZeneca's existing outsource relationship for IS infrastructure services and transition to a new multi-sourcing operating model. In addition, regular progress updates from IS/IT on the status of the transition from the existing outsource provider to the new providers.
- > Accounting issues relevant to litigation and taxation matters.
- > Reports from the Group Treasury function and, in particular, reports concerning 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 function.
- > Reports from the General Counsel on the status of certain litigation matters and governmental investigations.
- > The provisions of the new UK Bribery Act, the Company's revised Global Anti-Bribery Policy and its Global External Interactions Policy. These revised policies are available on our website, astrazeneca.com.
- > The amount of audit and non-audit fees of the external auditor throughout 2011. The Audit Committee was satisfied throughout the year that the objectivity and independence of the external auditor were not in any way impaired by the nature of the non-audit work undertaken by the external auditor during the year, the level of non-audit fees charged for such work or any other facts or circumstances. Further information about the audit and non-audit fees for 2011 is disclosed in Note 27 to the Financial Statements on page 190.
- > A review of compensation policy across the Commercial organisation. This review was held with the Chairman of the Remuneration Committee.
- > A review and assessment of the Audit Committee's performance (including an externally facilitated review of performance) which concluded that such performance was satisfactory.

In addition to the quarterly reporting stipulated by the CIA as described above, a number of other obligations required by the CIA were discharged by members of the Board and the Audit Committee during 2011. For example, all members of the Board completed the annual CIA-required training, addressing the Code of Conduct and the elements of the CIA and the US compliance programme. Furthermore, the Board adopted a resolution (signed by each member) in respect of the first 12 month reporting period under the CIA. The resolution summarised the Board's oversight of the US compliance programme and stated that, to the best of the Board's knowledge, AstraZeneca Pharmaceuticals, LP and AstraZeneca LP (AstraZeneca's principal US trading entities) have implemented an effective US compliance programme to meet Federal healthcare programme, FDA and CIA requirements.

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. In accordance with its normal practice, the Audit Committee reviewed a satisfaction survey and performance evaluation of our external auditor, which included in addition to the Audit Committee's own consideration, assessment and input from key stakeholders within the Group. In addition, in 2011, the Audit Committee requested and reviewed a formal proposal from KPMG Audit Plc (KPMG) to continue as the Company's auditors for the period 2012 to 2014. The Audit Committee considered KPMG's compliance with the independence criteria under the relevant statutory, regulatory and ethical standards applicable to auditors and assessed its objectivity, taking into account the level of challenge provided around the critical estimates and judgements involved in our financial reporting and the quality of our internal control over financial reporting. Having considered all these factors and weighed them against its experience of working with other external firms, the Audit Committee unanimously recommended to the Board that a resolution for the re-appointment of KPMG as the Company's external auditor for the year ending 31 December 2012, be proposed to shareholders at the AGM in April 2012. Consistent with current market practice, KPMG's services to the Company are provided pursuant to terms of engagement which are reviewed by the Audit Committee. These terms of engagement do not include any contractual obligations under which the Directors would be prevented from appointing a different audit firm were they to consider this to be in the best interests of the Group. The Audit Committee, through management, continues to maintain contact and dialogue with other major audit firms who are familiar with the Group's business for succession purposes as required. This is reported to the Audit Committee in order to ensure a smooth transition from the current auditor, should this be necessary.

At the January 2012 meeting, the CFO presented to the Audit Committee the conclusions of the CEO and the CFO following the evaluation of the effectiveness of our disclosure controls and procedures required by Item 15(a) of Form 20-F at 31 December 2011. 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 2012 and will meet at such other times as may be required.

The Audit Committee's terms of reference are available on our website, astrazeneca.com.

#### **Code of Conduct**

Our Code of Conduct (the Code), which is available on our website, astrazeneca.com, applies to all Directors, officers, full-time, part-time, and temporary staff at all levels in every country where we operate. Further information relating to the Code can be found in the Compliance section on page 43.

A Group Finance Code of Conduct complements the Code. 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. This reinforces the importance of the integrity of the Group's Financial Statements, the reliability of the accounting records on which they are based and the robustness of the relevant controls and processes.

#### **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 113.

#### **Nomination and Governance Committee**

The Nomination and Governance Committee's role is to recommend to the Board any new Board appointments and to consider more broadly succession plans at Board-level. 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 Nomination and Governance Committee also advises the Board periodically on significant developments in corporate governance and the Company's compliance with the UK Corporate Governance Code.

During 2011, the members of the Nomination and Governance Committee were Louis Schweitzer (Chairman of the Nomination and Governance Committee), Michele Hooper, John Varley, Jane Henney (until her retirement from the Board on 28 April 2011) and Nancy Rothwell (from 28 April 2011). 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 Code, the test of independence is not appropriate in relation to the Chairman after his appointment. The Company Secretary acts as secretary to the Nomination and Governance Committee.

The Nomination and Governance Committee met four times in 2011. The individual attendance record of its members is set out in the Board and Board Committee meeting attendance in 2011 table on page 105. 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. In addition, the Nomination and Governance Committee received reports about the most significant corporate governance developments and their potential impact on the Group.

The Nomination and Governance Committee's terms of reference are available on our website, astrazeneca.com.

#### Science Committee

The Science Committee's core role continues to be to provide assurance to the Board regarding the quality, 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
- > scientific technology and R&D capabilities deployed
- > decision making processes for R&D projects and programmes
- > 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 Science Committee does not review individual R&D projects.

During 2011, 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 Science Committee), Bruce Burlington, Marcus Wallenberg and Jane Henney (until her retirement from the Board on 28 April 2011), all Non-Executive Directors. The President, Global R&D; the Executive Vice-President, Innovative Medicines; the Executive Vice-President, Biologics R&D; and the Executive Vice-President, Global Medicines Development attend meetings of the Science Committee. The Vice-President, Strategy, Portfolio & Performance, R&D also attends all meetings and acts as secretary to the Science Committee.

The Science Committee met twice in 2011, at Alderley Park, UK and at Mölndal, Sweden.

The Science Committee's 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 110.

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 140.

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, applicable to foreign private issuers. 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. Katarina Ageborg joined the SET as Chief Compliance Officer on 1 July 2011.

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 Chief Compliance Officer; the Executive Vice-President, Human Resources & Corporate Affairs; and the Executive Vice-President, Operations & Information Services. The Company Secretary acts as secretary to the SET.

#### **Portfolio Investment Board (PIB)**

The CEO has established and chairs the PIB, 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 Executive Vice-President, Biologics R&D; 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 CEO; 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 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 quarterly 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**

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 assurance reporting to the Audit Committee. During 2012, 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 2011, a new Chief Compliance Officer (formerly designated Global Compliance Officer) was appointed to head the Global Compliance function. The reporting of all Global Compliance programme resources, including regional and local compliance officers, is centralised under the Chief Compliance Officer who reports to the CEO and is a member of the SET. The Chief Compliance Officer heads the Global Compliance leadership team, whose remit is to oversee and coordinate 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.

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 203).
- > Articles (contained in the Corporate Information section on page 208).
- > Amendments to the Company's Articles (contained in the Corporate Information section on page 208).

#### 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 191.

## 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, Azerbaijan, Belarus, Bulgaria, Chile, Costa Rica, Croatia, Cuba, Georgia, Ghana (scientific office), Ireland, Jordan, Kazakhstan, Kenya (scientific office), Macedonia, Nigeria, Romania, Russia, Serbia and Montenegro, Slovenia and Ukraine.
- > AstraZeneca AB: Egypt (scientific office), Saudi Arabia (scientific office) and Slovakia.
- > AstraZeneca Singapore Pte Limited: Cambodia and Vietnam.

#### Distributions to shareholders and dividends for 2011

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 90 and Notes 20 and 21 to the Financial Statements on page 170.

The Company's dividends for 2011 of \$2.80 (175.5 pence, SEK 18.54) per Ordinary Share amount to, in aggregate, a total dividend payment to shareholders of \$3,678 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 2011 AGM authorising the Company to purchase its own shares. Pursuant to this resolution, the Company repurchased (and subsequently cancelled) 127.4 million Ordinary Shares with a nominal value of \$0.25 each, at an aggregate cost of \$6,015 million, representing 9.9% of the total issued share capital of the Company. The Company will seek a renewal of permission from shareholders to purchase its own shares at the AGM on 26 April 2012.

During our share repurchase programmes that operated between 1999 and 2011, a total of 557.4 million Ordinary Shares were repurchased, and subsequently cancelled, at an average price of 2767 pence per share for a consideration, including expenses, of \$26,717 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 The pharmaceutical industry from page 15. Details of our product portfolio, our approach to product development and a summary of our development pipeline are included in the Business Review from page 30. Additional information on our Therapy Areas is included in the Therapy Area Review from page 56. The table showing our development pipeline can be found from page 199.

The financial position of the Group, our cash flows, liquidity position and borrowing facilities are described in the Financial Review from page 86. In addition, Notes 15 and 23 to the Financial Statements from pages 161 and 171 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 from pages 160 to 161 respectively.

We have considerable financial resources available. At 31 December 2011, we had \$9.2 billion in financial resources (cash balances of \$7.6 billion and committed undrawn bank facilities of \$3.6 billion, with only \$2.0 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 2011, 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 170.

#### **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 2011, 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 125. 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 from page 113.

## **Corporate Governance Report**

#### **Political donations**

Neither the Company nor its subsidiaries made any EU political donations or incurred any EU political expenditure in 2011 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 2012 AGM, similar to that passed at the 2011 AGM, to authorise the Company and its subsidiaries to:

- > make donations to political parties or independent election candidates
- > make donations to political organisations other than political parties
- > incur political expenditure, up to an aggregate limit of \$250,000.

Corporate political contributions in the US are permitted in defined circumstances under the First Amendment of the US Constitution and are subject to both federal and state laws and regulations. In 2011, the Group's US legal entities made contributions amounting in aggregate to \$1,099,450 (2010: \$1,999,150) to national political organisations, state-level political party committees and to campaign committees of various state candidates. No corporate donations were made at the federal level and all contributions were made only where allowed by US federal and state law. We publicly disclose details of our corporate US political contributions, which can be found at astrazeneca-us.com/ responsibility/transparency/. The annual corporate contributions budget is reviewed and approved by the US General Counsel, the US Vice-President, Corporate Affairs and the President of our US business to ensure robust governance and oversight. 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 161 and 171 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 50 days' average purchases (2010: 62 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 43 days is obtained (2010: 57 days).

The Company has no external trade creditors.

#### **Annual General Meeting**

The Company's AGM will be held on 26 April 2012. The meeting place will be in London, UK. 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 26 April 2012 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 2011. 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 190. 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 107, 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 2011.

#### **Bureau Veritas**

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.

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. The web page content assured by Bureau Veritas is marked at the bottom of each page.

#### **Directors' Report**

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

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

and has been signed on behalf of the Board.

#### A C N Kemp

Company Secretary 2 February 2012



John Varley
Non-Executive Director
and Chairman of the
Remuneration Committee

I am pleased to introduce our Directors' Remuneration Report (the Report) for 2011 for which we seek approval at the Company's AGM in April.

The job of the Remuneration Committee (the Committee) is to promote long-term, sustainable growth in shareholder value. So its main focus is on developing policy and remuneration decisions that support the Group's strategy as a focused, integrated, innovation-driven, global, prescription-based biopharmaceutical business. This involves taking careful account of the interests of our stakeholders.

As your elected representatives, our primary task is to invest shareholders' money, in the form of compensation resource, wisely. We are mindful of the UK Corporate Governance Code's main principle which guides us to award levels of remuneration that are sufficient to attract, retain and motivate senior employees (including Directors) of the quality required to run the Group successfully, while avoiding paying more than is necessary. This means paying close attention to the design of incentive arrangements for Executive Directors, SET members and other senior executives, as well as to how our pay structures operate in practice. To reinforce our objectivity, and to complement the objective mindset that is brought to bear on remuneration decisions, the Committee takes advice from Deloitte LLP, directly appointed by the Committee independently of the Company.

Base salaries are benchmarked against relevant industry market data to ensure that they remain competitive, but this is not done blindly, continuously or in isolation; the Committee takes care also to consider, before making its decisions, the overall performance of the business and the needs of the Company in terms of its strategic and operational targets. We will not award increases that are not justified by individual performance. For incentive arrangements, the Committee aims to select performance criteria which are appropriate to the Company's circumstances and which will promote AstraZeneca's success and competitiveness in the pharmaceutical industry. Whether it is the combination of a balanced scorecard, cash flow and EPS performance for the annual bonus, or longer-term measures relating to shareholder value, such as TSR used in the AstraZeneca Performance Share Plan (PSP) and the dividend hurdles in the AstraZeneca Investment Plan (AZIP), we seek to establish clear and fair links between individual and Group performance, and appropriate levels of reward.

We try to keep in touch with what our shareholders are thinking. There is an annual opportunity for our larger investors to meet me and Board colleagues to share their opinions and, of course, shareholders

express their views by way of the shareholder vote on this Report at the AGM in April, which is attended by many of our owners. We are grateful for the support that shareholders have shown for our approach to executive remuneration; last year, 95% of the votes cast by shareholders supported the 2010 Directors' Remuneration Report.

The Committee is also very aware of the position of employees throughout the Group, how the remuneration principles established by the Committee translate into rewards for employees, and the fairness of the rewards earned by Executive Directors, SET members and other senior executives in the overall Group context, especially in relation to annual salary increases. We call for, and analyse, a significant amount of data relating to salaries, bonus levels and incentive scheme awards across the Group. We also consider the levels of share ownership among SET members and other senior executives. We know that in making judgements about the pay of senior employees, particularly the Executive Directors, we must ensure that our decisions take account of the wider employee context. How, for example, does any percentage increase in the base pay of the CEO sit alongside base pay increases of junior staff? I hope that you can see in our decisions this year, and in the behaviour of the CEO himself (who has again declined an increase in base pay), that we are sensitive to these important issues. Before awarding an increase in base pay and long-term compensation opportunity to our CFO, we consulted widely with our major shareholders. The salary increase we have decided to award sits within the range of base pay increases awarded to the wider UK employees of the Group for 2012. Going forward, our intention is that any future increases for Executive Directors will be cost of living type increases made on an annual basis.

In the decisions that it makes, the Committee seeks always to assess how these might affect AstraZeneca's reputation. We use our discretion to avoid mechanistic outcomes of remuneration arrangements that are not justified by the prevailing circumstances, be it underlying financial performance or the way in which the Company does business. We defer awards and have the ability to use claw-back arrangements (where appropriate) to reinforce the importance of the Company's reputation and to deter inappropriate risk taking.

We have changed the format of the Report this year. Without reducing disclosure, we have sought in the first part to answer the question: What was paid to the Executive Directors in 2011 and why? We then set out extensive information of the sort that our shareholders are familiar with. So the Report that follows is divided into three sections. We start with 'What was paid to the Executive Directors in 2011 and why?'. We follow this with a section headed 'How the Remuneration Committee approaches its work' that describes how we aim to support business strategy; link reward with performance; and exercise judgement. The third section describes the work of the Committee in 2011. We conclude with an Additional information section containing the remainder of the information which shareholders habitually wish to see. We would find it useful to receive feedback from shareholders on this new approach in due course.

We have noted the proposals on executive remuneration announced in January 2012 by the UK Secretary of State for Business, Innovation & Skills. This Report is likely to evolve further in response to developing legislation.

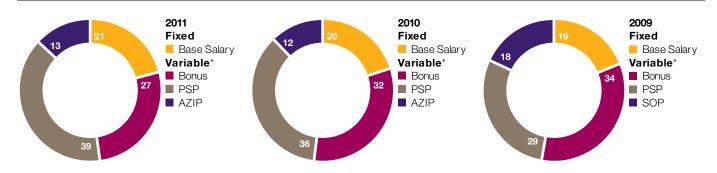
On behalf of the Committee, I commend this Report to you.

#### John Varley

Chairman of the Remuneration Committee

#### **David Brennan**

#### Components of remuneration - What was paid to the Chief Executive Officer (%)



<sup>\*</sup> Bonus element is the actual bonus paid for the year in question. PSP, AZIP and SOP elements are on an expected value basis.

In this section, we have set ourselves the task of explaining, as simply as we can, what was paid to the Executive Directors during 2011 and why.

This 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 26 April 2012.

#### What was paid to the Executive Directors in 2011 and why?

The summaries below set out the quantitative data for each Executive Director, including certain data for the preceding year to enable comparison. We follow this with short qualitative comments relating to base pay, annual bonus or Short Term Incentive (STI), Long Term Incentive (LTI) and benefits, including pension.

#### **David Brennan**

Base pay per annum and % changes over previous year					
2012	2011	2010			
£997,223	£997,223	£972,900			
+0%	+2.5%	+0%			

- > The Committee reviewed the CEO's base pay in December 2011 and decided to award an increase for 2012 of 2.5%. This was within the range of salary increases for employees across the Group. As in 2010, the CEO declined to accept any increase.
- > The CEO was awarded a bonus for performance during 2011 of £1,325,609 (133% of base salary out of a maximum possible award of 180% of base salary), the cash element of which will be paid in 2012¹. His bonus for performance during 2010, the cash element of which was paid in 2011, was £1,583,025 (163% of base salary out of a maximum possible award of 180% of base salary)². The 2011 bonus was lower than the 2010 bonus by 16%. The reasons for this are set out in the section below headed Variable elements of the CEO's and CFO's remuneration in 2011.

- > The CEO must defer one-third of any pre-tax bonus into Ordinary Shares or ADSs. These are held for three years before being released. The bonus is not pensionable.
- > The CEO received an LTI award in 2011 with an expected value of 250% of base salary<sup>3</sup>. Full details can be found on page 126. Under the rules of the PSP and the AZIP, in respect of any financial year of the Company, the maximum market value of shares that may in theory be put under a PSP or an AZIP share award in respect of an employee, is 500% of that employee's base salary.
- > In respect of the LTI award made in 2011, the distribution between the PSP and the AZIP was in the ratio 75% to 25%.
- > During 2011, as a result of the vesting of the 2008 share award under the PSP, the CEO received 201,932 Ordinary Shares and a cash payment in respect of dividends accrued.
- > The CEO is entitled to standard non-cash employment benefits, such as healthcare benefits, insurances and car purchase arrangements.
- > In relation to pension arrangements, the CEO's pension entitlement is provided through a combination of the AstraZeneca US Defined Benefit Pension Plan and US defined contribution arrangements. He has an accrued pension at 31 December 2011 of £978,000 per annum (2010: £972,000 per annum) from his defined benefit arrangements. Full details can be found on page 118.
- > The Committee increased the CEO's shareholding requirement in January 2012 from 200% to 300% of base salary.
- > At 31 December 2011, the CEO had a beneficial shareholding of 273,263<sup>4</sup> AstraZeneca shares which, at that date, had a value approximately equivalent to 815% of his 2011 base salary.

<sup>&</sup>lt;sup>1</sup> The factors considered by the Committee in assessing performance during 2011 and determining the bonus are summarised on page 116.

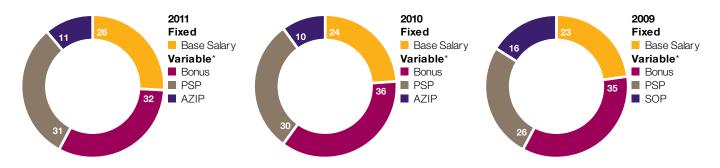
<sup>&</sup>lt;sup>2</sup> Each year in January, the Committee determines bonuses for performance in the previous year and these are paid in February.

<sup>&</sup>lt;sup>3</sup> The Company estimates the expected value of LTI awards taking account of the likelihood of performance conditions and targets being achieved.

<sup>&</sup>lt;sup>4</sup> This figure includes an estimated 27,089 shares post-tax held in retention in the Deferred Bonus Plan.

#### **Simon Lowth**

#### Components of remuneration – What was paid to the Chief Financial Officer (%)



<sup>\*</sup> Bonus element is the actual bonus paid for the year in question. PSP, AZIP and SOP elements are on an expected value basis.

#### **Simon Lowth**

Base pay per annum and % changes over previous year					
2012	2011	2010			
£660,000	£635,500	£620,000			
+3.85%	+2.5%	+13%			

- > The Committee reviewed the CFO's base pay in December 2011 and decided to award an increase for 2012 of 3.85%. This was within the range of salary increases for employees across the Group. The Committee consulted major shareholders and took their views into account before awarding this increase.
- > The CFO was awarded a bonus for performance during 2011 of £769,902 (121% of base salary out of a maximum possible award of 150% of base salary), the cash element of which will be paid in 2012¹. His bonus for performance during 2010, the cash element of which was paid in 2011, was £918,245 (148% of base salary out of a maximum possible award of 150% of base salary)². The 2011 bonus was lower than the 2010 bonus by 16%. The reasons for this are set out in the section below headed Variable elements of the CEO's and CFO's remuneration in 2011.
- > The CFO must defer one third of any pre-tax bonus into Ordinary Shares or ADSs. These are held for three years before being released. The bonus is not pensionable.
- > The CFO received an LTI award in 2011 with an expected value of 160% of base salary<sup>3</sup>. Full details can be found on page 126. Under the rules of the PSP and the AZIP, in respect of any financial year of the Company, the maximum market value of shares that may in theory be put under a PSP or an AZIP share award in respect of an employee is 500% of that employee's base salary.

- > After consulting major shareholders and taking their views into account, starting in 2012 the Committee has decided to increase the target LTI award for the CFO from an expected value of 160% of base salary to 200%.
- > In respect of the LTI award made in 2011, the distribution between the PSP and the AZIP was in the ratio 75% to 25%.
- > During 2011, as a result of the vesting of the 2008 share award under the PSP, the CFO received 73,060 Ordinary Shares and a cash payment in respect of dividends accrued.
- > The CFO is entitled to standard non-cash employment benefits, such as healthcare benefits, insurances and car purchase arrangements.
- > In relation to pension arrangements, the CFO receives a payment equivalent to 24% of his base salary, which amounted to £153,000 in 2011 (2010: £149,000), as a cash alternative to participation in a defined contribution pension scheme. Full details can be found on page 118.
- > The Committee increased the CFO's shareholding requirement in January 2012 from 125% to 200% of base salary.
- > At 31 December 2011, the CFO had a beneficial shareholding of 68,538<sup>4</sup> AstraZeneca shares which, at that date, had a value approximately equivalent to 321% of his 2011 base salary.

<sup>&</sup>lt;sup>1</sup> The factors considered by the Committee in assessing performance during 2011 and determining the bonus are summarised on page 116.

<sup>&</sup>lt;sup>2</sup> Each year in January, the Committee determines bonuses for performance in the previous year and these are paid in February.

<sup>&</sup>lt;sup>3</sup> The Company estimates the expected value of LTI awards taking account of the likelihood of performance conditions and targets being achieved.

<sup>&</sup>lt;sup>4</sup> This figure includes an estimated 14,312 shares post-tax held in retention in the Deferred

## Variable elements of the CEO's and CFO's remuneration in 2011

#### Bonus outcomes for 2011

For Executive Directors, the principal drivers of annual bonus opportunity are EPS (27% weighting), cash flow (9% weighting), the Group scorecard (24% weighting) and the relevant SET area scorecards (40% weighting). In terms of the SET area scorecards, an average of all SET area scorecards is used for the CEO and the Finance scorecard is used for the CFO. The scorecards include categories relating to Values, Pipeline and People. At the beginning of 2011, the Committee set EPS, cash flow and scorecard targets against which the performance of the Executive Directors has been measured. At CER, both revenue and Core operating profit for the year declined by 2% and 4% respectively. This partly accounts for the reduction of 16% in the bonuses of the CEO and the CFO. However, Core EPS increased by 7%. There was strong double-digit growth for Crestor, Seroquel XR and Symbicort. Emerging markets sales growth was 10% at CER. Brilinta was approved and launched in the US and a number of other countries; other products made good progress through regulatory approvals. Both cash flow and EPS performance exceeded internal and external expectations. Balanced against this were a number of pipeline disappointments, including olaparib and TC-5214, which both resulted in impairment charges. The Company made net cash distributions to shareholders of \$9,370 million by way of dividends and the share buy-back programme, boosted by the successful disposal of Astra Tech. In addition to a strong financial performance in a challenging environment, significant work was undertaken in 2011 to continue promoting a culture of responsibility, accountability and compliance. The Company is ranked in the top 7% in the sector in the Dow Jones Sustainability World and European Indexes, with its highest assessment score to date of 85%.

The annual bonus ranges for the CEO and the CFO in 2012 are unchanged from 2011. For the CEO, the range is 0-180% of base salary and for the CFO it is 0-150% of base salary.

#### Vesting of PSP awards in 2011 and 2012

The PSP share awards granted in 2008 in respect of the 2008-2010 performance period vested during 2011 at 125% for SET members, including the CEO and the CFO (whose awards were based on TSR alone), following achievement of a relative TSR ranking of first in the comparator group over the performance period. The Committee used its discretion to determine this vesting of the maximum PSP award because the Company's TSR performance was substantially better than that of the upper quartile of the comparator group in the 2008-2010 performance period (a TSR of 55% for the Company versus 16% for the next best performing company in the comparator group).

The PSP share awards granted in 2009 in respect of the 2009-2011 performance period will vest during 2012 at 78% for SET members, including the CEO and the CFO (whose awards were based on TSR alone), following achievement of a relative TSR ranking of fourth in the comparator group with a TSR of 35% over the performance period. This is in accordance with the performance measures determined by the Committee.

#### Performance under the PSP in 2011

The TSR graphs on page 124 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 2011 and how the Company ranks against those other peer companies on this basis. At the end of 2011, 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.

#### Performance under the AZIP in 2011

Previously granted AZIP awards continued without lapsing as the full-year dividend for 2011 was \$2.80 per Ordinary Share, which exceeded the 2009 and 2010 full-year dividends of \$2.30 and \$2.55 per Ordinary Share respectively. Dividend cover did not fall below the 1.5 times threshold.

# How the Remuneration Committee approaches its work Remuneration Committee membership

The Committee members are John Varley (Chairman of the Committee), Rudy Markham, Louis Schweitzer and Nancy Rothwell. Louis Schweitzer was considered by the Board to be independent upon his appointment as Chairman of the Board. All other members of the Committee are independent Non-Executive Directors. The Company Secretary acts as the secretary to the Committee.

The Committee retains Deloitte LLP (Deloitte), represented by Carol Arrowsmith, who provided independent advice on various matters it considered in 2011. The cost of this service to the Company in 2011 was £118,380 (including VAT). 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 were no conflicts.

#### Committee terms of reference

A copy of the Committee's terms of reference is available on our website, astrazeneca.com.

The Committee conducted a review of its terms of reference during 2011. A small number of changes were recommended to the Board, principally to reflect updated guidance issued by the Association of British Insurers in September 2011. The changes were approved by the Board in January 2012.

#### Supporting the business strategy

The principal role of the Committee is to develop remuneration policies and practices that support the implementation of our business strategy and help create shareholder value over time.

The remuneration components for all employees (including Executive Directors and SET members) comprise fixed and variable performance-related elements. A summary of the main components of remuneration is set out on page 119.

Base pay and total compensation positioning against the relevant market is intended to be sufficient (but no more than necessary) to attract, retain and develop high-calibre talent.

Variable pay forms a significant part of the overall remuneration opportunity for Executive Directors, SET members and other senior executives. It is linked to a range of measures designed to promote individual and team performance in a way that supports the Group's success. Such measures are intended 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. This is made up of three elements:

- > The annual bonus drives and rewards short-term performance against specific Group, functional and individual business objectives.
- > The PSP rewards the generation of cash at levels to finance investment in the business, debt repayment and the Company's shareholder distribution policy; and outperformance of industry peers in terms of shareholder value-creation measured by relative TSR.
- > The performance and holding periods of the AZIP are aligned to the Company's product development cycle, reflecting the long-term investment horizons that are a feature of the industry. Dividendbased performance hurdles motivate the generation of returns for shareholders on a sustainable basis over an extended period of time.

#### Linking reward with performance

Executive Directors and other SET members are eligible to participate in different elements of variable performance-related pay, which are described in the Additional information section 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.

The Committee works with the Audit Committee to ensure that the Group's remuneration policies and practices achieve the right balance between appropriate incentives to reward good performance and managing risk in terms of employee behaviour and how the Company achieves its business objectives.

The AstraZeneca annual bonus plan, in which all employees participate, contains goals demonstrating a commitment to distinction through integrity, to enhance reputation and avoid reputational damage. All LTI plans operated by AstraZeneca contain claw-back provisions.

#### **Exercising judgement**

The Committee believes that an essential element of its approach is the exercise of its judgement and discretion in determining remuneration in order to reflect relevant circumstances and achieve the right balance between the interests of the business, shareholders and employees. The Committee always considers the overall performance of the Group when using its discretion under the terms of AstraZeneca's remuneration arrangements. This is to avoid mechanistic outcomes under the terms of any remuneration plan which would provide for rewards that are not justified either by underlying business performance or in circumstances where AstraZeneca has suffered reputational damage.

## Aligning senior executives' interests with those of shareholders

Part of the annual bonus of Executive Directors and SET members is deferred into shares, helping align senior executives' interests with those of shareholders.

The proportion currently deferred into shares is one-third of the pre-tax annual bonus for Executive Directors and one-sixth for other SET members. The Committee reviews annually whether the proportion of bonus to be deferred should be changed in the light of market and/or best practice developments. The shares 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.

In addition to partial bonus deferral, there is a requirement for Executive Directors and other SET members to hold shares in the Company. The shareholding requirement for the CEO was increased in January 2012 from 200% to 300% of base salary, and for the CFO from 125% to 200% of base salary. The requirement for all other SET members is 125% of base salary.

In all aspects of its work, the Committee considers both the external environment in which the Company operates and the guidance issued by organisations representing institutional shareholders. It consults the Company's largest investors on general and specific remuneration and provides an annual opportunity for representatives of those investors to meet the Chairman of the Committee and other Committee and Board members.

#### Considering the wider employee context

The Committee sets overall remuneration policy and makes decisions about specific remuneration arrangements in the broader context of employee remuneration throughout the Group. The Committee annually reviews Group remuneration data including bonus data;

gender and geographical data in relation to base salaries; and aggregate data about the shareholding levels of senior managers. In particular, in reviewing the base salaries of Executive Directors and SET members, the Committee considers the overall level of any salary increases being awarded to employees across the Group in the relevant year.

#### Main work of the Remuneration Committee during the year

The Committee met five times in 2011. The individual attendance record of Committee members is set out on page 105. At the invitation of the Committee, except where their own remuneration was being discussed, the CEO; the Executive Vice-President, Human Resources & Corporate Affairs; the Global Head, Reward & Employment; and the Vice-President, Global Compensation attended one or more Committee meetings in 2011 and provided advice and services that materially assisted the Committee.

The work of the Committee focused on the following principal matters during 2011:

- > 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 2010 and to set executive bonus performance targets for 2011.
- > The assessment of performance against targets to determine the level of vesting in 2011 under the PSP and to set PSP and AZIP performance thresholds for awards made in 2011.
- > The determination of awards made under the Group's main LTI plans: the PSP, the AZIP and the Global Restricted Stock Plan (GRSP) to SET members and other participants.
- > The determination of restricted share awards to a limited number of senior executives under the AstraZeneca Restricted Share Plan (RSP).
- > The setting of the terms of appointment of Katarina Ageborg as Chief Compliance Officer and a SET member.
- > A review of performance metrics used by the R&D organisation.
- > The approval of rules of a new UK all-employee savings-related share option scheme, which will be proposed to shareholders for approval at the 2012 AGM, to replace the AstraZeneca Savings-Related Share Option Plan, which expires in 2013.
- > Jointly with the Audit Committee, a review of compensation policy across the Commercial organisation.
- > The review and determination of incentive arrangements below SET level for a limited pool of eligible employees in the context of the Company's restructuring plans in Commercial and R&D.
- > A review of Group reward data, including average salary data analysed by gender.
- > Consideration of the review of the Committee's effectiveness carried out by the Board.
- > 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, other SET members and senior executives immediately below SET level.
- > A review of the pension entitlements of Executive Directors and other SET members.
- > A review of the proportion of Executive Directors' and SET members' annual cash bonuses that are deferred into shares with a three-year vesting period.
- > A review of the performance of Deloitte, the independent adviser to the Committee.
- > The submission by the Company of a response to the executive remuneration discussion paper published by the UK Department for Business, Innovation & Skills in September 2011.
- > The preparation, review and approval (in January 2012) of this Report.

#### **Additional information**

#### **Audit**

The Executive Directors' pension arrangements disclosed in the Pension arrangements section on page 118, the Directors' emoluments disclosed in the Directors' emoluments in 2011 section from pages 123 to 124 and the details of the Directors' interests in Ordinary Shares disclosed in the Directors' interests in shares section (excluding the Beneficial interests sub-section) from page 125 have been audited by KPMG Audit Plc.

#### **Pension arrangements**

#### **CEO's pension arrangements**

#### Defined benefit 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 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.

David Brennan's participation in the US DBP is subject to a service cap at 35 years' service, which has now been attained and therefore service beyond 35 years is not shown in the table below. No further service accrual can be earned.

Members and, in the event of death, surviving spouses/dependants can elect, in relation to those benefits delivered on a tax-qualified basis under the US DBP, to take pensions in lump sum form based on actuarial valuation. Members or spouses/dependants may not make such an election in relation to any supplementary non-qualified benefits which must be taken in lump sum form.

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 2011 set out on page 124. Transfer values are calculated to be consistent with the value of the lump sum distribution equivalent to his deferred accrued pension annually.

#### Defined contribution arrangements

In addition, David Brennan (as a US citizen) is a contributing member of the US 401(k) savings 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 2011, total employer matching contributions of \$96,000 (£60,000) (2010: \$91,000 (£59,000)) were made to his 401(k) plan and EDCP. Member contributions of \$719,000 (£447,000) were paid through salary sacrifice into the plans.

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. Since joining AstraZeneca, he has elected to take the cash allowance in lieu of a pension, which during 2011, amounted to £153,000 (\$245,000) (2010: £149,000 (\$230,000)).

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 lump sum secured from a multiple of 10 times salary (capped at £4.3 million).

#### **David Brennan**

	2000	\$000
Defined benefit arrangements		
Accrued pension at 1 January 2011	972	1,555
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	6	10
4. Increase in accrued pension as a result of additional service	-	_
5. Accrued pension at 31 December 2011	978	1,565
6. Employee contributions during 2011	_	_
7. Transfer value of accrued pension at 31 December 2010	14,211	22,738
8. Transfer value of accrued pension at 31 December 2011	14,055	22,488
9. Change in transfer value during the period less employee contributions	(156)	(250)
10. Age at 31 December 2011	584/12	
11. Pensionable service (years) at 31 December 2011	35	

## Components of remuneration for all employees

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	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
taking into account external expectations of performance.		The functional goals are agreed by the Committee at the start of the year and are derived from the business scorecard, the key elements of which are set out in the Our strategy section from page 19, and are monitored as part of the quarterly business review (QBR) process. Embedded into these goals is a commitment to distinction through integrity to avoid any damage to reputation. Individual goals are based on annual objectives, which are linked to functional goals.	
		Performance measures for the annual bonus in respect of Executive Directors are set out in the Variable elements of the CEO's and CFO's remuneration in 2011 section on page 116.	
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, strong financial performance and actions that are closely	AstraZeneca Investment Plan.	SET members
	aligned with the interests of shareholders. The primary LTI plans in which SET members participate are the PSP and the AZIP.	Share Option Plan (final awards made in 2009).	SET members and other senior executives
		Global Restricted Stock Plan.	Eligible employees globally
		Note: Performance measures for the PSP and the AZIP are set out in the summary of those plans in the next section.	<u> </u>
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 the 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 300% of base salary, the CFO 200% and other SET members 125%.	SET members
Overall approach	When assessing the overall value of a SET member's remuneration, the Committee considers, both separately and in aggregate, each component of the SET member's total remuneration.		

 $<sup>^{\</sup>mbox{\tiny 1}}$  Further information on these plans is provided in Note 24 to the Financial Statements from page 176.

#### Summary of the AstraZeneca Performance Share Plan (PSP) and the AstraZeneca Investment Plan (AZIP)

#### History

#### **PSP**

The PSP was approved by shareholders at the 2005 AGM and provides for the grant of performance share awards (PSP Share Awards) over Ordinary Shares or ADSs (together, Shares).

#### **AZIP**

The AZIP was approved by shareholders at the 2010 AGM and provides for the grant of share awards (AZIP Share Awards) over Shares.

#### Rasis of participation

#### **PSP**

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 2011, the main grant of PSP Share Awards was made on 28 March, with a smaller grant of Share Awards approved by the Committee in relation to, for example, new appointments, promotions and assignments being made on 26 August. The number 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 126.

#### **AZIP**

Participation in the AZIP is highly selective and usually includes only senior employees on the basis of their performance.

In 2011, the main grant of AZIP Share Awards was made on 28 March, with a further Share Award approved by the Committee in relation to Katarina Ageborg's appointment to the SET on 26 August. The number 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 126.

#### Individual limit

#### **PSP**

Under the PSP rules, 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.

#### AZIP

Under the AZIP rules, 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.

#### Performance conditions and performance targets

#### **PSP**

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 (balanced equally between cash flow and TSR) 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.

Fifty percent 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
- > 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.

The peer group for the TSR measure is: Abbott, BMS, Eli Lilly & Company, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, 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.

TSR ranking of the Company	Vesting %
Below median	0
	25
Between median and upper quartile	Pro rata
Upper quartile	75
Significantly above upper quartile	Up to 100

In addition to the above TSR performance target being met for each PSP Share Award, the Committee has to satisfy itself that achievement of the TSR performance target is a genuine reflection of the Group's underlying financial performance. It 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.

Fifty percent of the award vests subject to the achievement of the free cash flow target, which operates as a cumulative cash flow 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 allows performance to 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.

#### Performance conditions and performance targets continued

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

#### **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.

The AZIP is operated over a four-year performance period (Performance Period) and a four-year holding period (Holding Period). 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 2011 is that:

- > The annual dividend per share paid to holders of Ordinary Shares is increased from \$2.55 over the four-year Performance Period (\$2.55 being the full-year dividend for 2010): and
- > Dividend cover (based on reported earnings before restructuring costs) does not fall below 1.5 times.

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 period 1 January 2010 to 31 December 2013 (\$2.30 being the full-year dividend for 2009); and
- > Dividend cover over the same period (based on reported earnings before restructuring costs) does not fall below 1.5 times.

#### Performance Period/Holding Period and vesting dates

#### PSP

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 2011, the performance period runs from 1 January 2011 to 31 December 2013. The vesting date is the third anniversary of the date of grant.

#### AZIP

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 performance period. As described above, the AZIP is currently operated over a four-year performance period (Performance Period) and a four-year holding period (Holding Period).

## Cessation of employment

#### PSP

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, subject to the achievement of the relevant performance targets measured over the entire Performance Period.

#### AZIF

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/her 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 Ordinary 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.

**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 Ordinary 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.

#### 2011 performance

#### PSP

The TSR graphs on page 124 compare for each PSP Share Award, the Company's TSR performance against the TSR for companies in the comparator group from the first day of the relevant performance period to 31 December 2011. At the end of 2011, the Company is on track to meet the cash flow target.

#### AZIP

The full-year dividend was \$2.80 for 2011 and dividend cover did not fall below the 1.5 times threshold.

## Claw-back of Shares

#### PSP

In the event that an employee leaves the Company's employment for anything other than a Good Leaver Reason, any unvested award shall lapse unless the Committee decides otherwise.

#### Δ*7*ΙΕ

The Committee can claw back some or all of the Ordinary 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 Company performance, 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 Ordinary Shares. No Ordinary Shares were subject to claw-back in 2011.

#### Summary of other plans

**AstraZeneca Share Option Plan** 

The Share Option Plan (SOP) was approved by shareholders for a period of 10 years and expired in May 2010.

Details of outstanding grants of option awards (Option Awards) granted to Executive Directors are shown in the Share option plans table on page 127.

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. No such determination was made in 2011.

#### **Global Restricted Stock Plan**

The AstraZeneca Global Restricted Stock Plan (GRSP) was introduced in 2010 and provides for the grant of restricted stock awards (Stock Awards) over Shares. The GRSP is operated for below SET-level employees only.

In 2011, Stock Awards were made under the GRSP on 28 March, with other Stock Awards approved by the Committee in relation to, for example, new appointments, promotions and assignments being granted on 26 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 Ordinary 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 Share Plan**

The AstraZeneca Restricted Share Plan (RSP) was introduced in 2008 and provides for the granting 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 Ordinary Shares which are newly issued or transferred from treasury. The RSP was used seven times in 2011 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 the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca All-Employee Share Plan in the UK, both of which are HM Revenue & Customs approved plans. Certain Executive Directors and other SET members are eliqible to participate in these plans, more detailed descriptions of which can be found in Note 24 to the Financial Statements from page 176.

#### Dilution under share plans

Other than the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca All-Employee Share Plan, which operate in the UK only, and the SOP, none of the Company's share plans has a dilutive effect because they do not involve the issue and allotment of new Ordinary Shares but rather rely on the market purchase of Ordinary Shares that have already been issued.

#### **Terms of employment for Executive Directors**

#### Service contracts

Details of the service contracts for each of the Executive Directors are set out below. 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.

Details of Executive Directors' service contracts at 31 December 2011 are shown in the table below:

Executive Director	Date of service contract	Unexpired term at 31 December 2011	Notice period
David Brennan	1 January 2006	12 months	12 months
Simon Lowth	5 November 2007	12 months	12 months

#### Policy on external appointments and retention of fees

Subject to specific Board approval 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 their role within the Group to the required standard. Simon Lowth is a Non-Executive Director of Standard Chartered PLC. In respect of such position, he received fees of £105,000 for his services in 2011.

#### **Non-Executive Directors**

None of the Non-Executive Directors has a service contract but all have letters of appointment. 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.

The annual Board fees applicable to Non-Executive Directors, including the Non-Executive Chairman, are set out in the Non-Executive Directors' fees table on page 123. In addition to the mandatory shareholding requirement imposed on all Directors under the Articles described in the Directors section on page 208, the Board encourages each Non-Executive Director 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).

#### **Non-Executive Directors' fees**

	£
Chairman's fee	500,000
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 Committee¹	20,000
Membership of the Science Committee	10,000
Chairman of the Science Committee <sup>1</sup>	7,000

<sup>&</sup>lt;sup>1</sup> This fee is in addition to the fee for membership of the relevant Committee.

#### **Directors' emoluments in 2011**

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 2011 was £6,535,000 (\$10,458,000). 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 2011 £000	Total 2010 £000	Total 2009 £000
Louis Schweitzer	500	-	-	-	-	500	456	325
David Brennan	9972	884	442	24	1,023 <sup>3</sup>	3,370	3,044	3,186
Simon Lowth	636	513	257	6	373⁴	1,785	1,642	1,426
Bruce Burlington	98	-	_	_	_	98	33	_
Jean-Philippe Courtois	95	-	_	_	_	95	80	75
Michele Hooper	145	-	_	-	_	145	120	100
Rudy Markham	110	-	_	_	_	110	90	75
Nancy Rothwell	107	_	_	-	_	107	96	92
Shriti Vadera	95	_	_	_	_	95	_	_
John Varley	110	_	_	-	_	110	99	95
Marcus Wallenberg	85	_	_	_	_	85	71	60
Former Directors								
Jane Henney	35 <sup>5</sup>	-	_	_	_	35	90	85
Others	-	-	-	_	_	-	59	659
Total	3,013	1,397	699	30	1,396	6,535	5,880	6,178

#### Directors' remuneration - US dollars

Name	Salary and fees \$000	Bonus cash \$000	Bonus Shares¹ \$000	Taxable benefits \$000	Other payments and allowances \$000	Total 2011 \$000	Total 2010 \$000	Total 2009 \$000
Louis Schweitzer	800	-	-	-	-	800	705	504
David Brennan	1,596²	1,415	707	38	1,637³	5,393	4,705	4,937
Simon Lowth	1,018	821	411	10	5974	2,857	2,537	2,209
Bruce Burlington	157	_	_	_	_	157	51	-
Jean-Philippe Courtois	152	_	_	-	_	152	124	116
Michele Hooper	232	_	_	_	_	232	185	155
Rudy Markham	176	_	_	-	_	176	139	116
Nancy Rothwell	171	_	_	_	-	171	148	143
Shriti Vadera	152	_	_	-	_	152	_	_
John Varley	176	_	_	-	_	176	153	147
Marcus Wallenberg	136	_	_	_	_	136	110	93
Former Directors								
Jane Henney	56⁵	_	_	_	_	56	139	132
Others	_	_	_	-	_	-	92	1,021
Total	4,822	2,236	1,118	48	2,234	10,458	9,088	9,573

<sup>1</sup> These figures represent that portion of the 2011 bonuses required to be deferred into Ordinary Shares to be held for a three-year period under the Deferred Bonus Plan.

<sup>&</sup>lt;sup>2</sup> This figure includes a sum of £447,000 (\$719,000) in respect of member contributions to the 401(k) plan and to the AstraZeneca Executive Deferred Compensation Plan which was paid into the plans by means of a salary sacrifice (see the Defined contribution arrangements section on page 118 for further details).

Relates to relocation allowances, a car allowance and cash of £880,000 (\$1,408,000) on the vesting of a PSP Share Award and £73,000 (\$117,000) on the release of Ordinary Shares under the Deferred

Bonus Plan, in each case paid in respect of dividends accrued.

Relates to remaining cash following selection of benefits within AstraZeneca's UK flexible benefits programme and cash of £318,000 (\$509,000) on the vesting of a PSP Share Award and £6,000 (\$10,000) on the release of shares under the Deferred Bonus Plan, in each case paid in respect of dividends accrued.

 $<sup>^{\</sup>rm 5}$  Part-year only as ceased to be a Director on 28 April 2011.

In the tables in the Directors' emoluments in 2011 section on page 123, 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
2011	0.625
2010	0.647
2009	0.645

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 Directors' interests in shares section from page 125.

No Director has a family relationship with any other Director.

#### **Transactions with Directors**

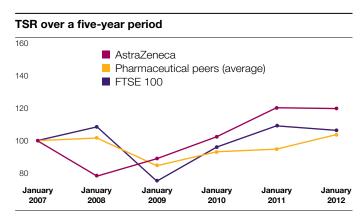
There were no material recorded transactions between the Company and the Directors during 2011 or 2010.

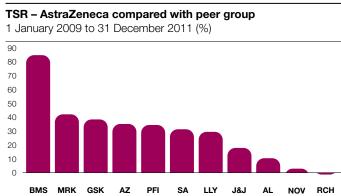
#### Total shareholder return

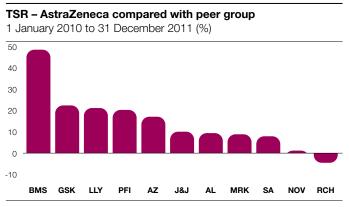
The Regulations require the inclusion of a graph showing TSR over a five-year period in respect of a holding of the Company's shares, plotted against TSR in respect of a hypothetical holding of shares of a similar kind and number by reference to which a broad equity market index is calculated. The Company 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 'Pharmaceutical peers (average)', which reflects the TSR of the same comparator group used for the PSP graphs below.

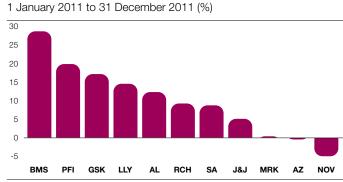
The PSP requires that the TSR in respect of a holding of the Company's shares over the relevant performance period be compared with the TSR of a peer group of pharmaceutical companies (as described on page 120). The graphs below show how the Company's TSR performance has compared with the TSR for the 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 2011 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 2011.









TSR - AstraZeneca compared with peer group

Key: AZ AstraZeneca, AL Abbott Laboratories, BMS Bristol-Myers Squibb, GSK GlaxoSmithKline, J&J Johnson & Johnson, LLY Eli Lilly, MRK Merck, NOV Novartis, PFI Pfizer, RCH Hoffmann-La Roche Ltd, SA Sanofi-Aventis

#### **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 2011 to 31 December 2011 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 from page 126. 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. None of the Directors has a beneficial interest in the shares of any of the Company's subsidiaries. Between 31 December 2011 and 2 February 2012, there was no change in the interests in Ordinary Shares shown in the table below.

	Beneficial interest in Ordinary Shares at 1 January 2011 or (if later) appointment date	Change to beneficial interest	Beneficial interest in Ordinary Shares at 31 December 2011 or (if earlier) resignation date
Louis Schweitzer	16,615	_	16,615
David Brennan	186,982	59,192	246,174
Simon Lowth	9,346	44,880	54,226
Bruce Burlington	553	-	553
Jean-Philippe Courtois	2,635	-	2,635
Jane Henney <sup>1</sup>	1,314	-	1,314
Michele Hooper	2,400	-	2,400
Rudy Markham	1,940	512	2,452
Nancy Rothwell	1,314	518	1,832
Shriti Vadera	3,000	-	3,000
John Varley	1,294	450	1,744
Marcus Wallenberg	63,646	-	63,646

<sup>&</sup>lt;sup>1</sup> Ceased to be a Director on 28 April 2011.

#### **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 2011	Net ADSs acquired during 2011	ADSs held at 31 December 2011
AstraZeneca Executive Deferral Plan	37,741	2,261	40,002
AstraZeneca Savings and Security Plan	8,523	499	9,022

#### **Performance Share Plan**

The interests of Directors at 31 December 2011 in Ordinary Shares that are the subject of Share Awards under the PSP are not included in the Beneficial interests in Ordinary Shares table on page 125 but are shown below:

	Number of	Award price	Price on vesting		Vesting	
	Ordinary Shares	(pence)	date (pence)	Grant date <sup>1</sup>	date <sup>1</sup>	Performance period <sup>1</sup>
David Brennan						
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
2010 Share Award	127,520	2861		07.05.10	07.05.13	01.01.10 - 31.12.12
Total at 1 January 2011	422,413			'		
Discretionary enhancement of 2008 Share Award <sup>2</sup>	40,386					
Vesting of 2008 Share Award <sup>2</sup>	(201,932)3,5		2874			
2011 Share Award	131,075	2853		28.03.11	28.03.14	01.01.11 - 31.12.13
Total at 31 December 2011	391,942					
Simon Lowth						
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
2010 Share Award	52,009	2861		07.05.10	07.05.13	01.01.10 - 31.12.12
Total at 1 January 2011	164,733					
Discretionary enhancement of 2008 Share Award <sup>2</sup>	14,612					
Vesting of 2008 Share Award <sup>2</sup>	(73,060)4,5		2874			
2011 Share Award	53,459	2853		28.03.11	28.03.14	01.01.11 - 31.12.13
Total at 31 December 2011	159,744		-			

<sup>&</sup>lt;sup>1</sup> UK date convention applies.

#### AstraZeneca Investment Plan

The interests of Directors at 31 December 2011 in Ordinary Shares that are the subject of Share Awards under the AZIP are not included in the Beneficial interests in Ordinary Shares table on page 125 but are shown below:

	Number of Ordinary 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 1 January 2011	21,253				
2011 Share Award	21,845	2853	28.03.11	01.01.19	01.01.11 - 31.12.14
Total at 31 December 2011	43,098				
Simon Lowth					
2010 Share Award	8,668	2861	07.05.10	01.01.18	01.01.10 - 31.12.13
Total at 1 January 2011	8,668				
2011 Share Award	8,909	2853	28.03.11	01.01.19	01.01.11 - 31.12.14
Total at 31 December 2011	17,577				

<sup>&</sup>lt;sup>1</sup> UK date convention applies.

<sup>&</sup>lt;sup>2</sup> The Remuneration Committee used its discretion to determine that Share Awards granted in 2008 should vest in 2011 at 125%, based on the outcome of the performance conditions and targets (which are set out in the Vesting of PSP awards in 2011 and 2012 section on page 116).

3 201,932 Ordinary Shares vested after the application of the 125% vesting percentage. Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 98,219.

<sup>473,060</sup> Ordinary Shares vested after the application of the 125% vesting percentage. Following certain mandatory tax deductions, Simon Lowth became beneficially interested in a net number of 35,799 Ordinary Shares <sup>5</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 123.

#### **Deferred Bonus Plan**

As described on page 117, 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 interests of Directors at 31 December 2011 in Ordinary Shares or ADSs that are the subject of awards under these arrangements are not included in the Beneficial interests in Ordinary Shares table on page 125 but are shown below:

	Number of	Award price	Price on vesting date	Grant	Vesting
	Ordinary Shares	(pence)	(pence)	date <sup>1</sup>	date <sup>1</sup>
David Brennan					
2008 award	16,810	1999		25.02.08	25.02.11
2009 award	17,992	2400		25.02.09	25.02.12
2010 award	20,718	2817.5		25.02.10	25.02.13
Total at 1 January 2011	55,520				
Vesting of 2008 award	(16,810)²,⁴		2945		
2011 award	17,725	2977		25.02.11	25.02.14
Total at 31 December 2011	56,435				
Simon Lowth					
2008 award	1,340	1999		25.02.08	25.02.11
2009 award	9,775	2400		25.02.09	25.02.12
2010 award	9,760	2817.5		25.02.10	25.02.13
Total at 1 January 2011	20,875				
Vesting of 2008 award	(1,340) <sup>3,4</sup>		2945		
2011 award	10,281	2977		25.02.11	25.02.14
Total at 31 December 2011	29,816				

<sup>&</sup>lt;sup>1</sup> UK date convention applies.

#### Share option plans

The interests of Directors who served during 2011, in options to subscribe for Ordinary Shares, granted under the SOP are included in the following table. None of the Directors in the table below holds options under the AstraZeneca Savings-Related Share Option Plan. There were no grants of options made to Directors under any of the plans in 2011.

		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 2011 – 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 2011 – options over Ordinary Shares	592,975	2375p		24.03.09	26.03.19
	- market price above option price (Ordinary Shares)	505,244	2271p		19.05.09	26.03.19
	<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 2011 – options over ADSs	322,519	\$45.35		29.03.04	23.03.15
	- market price above option price (ADSs)	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
	Exercised 18 February 2011	(29,354)	\$47.14	\$49.10	29.03.04	28.03.11
	Exercised 18 February 2011	(39,942)	\$47.73	\$49.10	29.06.04	28.06.11
	At 31 December 2011 – options over ADSs	253,223	\$44.76		28.03.05	23.03.15
	- market price above option price (ADSs)	110,987	\$40.35		24.03.08	23.03.15
	- market price at or below option price (ADSs)	142,236	\$48.21		28.03.05	25.03.14
Simon Lowth	At 1 January 2011	135,269	2074p		28.03.11	26.03.19
	- market price above option price	135,269	2074p		28.03.11	26.03.19
	- market price at or below option price	_	n/a		n/a	n/a
	Exercised 9 August 2011	(70,138)	1882p	2568p	28.03.11	27.03.18
	At 31 December 2011	65,131	2280p		27.03.12	26.03.19
	- market price above option price	65,131	2280p		27.03.12	26.03.19
	- market price at or below option price	_	n/a		n/a	n/a

<sup>&</sup>lt;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 122.

<sup>&</sup>lt;sup>2</sup> Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 8,213 Ordinary Shares

<sup>&</sup>lt;sup>3</sup> Following certain mandatory tax deductions, Simon Lowth became beneficially interested in a net number of 656 Ordinary Shares.

<sup>&</sup>lt;sup>4</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 123.

 $<sup>^{\</sup>scriptscriptstyle 2}$  Exercise prices are weighted averages.

<sup>&</sup>lt;sup>3</sup> First and last exercise dates of groups of options, within which period there may be shorter exercise periods.

<sup>&</sup>lt;sup>4</sup> UK date convention applies.

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 \$
2011	882,089	112,254
2010	260,182	11,454
2009	-	

During 2011, the market price of Ordinary Shares or ADSs was as follows:

Stock Exchange	Ordinary Share/ADS market price at 31 December 2011	Range of the Ordinary Share/ADS market price during 2011
London	2975p	2543.5p to 3194p
Stockholm	316.0 SEK	269.3 SEK to 328.5 SEK
New York	\$46.29	\$40.95 to \$52.40

On behalf of the Board

#### A C N Kemp

Company Secretary 2 February 2012

# Risk

In this section we describe our key risk management and assurance mechanisms and the principal risks and uncertainties which we consider to be material to our business as they may have a significant effect on our financial condition, results of operations and/or reputation. Specific risks and uncertainties are also discussed in the Business Review from page 29, 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 and how these are managed, based on an understanding of the potential strategic, 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 external and internal environments for new, emerging and changing risks to ensure that these are managed appropriately as they arise.

The Board believes that the processes and accountabilities which are in place (described below) provide it with adequate information on the key risks and uncertainties we face. Further information about these risks and uncertainties is set out in the Principal risks and uncertainties section from page 130.

## **Embedded in business processes**

We strive to ensure that 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. These are (i) earnings and cash flow, (ii) return on investment, and (iii) potential impact on our reputation. This definition provides a clear statement by the Board of its position on risk which enables the Group, in both quantitative and qualitative terms, to judge the level of risk it is prepared to take so as to achieve its overall objectives.

Annually, the Group develops a long-term business plan to support the delivery of its strategy which the Board reviews and confirms that it conforms to its risk appetite. Line management are accountable for identifying and managing risks, and for delivering business objectives in accordance with 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', providing a structured disaggregation of the various potential 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, which are then consolidated to create a list of key risks for that SET function to review at 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 this process.

We develop 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. These plans are supported by the provision of training and crisis simulation activities for business managers.

One of our strategic priorities is to ensure that a culture of ethics and integrity is embedded in all our business practices. Our Code of Conduct (the Code) 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 the Code, as well as more specific targeted training on particular policies and standards if required for their role. 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 the Code.

For information about how we identify and manage the risks associated with 'responsible business', see Accountabilities and responsibilities in the Responsible Business section on page 48.

#### **Key responsibilities**

#### Management of risk

Day-to-day risk management 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 managers have primary responsibility, within the context of their functional area, for identifying and managing risk as well as for putting in place appropriate controls and procedures to monitor effectiveness.

#### Oversight and monitoring

The SET is responsible for overseeing and monitoring the effectiveness of the risk management processes implemented by management. Our Global Compliance and Group Internal Audit (GIA) business functions support the SET by advising on policy and standard setting, monitoring and auditing, communication and training, as well as reporting on the adequacy of line management processes as they apply to managing our risk.

Our compliance organisation is comprised of the Global Compliance function together with a wide range of specialist compliance functions. Further information about Global Compliance and the Code can be found in the Global Compliance section on page 43.

## **Risk**

Management reporting and assurance

We provide regular quarterly risk reports to the SET and to the Board. Among other things, these summarise our current assessment of the principal risks facing the Group, including environmental, social and governance risks, senior management accountability and our expected plans in order to address these risks, to the extent possible.

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 our external auditor and the following business functions:

- > 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 our biologics capabilities help-lines.
- > 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 107.

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 annually and the findings from its audit work are reported to, and discussed at, each Audit Committee meeting. A core part of the audit work carried out by GIA includes assessing how we are managing risk and reviewing the effectiveness of selected aspects of our risk control framework, including the effectiveness of other assurance and compliance functions within the business.

#### Principal risks and uncertainties

The pharmaceutical sector is inherently risky and a variety of risks and uncertainties may affect our business. Below we describe the principal risks and uncertainties which we 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 particular 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. They relate to events that may occur in the future, that may be influenced by factors beyond our control and that 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 lengthy process involving significant financial, R&D and other resources, which may fail at any stage of the process due to a number of factors. These include: failure to obtain the required regulatory or marketing approvals for the product candidate or its manufacturing facilities; unfavourable clinical efficacy data; safety concerns; failure of R&D to develop new product candidates; and failure to demonstrate adequate cost effective benefits to regulators and the emergence of competing products.

Production and release schedules for biologics may be more significantly impacted by regulatory processes than other products. This is due to more complex and stringent regulation on the manufacturing of biologics and their supply chain.

#### **Impact**

A succession of negative drug project results and a failure to reduce development timelines effectively or produce new products that achieve commercial success could adversely affect the reputation of our R&D capabilities and is likely to materially adversely affect our financial condition and results of operations.

# Difficulties of obtaining and maintaining regulatory approvals for new products

We are subject to strict controls on the commercialisation processes for our pharmaceutical products, including in their development, manufacture, distribution and marketing. The requirements to obtain regulatory approval based on a product's safety, efficacy and quality before it can be marketed for an indication in a particular country, as well as to maintain and comply with licences and other regulations relating to its manufacture and marketing, are particularly important. The submission of an application to regulatory authorities (which vary, with different requirements, in each region or country) may or may not lead to the grant of marketing approval. 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 countries. 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.

In recent years, companies sponsoring new drug applications and regulatory authorities have been under increased public pressure to apply more conservative benefit/risk criteria. In some instances, 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.

#### **Impact**

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. In addition, the drive for public transparency of the review processes through the more extensive use of public advisory committees increases the unpredictability of the process. For example, in the US, the approval date for *Brilinta* was delayed in December 2010 by the issuance of a Complete Response Letter by the FDA requesting further data and analysis, which led to the product ultimately receiving US approval in the third quarter of 2011.

#### Failure to obtain and enforce effective IP protection

Our ability to obtain and enforce patents and other IP rights in relation to our products is an important element of our ability to protect our investment in R&D and create long-term value for the business. A number of the countries in which we operate are still developing their IP laws or may even be limiting the applicability of these laws to pharmaceutical inventions. Adverse political perspectives on the desirability of strong IP protection for pharmaceuticals in certain emerging and even developed markets may limit the scope for us to obtain effective IP protection for our products. As a result, certain countries may seek to limit or deny effective IP protection for pharmaceuticals.

#### **Impact**

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 those products. More information about protecting our IP is contained in the Intellectual Property section from page 34. Information about the risk of patent litigation and the early loss of IP rights is contained in the Expiry or loss of, or limitations on, IP rights section on page 132.

#### **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 product stocks, investment in marketing materials pre-launch, sales force training and the timing of anticipated future revenue streams from new product sales. 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 negotiations. Delays to anticipated launch dates can result from a number of factors including adverse findings in preclinical or clinical studies, regulatory demands, competitor activity and technology transfer.

#### **Impact**

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 in regulatory approvals or manufacturing difficulties may delay 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 lead to increased costs if, for example, marketing and sales efforts need to be rescheduled or protracted for longer than expected.

#### Strategic alliances and acquisitions may be unsuccessful

We seek technology licensing arrangements and strategic collaborations to expand our product If we fail to complete these types of collaborative portfolio and geographical presence as part of our business strategy.

Such licensing arrangements and strategic collaborations are key, enabling us to grow and strengthen the business. The success of such arrangements is largely dependent on the technology and other IP we acquire and the resources, efforts and skills of our partners. 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.

Furthermore, we experience strong competition from other pharmaceutical companies in respect of licensing arrangements and strategic collaborations, and therefore may be unsuccessful in establishing some of our intended projects.

We may also seek to acquire complementary businesses as part of our 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 the implementation of long-term assets. We may also experience difficulties in integrating geographically separated organisations, systems and facilities, and personnel with different organisational cultures.

#### **Impact**

If we fail to complete these types of collaborative projects in a timely manner, on a cost effective basis, or at all, this may limit our ability to access a greater portfolio of products, IP, technology and shared expertise.

Additionally, disputes or difficulties in our relationship with our collaborators or partners may arise, often due to conflicting priorities or conflicts of interest between parties, which may erode or eliminate the benefits of these alliances.

The incurrence of significant debt or liabilities as a result of integration of an acquired business could cause deterioration in our credit rating and result in increased borrowing costs and interest expense.

Further, if, following an acquisition, liabilities are uncovered in the acquired business, the Group may suffer losses and may not have remedies against the seller or third parties. The integration process may also result in business disruption, diversion of management resources, the loss of key employees, and other issues such as a failure to integrate IT and other systems.

#### 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 lost sales following patent expiry. We may ultimately be unable to achieve commercial success for any number of reasons. These include difficulties in manufacturing sufficient quantities of the product candidate for development or commercialisation in a timely manner, erosion of IP rights including infringement by third parties and failure to show a differentiated product profile.

As a result, we cannot be certain that compounds currently under development will achieve success, and our ability to accurately assess, prior to launch, the eventual efficacy or safety of a new product once in broader clinical use can only be based on data available at that time, which is inherently limited due to relatively short periods of product testing and small clinical study patient samples.

Additionally, the commercialisation of biologics is often more complex than for traditional pharmaceutical products, primarily due to differences in the mode of administration, technical aspects of the product and rapidly changing distribution and reimbursement environments.

#### **Impact**

If a new product does not succeed as anticipated or its rate of sales growth is slower than anticipated, there is a risk that we are unable to fully recoup the costs incurred in launching it, which could materially adversely affect our financial condition and results of operations.

Due to the complexity of the commercialisation process for biologics, the methods of distributing and marketing biologics could materially adversely impact our revenues from the sales of products such as *Synagis* and *FluMist/Fluenz*.

#### Illegal trade in our products

Illegal trade covers the theft, illegal diversion and counterfeiting of our products. Illegal trade in pharmaceutical products is estimated to exceed \$75 billion per year and is generally considered by the industry, NGOs and governmental authorities to be increasing. We suffer a commensurate financial exposure to illegal trade, but in many cases, due to the nature of our portfolio, this exposure has a greater impact on public health. Regulators and the public expect us to secure the integrity of our supply chain and to actively cooperate in the reduction of illegal trade in genuine AstraZeneca products, whether illegally diverted or stolen, and in counterfeited products.

#### **Impact**

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 may induce some patients to stop taking their medicines, with consequential risks to their health. There is also a direct financial loss where counterfeit medicines replace sales of genuine products and where genuine products are recalled following discovery of counterfeit, stolen and/or illegally traded products in an effort to regain control of the integrity of the supply chain. In many countries, particularly developing markets, a robust programme to tackle illegal trade is seen as part of the licence to operate.

#### **Developing our business in Emerging Markets**

The development of our business in Emerging Markets is a critical factor in determining our future ability to sustain or increase our global product revenues. This poses various challenges including: more volatile economic conditions; competition from companies with existing market presence; the need to identify correctly and to leverage appropriate opportunities for sales and marketing; poor IP protection; inadequate protection against crime (including counterfeiting, corruption and fraud); the need to impose developed market compliance standards; inadvertent breaches of local and international law; not being able to recruit appropriately skilled and experienced personnel; identification of the most effective sales channels and route to market; and interventions by national governments or regulators restricting access to market and/or introducing adverse price controls.

#### **Impact**

The failure to exploit potential opportunities appropriately in Emerging Markets may materially adversely affect our reputation, financial condition and results of operations.

#### Expiry or loss of, or limitations on, IP rights

Pharmaceutical products are only protected from being copied during the limited period of protection under patent rights and/or related IP rights such as Regulatory Data Protection or Orphan Drug status. Expiry or loss of these rights typically leads to the immediate launch of generic copies of the product in the country where the rights have expired or been lost. See the Intellectual Property section from page 34 which contains a table of certain patent expiry dates for our key marketed products.

Additionally, the expiry or loss of patents covering other innovator companies' products may also lead to increased competition for our own, still-patented, products in the same product class due to the availability of generic products in that product class.

#### **Impact**

Products under patent protection or within the period of Regulatory Data Protection typically generate significantly higher revenues than those not protected by such rights. Our revenues, financial condition and results of operations may be materially adversely affected upon expiry or early loss of our IP rights, due to generic entrants into the market for the applicable product. Additionally, the loss of patent rights covering major products of other pharmaceutical companies, such as Lipitor<sup>TM</sup> (in November), may adversely affect the growth of our still-patented products in the same product class (ie *Crestor*) in that market.

## Pressures resulting from generic competition

Our products compete not only with other products approved for the same condition, marketed by research-based pharmaceutical companies but also with generic drugs marketed by generic pharmaceutical manufacturers. These competitors may invest more of their resources into 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 as the manufacturer does not have to recoup the significant cost of R&D investment and market development. All our patented products, including *Nexium*, *Crestor* and *Seroquel* are subject to price pressures as a result of competition from generic copies of these products and from generic forms of other drugs in the same product class.

As well as facing generic competition upon expiry or loss of IP rights, we also face the risk that generic drug manufacturers seek to market generic versions of our products prior to expiries of our patents and/or the Regulatory Exclusivity periods. For example, we are currently facing challenges in the US from numerous generic drug manufacturers regarding our patents for Seroquel XR, Nexium and Crestor, three of our best selling products. Generic manufacturers may also take advantage of the failure of certain countries to properly enforce Regulatory Data Protection and may launch generics during this protected period. This is a particular risk in some Emerging Markets where appropriate patent protection may be difficult to obtain or enforce.

#### **Impact**

If challenges to our patents by generic drug manufacturers succeed and generic products are launched, or generic products are launched 'at risk' on the expectation that challenges to our IP will be successful, this may materially adversely affect our financial condition and results of operations. In 2011, US sales for Seroquel XR, Nexium and Crestor were \$779 million, \$2,397 million, and \$3,074 million respectively. Furthermore, if limitations on the availability, scope or enforceability of patent protection are implemented in jurisdictions in which we operate, generic manufacturers in these countries may be increasingly able to introduce competing products to the market earlier than they would have been able to, had more robust patent or Regulatory Data Protection been available.

#### Effects of patent litigation in respect of IP rights

Any of the IP rights protecting our products may be asserted or challenged in IP litigation initiated against or by alleged infringers. Such IP rights may be affected by validity challenges in patent offices. Regardless, 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 protecting our patents from such litigation or other challenges.

We also 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. Infringement accusations may implicate, for example, our manufacturing processes, product intermediates or use of research tools. Details of significant infringement claims against us by third parties enforcing IP rights can be found in Note 25 to the Financial Statements from page 181.

#### **Impact**

If we are not successful in maintaining exclusive rights to market one or more of our major products, particularly in the US where we achieve our highest revenue, our revenue and margins could be materially adversely affected.

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 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 patent infringement claims may relate to research tools, methods and biological materials. While we seek to manage such risks by, for example, acquiring licences, foregoing certain activities or uses, or modifying processes to avoid infringement claims and permit commercialisation of our products, such steps entail significant cost and there is no guarantee that they will be successful.

#### **Price controls and reductions**

Most of our key markets have experienced the implementation of various cost control or reimbursement mechanisms in respect of pharmaceutical products. For example, in the US, realised prices are being depressed through cost-control tools such as restricted lists and formularies, which employ 'generic first' strategies and 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 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, principally, to encourage patients to use generic medicines.

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 77 and these economic pressures are also further discussed below in the following risk factor.

#### Impact

Due to these pressures on the pricing of our products, 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 product investment. These pressures, including the increasingly restrictive reimbursement policies to which we are subject and the potential adoption of new legislation expanding the scope of permitted commercial importation of medicines into the US, could materially adversely affect our financial condition and results of operations.

We expect that these pressures on pricing will continue, and there can be no assurance that they will not increase.

#### Commercialisation and business execution risks continued

#### Economic, regulatory and political pressures

We face continued economic, regulatory and political pressures to limit or reduce the cost of our products.

In 2010, the US passed the Affordable Care Act, a comprehensive health reform package with provisions taking effect between 2010 and 2014. 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 'pay-fors'. 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 three 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 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 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.

Further information regarding these pressures is contained in the Regulatory requirements and Pricing pressure sections from page 17.

#### **Impact**

It is not possible to accurately estimate the financial impact of the potential consequences resulting from the Affordable Care Act or related legislative changes when taken together with the number of other market and industry related factors that can also result in similar impacts. While the overall reduction in our profit before tax for the year due to higher minimum Medicaid rebates on prescription drugs, discounts on branded pharmaceutical sales to Medicare Part D beneficiaries and an industrywide excise fee was \$750 million, this reflects only the limited number of known, quantifiable and isolatable effects of these legislative developments. Other potential indirect or associated consequences of these legislative developments, which continue to evolve and which cannot be estimated could have similar impacts. These include broader changes in access to, or eligibility for, coverage under Medicare, Medicaid or similar governmental programmes, such as the recent proposals to limit Medicare benefits, which could indirectly impact our pricing or sales of prescription products within the private sector.

These continued disparities in pricing systems could lead to marked price differentials between markets, which increase 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 on page 18, Germany, Spain, Portugal and Greece have all introduced a number of short-term measures to lower healthcare spending, including price cuts or increased mandatory rebates, which could have a material adverse effect on our financial condition and results of operations.

#### Commercialisation and business execution risks continued

#### **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', 'follow-on biologics' and 'follow-on protein products') that would compete with patented 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 the first quarter of 2012. In addition, the FDA and the industry have reached agreement on biosimilar user fees. In Europe, the EMA published a draft guideline on similar biological medicinal products containing MAbs. This draft guideline will likely be finalised in 2012 and is expected to include more clarification around the definition of biosimilars.

#### **Impact**

While it is uncertain when any such abbreviated approval processes may be fully adopted, particularly for more complex protein molecules such as MAbs, any such processes could materially adversely affect the future commercial prospects for patented biologics, such as the ones that we produce.

# Increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation

There is an increasing focus globally on the implementation and enforcement of anti-bribery and anti-corruption legislation. For example, the UK Bribery Act came into force in July. This act has extensive extra-territorial application, implements significant changes to existing UK anti-bribery legislation and broadens the scope of statutory offences and the potential applicable penalties, including, organisational liability for any bribe paid by persons or entities associated with 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 10 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 and non-US companies listed in the US.

We are 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.

#### **Impact**

We devote significant resources to the considerable challenge of compliance with this legislation, including in emerging and developing markets, at considerable cost. Investigations from governmental agencies require additional resources. Despite taking significant measures 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 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 materially adversely affect our financial condition and results of operations and 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 or price increases.

## Impact

If inappropriately managed, the expected value of these initiatives could be lost through low employee engagement and reduced 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, engagement, talent management, recruitment and retention), or the possibility that these efforts do not generate the level of cost savings we anticipate, could materially adversely affect our results of operations and financial condition.

#### 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.

#### **Impact**

Any significant disruption of these IT systems or failure to integrate new and existing IT systems could materially adversely affect our financial condition and results of operations.

### Failure of outsourcing

We have outsourced a number of business critical operations to third party providers. This includes certain R&D processes, IS/IT systems, human resources, finance and accounting services.

In 2011, we terminated our existing outsource relationship for IT infrastructure services and transitioned to a new multi-sourced operating model. This includes bringing critical strategic and control activities back into AstraZeneca.

### Impact

Failure of the outsource provider to deliver timely services and to the required level of quality could materially adversely affect our financial condition and results of operations and adversely impact 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.

A failure to successfully manage and effect the transfer of the provision of the IT infrastructure services in-house and to the new outsourcing providers could create disruption which could materially adversely affect our financial condition and results of operations.

#### Supply chain and delivery risks

#### **Manufacturing biologics**

Manufacturing biologics, especially in large quantities, is 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.

#### **Impact**

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

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.

Unexpected events and/or events beyond our control could result in the failure of the supply of goods. For example, suppliers of key goods we rely on may cease to trade. In addition, we may have limited 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.

#### **Impact**

Third party supply failure could materially adversely affect our financial condition and results of operations. This may lead to significant delays and/or difficulties in obtaining goods and services on commercially acceptable terms.

Loss of access to sufficient sources 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 39.

#### Legal, regulatory and compliance risks

#### Adverse outcome of litigation and/or governmental investigations

We may be subject to legal proceedings and governmental investigations. Litigation, particularly in the US, is inherently unpredictable and unexpectedly high awards for damages can result from an adverse verdict. In many cases, plaintiffs may claim compensatory, punitive and statutory damages in extremely high amounts. In particular, 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 governmental 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 which have resulted in substantial expense and other significant consequences. Note 25 to the Financial Statements from page 181 describes the material legal proceedings in which we are currently involved.

#### **Impact**

Investigations or legal proceedings, regardless of their outcome, could be costly, divert management attention, or damage our reputation and demand for our products. Unfavourable resolution of current and similar future proceedings against us could subject us to criminal liability, fines, penalties or other monetary or non-monetary remedies; require us to make significant provisions in our accounts relating to legal proceedings; and could materially adversely affect our financial condition and results of operations.

#### Substantial product liability claims

Pharmaceutical 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.

#### **Impact**

Substantial product liability claims that result in court decisions against us or in the settlement of proceedings could materially adversely affect our financial condition and results of operations, particularly where such circumstances are not covered by insurance. Further details of our Seroquel product liability litigation are set out in Note 25 to the Financial Statements from page 181.

#### Failure to adhere to applicable laws, rules and regulations

Any failure to comply with applicable laws, rules and regulations may result in civil and/or criminal legal proceedings being filed against us, or in us becoming subject to regulatory sanctions. 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 our third party contractors).

#### **Impact**

This could materially adversely affect the conduct of our business.

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 may be made at our discretion. It is possible, for example, that regulatory issues concerning compliance with current Good Manufacturing Practice or safety monitoring regulations for pharmaceutical products (often referred to as pharmacovigilance) could arise and lead to loss of product licences, product recalls and seizures, interruption of production leading to product shortages and delays in new product approvals pending resolution of the issues.

#### Legal, regulatory and compliance risks continued

#### 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 from page 181.

#### **Impact**

While we carefully manage these liabilities, if a significant non-compliance issue, environmental, occupational health or safety incident for which we are responsible were to arise, this could result in us being liable to pay compensation, fines or remediation costs. In some circumstances, such liability could materially adversely affect 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. 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, our customers may cease to trade, which may result in losses from writing off debts.

We are highly dependent on being able to access a sustainable flow of liquid funds due to the high fixed costs of operating our business and the long and uncertain development cycles of our products. In a sustained economic downturn, financial institutions with whom we deal may cease to trade and there can be no guarantee that we will be able to access monies owed to us without a protracted, expensive and uncertain process, if at all.

Our cash investments are managed centrally and more than 95% of deposits are invested directly in short-term, liquid US dollar funds and US Treasury Bills. Therefore, our major credit exposure is US sovereign default risk.

#### **Impact**

While we have adopted cash management and treasury policies to manage this risk (see Financial risk management policies section on page 93), we cannot be certain that these will be completely effective in particular in the event of a global liquidity crisis. In addition, open positions where we are owed money and deposits with financial institutions cannot be guaranteed to be recoverable. 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, for instance, be the case in the event of any default by the Group on its debt obligations, which may materially adversely affect 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 93.

#### Impact of fluctuations in exchange rates

As a global business, currency fluctuations can significantly affect our results of operations, which are reported in US dollars. Approximately 40% of our global 2011 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 have a growing exposure to emerging market currencies, where some have exchange controls in place, but for others the exchange rates are also linked to the US dollar. Major components of our cost base are located in the UK and Sweden, where an aggregate of approximately 26.7% of our employees are based.

#### **Impact**

Movements in the exchange rates used to translate foreign currencies into US dollars may materially adversely affect 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. See Note 23 to the Financial Statements from page 171.

#### Economic and financial risks continued

#### Limited third party insurance coverage

Recent insurance loss experience in our industry, including product liability exposures, has increased the cost of, and narrowed the coverage afforded by, pharmaceutical companies' product liability insurance. 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.

#### **Impact**

If such denial of coverage is ultimately upheld, this could result in material additional charges to our earnings. An example of a dispute with insurers relating to the availability of insurance coverage and in relation to which costs incurred by the Group may not ultimately be recovered through such coverage is included in Note 25 to the Financial Statements in the Seroquel product liability section on page 187.

#### **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 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.

#### **Impact**

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.

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 materially adversely affect 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 93 for tax risk management policies and Note 25 to the Financial Statements on page 189 for details of current tax disputes.

#### **Pensions**

Our pension obligations are backed by assets invested across the broad investment market. Our most significant obligations relate to the UK pension fund.

#### Impact

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 165 for further details of the Group's pension obligations.

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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 2 February 2012

#### **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 2011 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 2011, the internal control over financial reporting is effective based on those criteria.

KPMG Audit PIc, an independent registered public accounting firm, has audited the effectiveness of internal control over financial reporting as at 31 December 2011 and, as explained on page 141, 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 PIc 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 2011

(Sarbanes-Oxley Act Section 404). The Directors' statement on internal control over financial reporting is set out on page 140.

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 192.

## 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 2011 set out on pages 142 to 191. 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 that have been 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 auditor

As explained more fully in the Preparation of the Financial Statements and Directors' Responsibilities Statement set out on page 140, 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 2011 and of its profit for the year then ended.
- > Have been properly prepared in accordance with IFRSs as adopted by the EU.
- > Have been prepared in accordance with the requirements of the Companies Act 2006 and Article 4 of the IAS Regulation.

#### Separate opinion in relation to IFRSs as issued by the IASB

As explained in the Group Accounting Policies section to the Group Financial Statements set out on pages 146 to 149, the Group, in addition to complying with its legal obligation to apply IFRSs as adopted by the EU, 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:

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 146, in relation to going concern.
- > The part of the corporate governance statement on pages 103 to 112 relating to the Company's compliance with the nine provisions of the UK Corporate Governance 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 2011 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

2 February 2012

## **Financial Statements**

## **Consolidated Statement of Comprehensive Income**

for the year ended 31 December

		2011	2010	2009
D	Notes 1	\$m	\$m	\$m
Revenue	l .	33,591	33,269	32,804
Cost of sales		(6,026)	(6,389)	(5,775)
Gross profit		27,565	26,880	27,029
Distribution costs		(346)	(335)	(298)
Research and development	2	(5,523)	(5,318)	(4,409)
Selling, general and administrative costs	2	(11,161)	(10,445)	(11,332)
Profit on disposal of subsidiary	2, 22	1,483		
Other operating income and expense	2	777	712	553
Operating profit	2	12,795	11,494	11,543
Finance income	3	552	516	462
Finance expense	3	(980)	(1,033)	(1,198)
Profit before tax		12,367	10,977	10,807
Taxation	4	(2,351)	(2,896)	(3,263)
Profit for the period		10,016	8,081	7,544
Other comprehensive income:				
Foreign exchange arising on consolidation		(60)	26	388
Foreign exchange differences on borrowings forming net investment hedges		24	101	(68)
Amortisation of loss on cash flow hedge		2	1	1
Net available for sale gains taken to equity		31	4	2
Actuarial loss for the period	18	(741)	(46)	(569)
Income tax relating to components of other comprehensive income	4	198	(61)	192
Other comprehensive income for the period, net of tax		(546)	25	(54)
Total comprehensive income for the period		9,470	8,106	7,490
Profit attributable to:				
Owners of the Parent		9,983	8,053	7,521
Non-controlling interests		33	28	23
Total comprehensive income attributable to:				
Owners of the Parent		9,428	8,058	7,467
Non-controlling interests		42	48	23
Basic earnings per \$0.25 Ordinary Share	5	\$7.33	\$5.60	\$5.19
Diluted earnings per \$0.25 Ordinary Share	5	\$7.30	\$5.57	\$5.19
Weighted average number of Ordinary Shares in issue (millions)	5	1,361	1,438	1,448
Diluted weighted average number of Ordinary Shares in issue (millions)	5	1,367	1,446	1,450
Dividends declared and paid in the period	21	3.752	3,494	3,026

All activities were in respect of continuing operations.

\$m means millions of US dollars.

# **Consolidated Statement of Financial Position**

# at 31 December

		2011	2010	2009
	Notes	\$m	\$m	\$m
Assets				
Non-current assets Property, plant and equipment	7	6,425	6,957	7,307
Goodwill Goodwill	8	9,862	9,871	9,889
Intangible assets	9	10,980	12,158	12,226
Derivative financial instruments	15	342	324	262
Other investments	10	201	211	184
Deferred tax assets	4	1,514	1,475	1,292
Deletted (dx dssets		29,324	30,996	31,160
		29,324	30,990	31,100
Current assets Inventories	11	1,852	1,682	1,750
Trade and other receivables	12	8,754	7,847	7,709
Other investments	10	4.248	1.482	1,484
Derivative financial instruments	15	25	9	24
Income tax receivable	10	1,056	3,043	2,875
	10	7,571		
Cash and cash equivalents	13		11,068	9,918
Total assets		23,506	25,131	23,760
		52,830	56,127	54,920
Liabilities				
Current liabilities		// aaa)	(105)	(4.000)
Interest-bearing loans and borrowings	14	(1,990)	(125)	(1,926)
Trade and other payables	16	(8,975)	(8,661)	(8,687)
Derivative financial instruments	15	(9)	(8)	(90)
Provisions	17	(1,388)	(1,095)	(1,209)
Income tax payable		(3,390)	(6,898)	(5,728)
		(15,752)	(16,787)	(17,640)
Non-current liabilities				
Interest-bearing loans and borrowings	14	(7,338)	(9,097)	(9,137)
Deferred tax liabilities	4	(2,735)	(3,145)	(3,247)
Retirement benefit obligations	18	(2,674)	(2,472)	(3,354)
Provisions	17	(474)	(843)	(477)
Other payables	16	(385)	(373)	(244)
		(13,606)	(15,930)	(16,459)
Total liabilities		(29,358)	(32,717)	(34,099)
Net assets		23,472	23,410	20,821
Equity				
Capital and reserves attributable to equity holders of the Company				
Share capital	20	323	352	363
Share premium account		3,078	2,672	2,180
Capital redemption reserve		139	107	94
Merger reserve		433	433	433
Other reserves	19	1,379	1,377	1,392
Retained earnings	19	17,894	18,272	16,198
		23,246	23,213	20,660
Non-controlling interests		226	197	161
Total equity		23,472	23,410	20,821

The Financial Statements from page 142 to 191 were approved by the Board on 2 February 2012 and were signed on its behalf by

David R BrennanSimon LowthDirectorDirector

# **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 2009	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
Profit for the period	_	_	_	_	_	9,983	9,983	33	10,016
Other comprehensive income	_	_	_	_	_	(555)	(555)	9	(546)
Transfer to other reserves <sup>1</sup>	-	-	_	-	2	(2)	-	-	_
Transactions with owners									
Dividends	_	-	_	_	_	(3,752)	(3,752)	_	(3,752)
Issue of Ordinary Shares	3	406	_	-	-	-	409	_	409
Repurchase of Ordinary Shares	(32)	_	32	_	-	(6,015)	(6,015)	_	(6,015)
Share-based payments	-	_	_	_	-	(37)	(37)	_	(37)
Transfer from non-controlling interests to payables	-	-	_	-	-	-	-	(9)	(9)
Dividend paid by subsidiary to non-controlling interests	-	-	-	-	-	_	-	(4)	(4)
Net movement	(29)	406	32	-	2	(378)	33	29	62
At 31 December 2011	323	3,078	139	433	1,379	17,894	23,246	226	23,472

<sup>&</sup>lt;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

		2011	Restated 2010	Restated 2009
	Notes	\$m	\$m	\$m
Cash flows from operating activities				
Profit before tax		12,367	10,977	10,807
Finance income and expense	3	428	517	736
Depreciation, amortisation and impairment		2,550	2,741	2,087
(Increase)/decrease in trade and other receivables		(1,108)	10	(256
(Increase)/decrease in inventories		(256)	88	6
Increase/(decrease) in trade and other payables and provisions		467	(16)	1,579
Profit on disposal of subsidiary	22	(1,483)		-
Other non-cash movements		(597)	(463)	(200
Cash generated from operations		12,368	13,854	14,759
Interest paid		(548)	(641)	(639
Tax paid		(3,999)	(2,533)	(2,381
Net cash inflow from operating activities		7,821	10,680	11,739
Cash flows from investing activities				
Acquisitions of business operations	22	_	(348)	-
Movement in short-term investments and fixed deposits <sup>1</sup>		(2,743)	(125)	(1,339
Purchase of property, plant and equipment		(839)	(791)	(962
Disposal of property, plant and equipment		102	83	138
Purchase of intangible assets		(458)	(1,390)	(624
Disposal of intangible assets		_	210	269
Purchase of non-current asset investments		(11)	(34)	(31
Disposal of non-current asset investments		_	5	3
Net cash received on disposal of subsidiary	22	1,772	_	_
Interest received		171	174	113
Payments made by subsidiaries to non-controlling interests		(16)	(10)	(11
Net cash outflow from investing activities		(2,022)	(2,226)	(2,444
Net cash inflow before financing activities		5,799	8,454	9,295
Cash flows from financing activities				
Proceeds from issue of share capital		409	494	135
Repurchase of shares		(6,015)	(2,604)	_
Repayment of loans			(1,741)	(650
Dividends paid		(3,764)	(3,361)	(2,977
Hedge contracts relating to dividend payments <sup>1</sup>		3	(114)	(32
Movement in short-term borrowings		46	(8)	(137
Net cash outflow from financing activities		(9,321)	(7,334)	(3,661
Net (decrease)/increase in cash and cash equivalents in the period		(3,522)	1,120	5,634
Cash and cash equivalents at the beginning of the period		10,981	9,828	4,123
Exchange rate effects		(25)	33	71
Cash and cash equivalents at the end of the period	13	7,434	10.981	9.828

<sup>&</sup>lt;sup>1</sup> 2010 restated to reclassify \$114m cash paid in hedge contracts relating to dividend payments to cash flows from financing activities (2009: \$32m).

# **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 IFRSs) 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 Group adopted the revised IAS 24 'Related Party Disclosures', the amendments to IAS 32 'Classification of Rights Issues', IFRIC 14 'Prepayments of a Minimum Funding Requirement' and IFRIC 19 'Extinguishing Financial Liabilities with Equity Instruments'. The Group also applied the amendments contained in 'Improvements to IFRSs' issued in May 2010.

The adoption of the revisions, new interpretations and amendments did not have 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 193 to 197 and the accounting policies in respect of Company information are set out on page 194.

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 82. 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 2011, the Group has \$9.2bn in financial resources (cash balances of \$7.6bn and committed bank facilities of \$3.6bn, with only \$2.0bn 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 and taxation.

Further information on estimates and critical judgements made in applying accounting policies, including details of significant methods and assumptions used, is included in Notes 4, 6, 8, 9, 15, 18, 22 and 25 in the Financial Statements. Financial risk management policies are detailed in Note 23.

#### 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 2011, 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 recoverable amount (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 taxable profit 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 straightline 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

Financial assets included in 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

Financial liabilities included in 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
- > Trade receivables and trade payables.

#### 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 classified as 'available for sale', 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 on monetary available for sale investments or impairments are recognised in profit. All other changes in fair value are recognised in other comprehensive income.

Impairments are recorded in profit when there is a decline in the value of an investment that is deemed to be other than temporary. On disposal of the investment, the cumulative amount recognised in other comprehensive income is recognised in profit as part of the gain or loss on disposal.

# Bank and other borrowings

The Group uses derivatives, principally interest rate swaps, to hedge the interest rate exposure inherent in a portion of its fixed interest rate debt. In such cases the Group will either designate the debt as fair value through profit or loss when certain criteria are met or as the hedged item under a fair value hedge.

If the debt instrument is designated as fair value through profit or loss, 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 only when it is virtually certain.

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.

#### International accounting transition

On transition to using adopted IFRSs 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.

# Applicable accounting standards and interpretations issued but not yet adopted

IFRS 9 'Financial Instruments' was reissued in October 2010. 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 2015. 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.

IFRS 10 'Consolidated Financial Statements', IFRS 11 'Joint Arrangements', IFRS 12 'Disclosures of Interests in Other Entities' and IFRS 13 'Fair Value Measurement' were issued in May 2011, along with consequential amendments to IAS 27 'Separate Financial Statements' and IAS 28 'Investments in Associates and Joint Ventures'. They are all effective for accounting periods beginning on or after 1 January 2013. The new and revised standards have yet to be endorsed by the EU and are not expected to have a significant impact upon the Group's net results, net assets or disclosures.

The amendments to IFRS 7 'Disclosures – Transfer of Financial Assets', IAS 12 'Deferred Tax: Recovery of Underlying Assets', IAS 1 'Presentation of Items in Other Comprehensive Income', IAS 19 'Employee Benefits' and amendments to IAS 32 and IFRS 7 on offsetting financial assets and liabilities are effective for accounting periods beginning on or after 1 July 2011, 1 January 2012, 1 July 2012, 1 January 2013 and 1 January 2014 (IAS 32) and 1 January 2013 (IFRS 7) respectively. They are not expected to have a significant impact upon the Group's net results, net assets or disclosures. With the exception of IFRS 7 'Disclosures – Transfer of Financial Assets', these amendments have yet to be endorsed by the EU.

# **Notes to the Group Financial Statements**

# 1 Product revenue information

	2011 \$m	2010 \$m	2009 \$m
Gastrointestinal:	φιιι	φιιι	φιτι
Nexium	4,429	4,969	4,959
Losec/Prilosec	946	986	946
Others	161	133	106
Total Gastrointestinal	5,536	6,088	6,011
Cardiovascular: Crestor	6,622	5,691	4,502
Atacand	1,450	1,483	1,436
Seloken/Toprol-XL	986	1,210	1,443
Plendil	256	255	241
Onglyza™	211	69	11
Zestril	144	157	184
Others	543	538	559
Total Cardiovascular	10,212	9,403	8,376
Respiratory & Inflammation: Symbicort	3,148	2,746	2,294
Pulmicort	892	872	1,310
Rhinocort	212	227	264
Oxis	56	63	63
Others	160	191	201
Total Respiratory & Inflammation	4,468	4,099	4,132
	,,	.,000	.,
Oncology: Zoladex	1,179	1,115	1,086
Arimidex	756	1,512	1,921
Iressa	554	393	297
Casodex	550	579	844
Faslodex	546	345	262
Nolvadex	99	89	88
Others	21	12	20
Total Oncology	3,705	4,045	4,518
Neuroscience: Seroquel	5,828	5,302	4,866
Local anaesthetics	602	605	599
Zomig	413	428	434
Diprivan	294	322	290
Others	67	47	48
Total Neuroscience	7,204	6,704	6,237
Infection and Other: Synagis	975	1,038	1,082
Merrem	583	817	872
FluMist	161	174	145
Non Seasonal Flu	7	39	389
Other Products	130	108	143
Total Infection and Other	1,856	2,176	2,631
7000 111000001 01101	1,000	2,110	2,001
Astra Tech	386	535	506
Aptium Oncology	224	219	393
Total	33,591	33,269	32,804

#### 2 Operating profit

Operating profit includes the following items:

#### **Research and development**

In 2011, research and development includes a \$285m impairment charge related to the termination of development of the investigational compound olaparib and \$150m impairment charge related to the intangible assets held in relation to TC-5214 (see Note 9). In 2010, research and development included a \$445m impairment of intangible assets related specifically to motavizumab.

#### Selling, general and administrative costs

In 2011, selling, general and administrative costs includes \$135m of legal provision charges in respect of the ongoing *Seroquel* product liability litigation, Average Wholesale Price litigation in the US and the *Toprol-XL* antitrust litigation. In 2010, selling, general and administrative costs included legal provision of \$612m of which \$592m was in respect to *Seroquel* legal matters. The current status of these matters is described in Note 25. These provisions constituted our best estimate at that time of losses expected for these matters.

Also included within selling, general and administrative costs in 2010 were 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.

#### **Profit on disposal of subsidiary**

The profit on disposal of subsidiary in 2011 of \$1,483m relates to the sale of the Astra Tech business to DENTSPLY International Inc. Further details are included in Note 22.

### Other operating income and expense

	2011 \$m	2010 \$m	2009 \$m
Royalties		•	
Income	610	522	255
Amortisation	(51)	(59)	(79)
Impairment	-	(123)	(150)
Net gain on disposal of property, plant and equipment	33	66	8
Gains on disposal of product rights	-	_	170
Net (loss)/gain on disposal of other intangible assets	-	(1)	1
Gains on divestments of non-core products	_	_	216
Impairment of intangible assets relating to future licensing and contractual income	-	_	(115)
Other income	226	307	265
Other expense	(41)	_	(18)
Other operating income and expense	777	712	553

Royalty amortisation and impairment relates to income streams acquired with MedImmune.

#### **Restructuring costs**

During 2011, 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.

	2011 \$m	2010 \$m	2009 \$m
Cost of sales	54	144	188
Research and development	468	654	68
Selling, general and administrative costs	639	404	403
Total charge	1,161	1,202	659

	2011 \$m	2010 \$m	2009 \$m
Severance costs	403	505	262
Accelerated depreciation and impairment	290	299	148
Other	468	398	249
Total charge	1,161	1,202	659

Other costs are those incurred in designing and implementing the Group's various restructuring initiatives including internal project costs, external consultancy fees and staff relocation costs.

#### 3 Finance income and expense

	2011 \$m	2010 \$m	2009 \$m
Finance income Returns on fixed deposits and equity securities	9	9	20
Returns on short-term deposits	37	33	22
Expected return on post-employment defined benefit plan assets	502	451	388
Fair value gains on debt, interest rate swaps and investments	4	23	1
Net exchange gains	_	_	31
Total	552	516	462
Finance expense Interest on debt and commercial paper	(404)	(450)	(542)
Interest on overdrafts and other financing costs	(29)	(29)	(18)
Interest on post-employment defined benefit plan liabilities	(539)	(543)	(493)
Fair value charges on debt, interest rate swaps and investments	_	_	(145)
Net exchange losses	(8)	(11)	_
Total	(980)	(1,033)	(1,198)
Net finance expense	(428)	(517)	(736)

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 \$8m (2010: loss of \$11m; 2009: gain of \$31m).

#### 4 Taxation

Taxation recognised in the profit for the period in the consolidated statement of comprehensive income is as follows:

	2011 \$m	2010 \$m	2009 \$m
Current tax expense			•
Current year	2,680	3,065	2,854
Adjustment for prior years	(102)	370	251
	2,578	3,435	3,105
Deferred tax expense			
Origination and reversal of temporary differences	(141)	(369)	98
Adjustment to prior years	(86)	(170)	60
	(227)	(539)	158
Taxation recognised in the profit for the period	2,351	2,896	3,263

Taxation relating to components of other comprehensive income is as follows:

	2011 \$m	2010 \$m	2009 \$m
Current and deferred tax Foreign exchange arising on consolidation	12	(29)	16
Actuarial loss for the period	214	(18)	158
Share-based payments	21	9	17
Deferred tax impact of reduction in UK tax rate	(53)	(23)	_
Other	4	_	1
Taxation relating to components of other comprehensive income	198	(61)	192

Taxation has been provided at current rates on the profits earned for the periods covered by the Group Financial Statements. The 2011 prior period current tax adjustment relates to a benefit of \$520m arising from a number of tax settlements (including the transfer pricing and related matters described in Note 25), partially offset by an increase in provisions for other tax contingencies and tax accrual to tax return adjustments. 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 and tax accrual to tax return adjustments. The 2009 prior period current tax adjustment relates 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 2011 and 2010 prior period deferred tax adjustments relate 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 prior year deferred tax adjustment relates 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 \$9,155m at 31 December 2011 (2010: \$16,768m; 2009: \$14,846m).

#### 4 Taxation continued

#### **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 23% by 2014. In December 2011, the UK Government also released draft legislation 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.

#### Tax reconciliation to UK statutory rate

The table shown below reconciles the UK statutory tax charge to the Group's total tax charge.

	2011 \$m	2010 \$m	2009 \$m
Profit before tax	12,367	10,977	10,807
Notional taxation charge at UK corporation tax rate of 26.5% (28% for 2010, 28% for 2009)	3,277	3,074	3,026
Differences in effective overseas tax rates	(340)	(333)	(212)
Deferred tax credit relating to reduction in UK and other tax rates <sup>1</sup>	(53)	(21)	_
Unrecognised deferred tax asset	5	_	2
Items not deductible for tax purposes	71	12	156
Items not chargeable for tax purposes	(32)	(36)	(20)
Non-taxable gain arising from the Astra Tech disposal	(389)	_	_
Adjustments in respect of prior periods	(188)	200	311
Total tax charge for the year	2,351	2,896	3,263

<sup>&</sup>lt;sup>1</sup> The 2011 item relates to the reduction in the UK statutory corporation tax rate from 27% (the tax rate which was substantively enacted as effective from 1 April 2011 as at 31 December 2010) to the tax rate of 25% effective from 1 April 2012. The 2010 item relates to the reduction in the UK statutory corporation tax rate from 28% to 27% effective from 1 April 2011.

The tax rate of 19% for the year ended 31 December 2011 is lower than the UK corporation tax rate of 26.5% mainly as a result of the non-taxable gain on the Astra Tech disposal, the release of a tax provision following the settlement of a transfer pricing and related valuation matter (described in Note 25) and the difference in effective overseas tax rates as discussed below.

AstraZeneca is domiciled in the UK but operates in other countries where the tax rates and tax laws are different to those in the UK. The impact of differences in effective overseas tax rates on the Group's overall tax charge is shown above. Profits arising from our manufacturing operation in Puerto Rico are granted special status and are taxed at a reduced rate compared with the normal rate of tax in that territory under a tax incentive grant that expires in 2016.

# **Deferred tax**

The movements in the net deferred tax balance during the year are as follows:

	Property, plant and equipment \$m	Intangible assets \$m	Pension and post- retirement benefits \$m	Inter- company inventory transfers \$m	Untaxed reserves¹ \$m	Accrued expenses \$m	Share schemes \$m		Losses and tax credits carried forward <sup>4</sup> \$m	Other \$m	Total \$m
Net deferred tax balance at 1 January 2009	(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)
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)
Taxation expense	297	142	(137)	40	(36)	57	(16)	5	(129)	4	227
Other comprehensive income	_	_	159	_	_	_	(9)	_	_	4	154
Disposal of subsidiary undertaking <sup>3</sup>	9	41	(4)	(3)	_	(1)	-	_	(5)	_	37
Exchange	(3)	(1)	(6)	(8)	34	21	-	_	(4)	(2)	31
Net deferred tax balance at 31 December 2011	220	(2,384)	691	999	(1,533)	625	102	(61)	133	(13)	(1,221)

<sup>&</sup>lt;sup>1</sup> Untaxed reserves relate to taxable profits where the tax liability is deferred to later periods.

<sup>&</sup>lt;sup>2</sup> The deferred tax liability of \$143m relates to the acquisition of Novexel.

<sup>&</sup>lt;sup>3</sup> The deferred tax adjustment of \$37m relates to the Astra Tech disposal.
<sup>4</sup> Includes losses and tax credits carried forward which will expire within 15 to 20 years.

#### 4 Taxation continued

The net deferred tax balance, before the offset of balances within countries, consists of:

	Property, plant and equipment \$m	Intangible assets \$m	Pension and post- retirement benefits \$m	Inter- company inventory transfers \$m	Untaxed reserves \$m	Accrued expenses \$m	Share schemes \$m		osses and tax credits carried forward	Other \$m	Total \$m
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)
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)
Deferred tax assets at 31 December 2011	429	53	699	1,027	_	647	102	_	133	32	3,122
Deferred tax liabilities at 31 December 2011	(209)	(2,437)	(8)	(28)	(1,533)	(22)	_	(61)	_	(45)	(4,343)
Net deferred tax balance at 31 December 2011	220	(2,384)	691	999	(1,533)	625	102	(61)	133	(13)	(1,221)

Analysed in the statement of financial position, after offset of balances within countries, as:

	2011 \$m	2010 \$m	2009 \$m
Deferred tax assets	1,514	1,475	1,292
Deferred tax liabilities	(2,735)	(3,145)	(3,247)
Net deferred tax balance	(1,221)	(1,670)	(1,955)

### Unrecognised deferred tax assets

Deferred tax assets of \$169m have not been recognised in respect of deductible temporary differences (2010: \$128m; 2009: \$104m) 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

	2011	2010	2009
Profit for the financial year attributable to equity holders (\$m)	9,983	8,053	7,521
Basic earnings per Ordinary Share	\$7.33	\$5.60	\$5.19
Diluted earnings per Ordinary Share	\$7.30	\$5.57	\$5.19
Weighted average number of Ordinary Shares in issue for basic earnings (millions)	1,361	1,438	1,448
Dilutive impact of share options outstanding (millions)	6	8	2
Diluted weighted average number of Ordinary Shares in issue (millions)	1,367	1,446	1,450

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). The operation of the SET is principally driven by the management of the commercial operations, R&D, and manufacturing and supply. The SET also includes Finance, HR and Corporate Affairs, Compliance, IS 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 Group-wide impact of a new decision. For example, product launch decisions would be initially considered by the SET and, on approval, passed to an appropriate sub-team for implementation. The impacts of being able to develop, produce, deliver and commercialise a wide range of pharmaceutical products drive the SET decision making process.

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

Resources are allocated on a Group-wide basis according to need. In particular, capital expenditure, in-licensing, and R&D 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. The Group's acquisitions in the biologics area, MedImmune and Cambridge Antibody Technology Group plc (CAT), 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.

#### 6 Segment information continued

#### **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.

	2011 \$m	2010 \$m	2009 \$m	
UK	<b>4</b>	ψπ	φιιι	
External	1,980	1,952	1,809	
Intra-Group	9,901	9,957	9,056	
	11,881	11,909	10,865	
Continental Europe	343	331	353	
Belgium France	1,799	1,929	1,880	
	1,121	1,929	1,197	
Germany Italy	951	1,101	1,012	
Spain	688	762	742	
Sweden	964	1,157	1,070	
Others	2,363	2,440	2,622	
Intra-Group	5,101	5,144	4,944	
ilita-Group	13,330	13,914	13,820	
The Americas	10,000	10,011	10,020	
Canada	1,589	1,492	1,188	
US	13,745	14,010	14,994	
Others	1,452	1,387	1,113	
Intra-Group	2,819	2,341	1,962	
	19,605	19,230	19,257	
Asia, Africa & Australasia				
Australia	1,166	981	790	
Japan	2,905	2,458	2,214	
China	1,261	1,047	811	
Others	1,264	1,172	1,009	
Intra-Group	70	67	80	
	6,666	5,725	4,904	
Continuing operations	51,482	50,778	48,846	
Intra-Group eliminations	(17,891)	(17,509)	(16,042)	
	33,591	33,269	32,804	

Export sales from the UK totalled \$11,056m for the year ended 31 December 2011 (2010: \$10,944m; 2009: \$9,864m). Intra-Group pricing is determined on an arm's length basis.

		Operating profit				Profit before tax	
Profit from	2011 \$m	2010 \$m	2009 \$m	2011 \$m	2010 \$m	2009 \$m	
UK	2,221	3,258	3,124	1,803	3,098	2,813	
Continental Europe <sup>1</sup>	5,210	4,591	4,809	5,202	4,581	4,821	
The Americas	4,813	3,278	3,265	4,828	2,932	2,832	
Asia, Africa & Australasia	551	367	345	534	366	341	
Continuing operations	12,795	11,494	11,543	12,367	10,977	10,807	

		Non-current assets <sup>2</sup>				Total assets	
	2011 \$m	2010 \$m	2009 \$m	2011 \$m	2010 \$m	2009 \$m	
UK	2,941	3,397	3,810	15,752	17,171	17,092	
Continental Europe	3,785	4,470	3,966	6,811	7,596	6,706	
The Americas	20,090	20,808	21,354	26,673	28,175	28,397	
Asia, Africa & Australasia	652	522	476	3,594	3,185	2,725	
Continuing operations	27,468	29,197	29,606	52,830	56,127	54,920	

		Assets acquired <sup>3</sup>			Net	Net operating assets <sup>4</sup>	
	2011 \$m	2010 \$m	2009 \$m	2011 \$m	2010 \$m	2009 \$m	
UK	414	314	537	3,361	3,273	4,473	
Continental Europe	344	1,053	643	4,113	4,827	4,094	
The Americas	314	1,125	711	18,395	18,795	19,186	
Asia, Africa & Australasia	177	107	79	2,380	2,021	1,707	
Continuing operations	1,249	2,599	1,970	28,249	28,916	29,460	

<sup>&</sup>lt;sup>1</sup> 2011 includes profit on disposal of Astra Tech (see Note 22).

<sup>&</sup>lt;sup>2</sup> 'Non-current assets' exclude deferred tax assets and derivative financial instruments.
<sup>3</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>4 &#</sup>x27;Net operating assets' exclude short-term investments, cash, short-term borrowings, loans, retirement benefit obligations and non-operating receivables and payables.

#### 6 Segment information continued

		Property, plant and equipment	
		2010 \$m	2009 \$m
UK	1,387	1,628	1,901
Sweden	1,408	1,647	1,700
US	2,309	2,381	2,386
Rest of the world	1,321	1,301	1,320
Continuing operations	6,425	6,957	7,307

#### **Geographic markets**

The table below shows revenue in each geographic market in which customers are located.

	2011 \$m	2010 \$m	2009 \$m
UK	866	1,033	1,057
Continental Europe	8,896	9,315	9,286
The Americas	16,484	16,629	17,096
Asia, Africa & Australasia	7,345	6,292	5,365
Continuing operations	33,591	33,269	32,804

Revenue is recognised at the point of delivery, which is usually when title passes to the wholesaler. Transactions with two wholesalers (2010: two; 2009: two) individually represented greater than 10% of total revenue. The values of these transactions recorded as revenue were \$4,298m and \$4,170m (2010: \$4,164m and \$4,129m; 2009: \$4,319m and \$4,228m).

# 7 Property, plant and equipment

	Land and	Plant and	Assets in course	Total property, plant and
	buildings \$m	equipment \$m	of construction \$m	equipment \$m
Cost	<del></del>	****	****	Ψ…
At 1 January 2009	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
Capital expenditure	18	168	621	807
Transfer of assets into use	261	294	(555)	
Disposals and other movements	62	(738)	(10)	(686)
Reduction on disposal of subsidiaries	(87)	(170)	(15)	(272)
Exchange adjustments	(42)	(68)	(12)	(122)
At 31 December 2011	5,911	8,779	620	15,310
Depreciation				
At 1 January 2009	1,930	5,644	(3)	7,571
Charge for year	219	674		893
Impairment	44	6		50
Disposals and other movements	(343)	(859)	(4)	(1,206)
Exchange adjustments	117	434	2	553
At 31 December 2009	1,967	5,899	(5)	7,861
Charge for year	302	774	_	1,076
Impairment	2	20	_	22
Disposals and other movements	(29)	(396)	5	(420)
Exchange adjustments	32	55_		87
At 31 December 2010	2,274	6,352		8,626
Charge for year	271	815		1,086
Disposals and other movements	(62)	(542)		(604)
Reduction on disposal of subsidiaries	(22)	(99)	-	(121)
Exchange adjustments	(26)	(76)		(102)
At 31 December 2011	2,435	6,450		8,885
Net book value	2.222	2.22		7.00-
At 31 December 2009	3,369	2,904	1,034	7,307
At 31 December 2010	3,425	2,941	591	6,957
At 31 December 2011	3,476	2,329	620	6,425

#### 7 Property, plant and equipment continued

There were no impairment charges in 2011.

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.

	2011	2010	2009
	\$m	\$m	\$m
The net book value of land and buildings comprised: Freeholds	3,476	3,425	3,369

# 8 Goodwill

1	2011 \$m	2010 \$m	2009 \$m
Cost			
At 1 January	10,206	10,228	10,211
Exchange and other adjustments	(20)	(22)	17
At 31 December	10,186	10,206	10,228
Amortisation and impairment losses			
At 1 January	335	339	337
Exchange and other adjustments	(11)	(4)	2
At 31 December	324	335	339
Net book value at 31 December	9,862	9,871	9,889

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. 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. The methods used to determine recoverable amounts have remained consistent with the prior year.

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 2011; 7.0% for 2010; 7.6% for 2009) 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% (10% for 2010; 11% for 2009).

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 2011 (and 31 December 2010 and 31 December 2009).

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, marketing and	Other	Software development	
	distribution rights	intangibles	costs	Total
	\$m	\$m	\$m	\$m
Cost				
At 1 January 2009	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
Additions – separately acquired	189	14	239	442
Reduction on disposal of subsidiaries		(152)		(152)
Exchange and other adjustments	(94)	(9)	(4)	(107)
At 31 December 2011	15,899	2,188	1,634	19,721
Amortisation and impairment losses	0.004		0.40	4.005
At 1 January 2009	3,061	688	616 86	4,365
Amortisation for year	481	162		729
Impairment	93	273	49	415
Disposals	(67)	-		(67)
Exchange and other adjustments	159	25	768	201
At 31 December 2009	3,727	1,148		5,643
Amortisation for year	573	121	116	810
Impairment	699	131	3	833
Disposals		(1)	- (22)	(1)
Exchange and other adjustments	89	26	(20)	95
At 31 December 2010	5,088	1,425	867	7,380
Amortisation for year	652	119	140	911
Impairment	552	1		553
Reduction on disposal of subsidiaries	_	(39)		(39)
Exchange and other adjustments	(46)	(32)	14	(64)
At 31 December 2011	6,246	1,474	1,021	8,741
Net book value	10.606	1.150	444	10.006
At 31 December 2009	10,626	1,156	444	12,226
At 31 December 2010	10,716	910	532	12,158
At 31 December 2011	9,653	714	613	10,980

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 \$m	Other intangibles \$m	Software development costs \$m	Total \$m
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
Year ended 31 December 2011 Cost of sales	102	_	_	102
Selling, general and administrative costs	550	24	140	714
Other operating income and expense	-	95	_	95
	652	119	140	911

#### 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 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
Year ended 31 December 2011				
Research and development	548	1	-	549
Selling, general and administrative costs	4	-	-	4
	552	1	_	553

#### **Amortisation and impairment charges**

The 2011 impairment of product, marketing and distribution rights includes a charge of \$285m following the termination of development of the investigational compound olaparib for the maintenance treatment of serous ovarian cancer. The 2011 impairment charge of product, marketing and distribution rights also includes an impairment of \$150m reflecting a lower probability of success assessment for TC-5214, based on the results of the first two of four Phase III efficacy and tolerability studies of the compound as an adjunct therapy to an anti-depressant in patients with major depressive disorder who do not respond adequately to initial anti-depressant treatment. The value of the remaining intangible assets held in relation to TC-5214, determined using value in use calculations as detailed below, is \$50m. We are expecting results of further clinical trials in 2012 which will affect our assessment of the probability of success of TC-5214 which will result in either a reversal of all or part of the impairment recognised in 2011, or a further impairment charge. The remaining \$117m charge relates to the termination of other development projects during the year.

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 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 2011; 7.0% for 2010; 7.6% for 2009) 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% (2010: 14%; 2009: 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	149	2 and 6 years
Advance payment <sup>1</sup>	Product, marketing and distribution rights	420	7 years
Partial retirement <sup>1</sup>	Product, marketing and distribution rights	673	3-16 years
First Option <sup>1</sup>	Product, marketing and distribution rights	1,546	1-12 years
Non-refundable deposit (related to Merck & Co. Second Option) <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	304	4 and 9 years
RSV franchise assets arising from the acquisition of MedImmune	Product, marketing and distribution rights	3,895	14 years
Intangible assets arising from the acquisition of MedImmune	Licensing and contractual income	455	7-8 years
Intangible assets arising from the acquisition of MedImmune	Product, marketing and distribution rights	580	20 years
Intangible assets arising from the collaboration with BMS <sup>3</sup>	Product, marketing and distribution rights	471	11-12 years
Intangible assets arising from the acquisition of Novexel <sup>2</sup>	Product, marketing and distribution rights	294	Not amortised
Intangible assets arising from the collaboration with Pozen <sup>4</sup>	Product, marketing and distribution rights	189	12 years

<sup>&</sup>lt;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>&</sup>lt;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™ and dapagliflozin.

<sup>&</sup>lt;sup>4</sup> These assets arise from the collaboration agreement with Pozen for *Vimovo*.

#### 10 Other investments

	2011 \$m	2010 \$m	2009 \$m
Non-current investments			
Equity securities available for sale	201	211	184
	201	211	184
Current investments			
Equity securities and bonds available for sale	296	355	_
Equity securities held for trading	25	20	18
Fixed deposits	3,927	1,107	1,466
	4,248	1,482	1,484

The equity securities and bonds available for sale in current investments of \$296m (2010: \$355m; 2009: \$nil) 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 \$3m in respect of available for sale securities are included in other operating income and expense in profit (2010: \$2m; 2009: \$18m).

#### 11 Inventories

	2011 \$m	2010 \$m	2009 \$m
Raw materials and consumables	588	539	445
Inventories in process	645	665	726
Finished goods and goods for resale	619	478	579
	1,852	1,682	1,750

Inventory write-offs in the year amounted to \$51m (2010: \$69m; 2009: \$83m).

#### 12 Trade and other receivables

	2011 \$m	2010 \$m	2009 \$m
Amounts due within one year	<del></del>	ψ	ψ
Trade receivables	6,696	6,328	5,863
Less: Amounts provided for doubtful debts (Note 23)	(66)	(81)	(81)
	6,630	6,247	5,782
Other receivables	1,172	607	1,170
Prepayments and accrued income	725	733	580
	8,527	7,587	7,532
Amounts due after more than one year			
Other receivables	65	64	27
Prepayments and accrued income	162	196	150
	227	260	177
Trade and other receivables	8,754	7,847	7,709

# 13 Cash and cash equivalents

	2011 \$m	2010 \$m	2009 \$m
Cash at bank and in hand	1,488	1,750	1,077
Short-term deposits	6,083	9,318	8,841
Cash and cash equivalents	7,571	11,068	9,918
Unsecured bank overdrafts	(137)	(87)	(90)
Cash and cash equivalents in the cash flow statement	7,434	10,981	9,828

The Group's insurance subsidiaries hold cash and cash equivalents totalling \$776m (2010: \$415m; 2009: \$173m), of which \$543m (2010: \$370m; 2009: \$49m) 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	2011 \$m	2010 \$m	2009 \$m
<b>Current liabilities</b> Bank overdrafts		On demand	137	87	90
4.625% Non-callable bond	Euros	2010	-	_	1,073
5.625% Non-callable bond	Euros	2010	_	_	717
5.4% Callable bond	US dollars	2012	1,769	_	_
Other loans		Within one year	84	38	46
			1,990	125	1,926
Non-current liabilities					
5.4% Callable bond	US dollars	2012	-	1,800	1,805
5.4% Callable bond	US dollars	2014	834	837	821
5.125% Non-callable bond	Euros	2015	969	993	1,072
5.9% Callable bond	US dollars	2017	1,896	1,855	1,818
7% Guaranteed debentures	US dollars	2023	387	359	346
5.75% Non-callable bond	Pounds sterling	2031	536	535	558
6.45% Callable bond	US dollars	2037	2,716	2,718	2,717
			7,338	9,097	9,137

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 2011, 31 December 2010 and 31 December 2009.

	Non-current assets \$m	Current assets \$m	Current liabilities \$m	Total \$m
Designated in a fair value hedge	153	20	-	173
Related to instruments designated at fair value through profit or loss	189	-	-	189
Other derivatives	-	5	(9)	(4)
31 December 2011	342	25	(9)	358

	Non-current assets \$m	Current assets \$m	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	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

#### 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 2011, 31 December 2010 and 31 December 2009. None of the financial assets or financial liabilities have been reclassified during the year.

	Instruments in a fair value hedge	Instruments designated	Other financial instruments	Available	Held for	Amortised	Total carrying	Fair
	relationship <sup>1</sup> \$m	at fair value <sup>2</sup> \$m	at fair value <sup>3</sup> \$m	for sale \$m	trading \$m	cost \$m	value \$m	value \$m
	φm	<del></del> sm	-	<del> </del>		φm	— — — — — —	—
2011 Cash and cash equivalents	_	_	_	_	_	7,571	7,571	7,571
Overdrafts	<u>=</u>				<u>-</u>	(137)	(137)	(137)
Loans due within one year	(770)					(1,083)	(1,853)	(1,891)
Loans due after more than one year	(899)	(1,221)				(5,218)4	(7,338)	(8,765)
Derivative financial instruments	173	189				(5,216)	358	358
Other investments			(4)	497	25	3.927		
	<del>-</del>	-				-,-	4,449	4,449
Other financial assets				_		7,867	7,867	7,867
Other financial liabilities				_		(9,360)	(9,360)	(9,360)
2010						44.000	44.000	44.000
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)4	(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)	(90)	(90)
Loans due within one year	=	_	_	_	_	(1,836)	(1,836)	(1,867)
Loans due after more than one year	(1,629)	(1,167)	_	_	-	(6,341)4	(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)

<sup>&</sup>lt;sup>1</sup> Includes borrowings and derivatives designated as hedged items in fair value hedge relationships with respect to interest rate risk.

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.

A gain of \$4m was made during the year on the fair value of bonds designated at fair value through profit and loss, due to increased credit risk. A gain of \$44m has been made on these bonds since designation due to increased credit risk. 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 instruments designated at fair value if related to debt designated at fair value or instruments in a fair value hedge relationship if formally designated as in a fair value hedge relationship) and forward foreign exchange contracts (included in other financial instruments at fair value). 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 less than one month 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.

<sup>&</sup>lt;sup>2</sup> Includes borrowings designated at fair value through profit or loss, and related derivatives.

<sup>&</sup>lt;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).

<sup>4</sup> Includes borrowings designated as hedges of net investments in foreign operations of \$1,505m (2010: \$1,528m; 2009: \$1,630m) held at amortised cost. The fair value of these borrowings was \$1,752m at 31 December 2011 (2010: \$1,687m; 2009: \$1,747m).

#### 15 Financial instruments continued

The interest rates used to discount future cash flows for fair value adjustments, where applicable, are based on market swap curves at the reporting date, and were as follows:

	2011	2010	2009
Derivatives	0.9% to 2.3%	0.7% to 4.0%	2.0% to 4.6%
Loans and borrowings	0.9% to 2.3%	0.7% to 4.0%	2.0% 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: guoted 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	Level 2	Level 3	Total
	\$m	\$m	\$m	\$m
31 December 2011				
Equity securities and bonds available for sale	338		159	497
Equity securities held for trading	25			25
Derivative assets	_	367	_	367
Assets	363	367	159	889
Borrowing designated at fair value through profit or loss	(1,221)	-	-	(1,221)
Derivative liabilities	-	(9)	-	(9)
Liabilities	(1,221)	(9)	-	(1,230)
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. In the absence of specific market data, 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. The table above does not include bonds designated in a fair value hedge relationship. The carrying value of these bonds is initially measured at fair value and remeasured only for fair value changes in respect of the hedged risk. Therefore, the bonds are not carried at full fair value at 31 December 2011 and have not been classified within the hierarchy.

# Net gains and losses on financial assets and financial liabilities

	2011 \$m	2010 \$m	2009 \$m
Included in operating profit			
(Losses)/gains on forward foreign exchange contracts	(75)	29	114
Gains/(losses) on receivables and payables	68	(80)	(141)
Losses on available for sale current investments	(22)	(2)	(18)
	(29)	(53)	(45)
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	(6)	(5)	(169)
Interest and changes in carrying values of debt designated as hedged items, net of derivatives	(17)	(18)	(35)
Interest and fair value changes on fixed and short-term deposits and equity securities	45	61	43
Interest on debt, overdrafts and commercial paper held at amortised cost	(405)	(452)	(501)
Exchange (losses)/gains on financial assets and liabilities	(8)	(11)	31
	(391)	(425)	(631)
Included in other comprehensive income			
Foreign exchange differences on borrowings forming net investment hedges	24	101	(68)
Amortisation of loss on cash flow hedge through profit	2	1	1
Available for sale gains taken to equity	31	4	2
	57	106	(65)

#### 15 Financial instruments continued

\$10m fair value gains (2010: \$29m fair value gains; 2009: \$95m fair value losses) on interest rate fair value hedging instruments and \$9m fair value losses (2010: \$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.

\$29m fair value gains (2010: \$33m fair value gains; 2009: \$94m fair value losses) on derivatives related to debt instruments designated at fair value through profit or loss and \$26m fair value losses (2010: \$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 146. 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 (2010: \$nil; 2009: \$nil). The accounting treatment for net investment hedges is disclosed in the Group Accounting Policies section from page 146.

#### 16 Trade and other payables

	2011 \$m	2010 \$m	2009 \$m
Current liabilities	ţ	ΨΠ	ψπ
Trade payables	2,155	2,257	2,316
Value added and payroll taxes and social security	343	323	342
Rebates and chargebacks	3,285	2,839	2,618
Other payables	718	945	1,038
Accruals	2,474	2,297	2,373
	8,975	8,661	8,687
Non-current liabilities			
Other payables	385	373	244

# 17 Provisions for liabilities and charges

	Severance \$m	Environmental \$m	Employee benefits \$m	Legal \$m	Other provisions \$m	Total \$m
At 1 January 2009	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	21	7	7	49
At 31 December 2010	659	119	127	562	471	1,938
Charge for year	450	5	16	135	110	716
Cash paid	(377)	(32)	(17)	(153)	(78)	(657)
Reversals	(55)	-	_	_	(85)	(140)
Exchange and other movements	(13)	-	16	(4)	6	5
At 31 December 2011	664	92	142	540	424	1,862

	2011 \$m	2010 \$m	2009 \$m
Due within one year	1,388	1,095	1,209
Due after more than one year	474	843	477
	1,862	1,938	1,686

AstraZeneca is undergoing a global restructuring initiative which involves rationalisation of the Global Supply Chain, the Sales and Marketing Organisation, IS and business support infrastructure and R&D. 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 or 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**

96.7% of the Group's defined benefit obligations at 31 December 2011 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 short-term volatility, but it is prepared to react appropriately to more significant deviations.
- > In the event that local regulations require an additional level of financing, the Group would consider the use of alternative methods of providing this that do not require immediate cash funding but help mitigate exposure of the pension arrangement to the credit risk of the Group.

These principles are appropriate to AstraZeneca's business at the present date; should circumstances change they may require review.

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 2010.

Under the agreed funding principles for the UK, cash contributions will be paid to the UK Pension 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 UK Pension Fund. The escrow account assets will be payable to the fund in agreed circumstances, for example, in the event of AstraZeneca and the Pension Fund 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 £3,129m (\$4,832m equivalent), representing 79% of the fund's actuarially assessed liabilities (Technical Provisions). The Company has agreed to fund the shortfall by making payments of £72.5m (\$112m) a year until 31 December 2011 and then lump sum payments totalling £715m (\$1,103m) before 30 June 2013. The first of these lump sum payments of £180m (\$278m) was paid into the UK Pension Fund in December 2011 from existing investments held in escrow for the Pension Fund. A further £300m (\$463m) was paid into the UK Pension Fund during January 2012 with the balance payable by 30 June 2013. This is in addition to the contributions required to meet the ongoing benefits accruing in the region of £24m (\$37m) per annum. In 2011, £132m (\$213m) was paid into the escrow account and a further £230m (\$355m) was paid in during January 2012. At 31 December 2011, £192m (\$296m) of escrow fund assets are included within other investments (see Note 10).

Under the agreed funding principles used to set the Technical Provisions, the key assumptions as at 31 March 2010 are as follows: long-term UK price inflation set at 3.8% per annum, salary increases at 0% per annum (as a result of pensionable pay levels being frozen in 2010), pension increases at 3.55% per annum and investment returns at 5.9% per annum.

During the first half of 2010, following consultation with its UK employees' representatives, AstraZeneca introduced a freeze on 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 was recognised in comprehensive income in 2010.

#### 18 Post-retirement benefits continued

**Rest of Group** 

The IAS 19 positions as at 31 December 2011 are shown below for each of the other countries with significant defined benefit plans. These plans account for 91% of the Group's defined benefit obligations outside of the UK. 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 2011, when plan obligations were \$1,987m and plan assets were \$1,593m. 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 2011, when plan obligations were estimated to amount to \$1,545m and plan assets were \$902m.
- > The German defined benefits programme was actuarially revalued at 31 December 2011, when plan obligations amounted to \$258m and plan assets were \$23m.

On current bases, it is expected that contributions (excluding those in respect of past service cost) during the year ended 31 December 2012 to the four main countries will be \$664m.

### 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 2011, some 3,431 retired employees and covered dependants currently benefit from these provisions and some 10,694 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 2011 was \$12m (2010: \$18m; 2009: \$19m). Plan assets were \$290m and plan obligations were \$330m at 31 December 2011. 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 2011. The assumptions used by the actuaries are chosen from a range of possible actuarial assumptions which, due to the long-term nature of the schemes, may not necessarily be borne out in practice. These assumptions were as follows:

		2011		2010	
	UK	Rest of Group	UK	Rest of Group	
Inflation assumption	3.2%	2.3%	3.6%	2.3%	
Rate of increase in salaries	_1	3.4%	_1	3.4%	
Rate of increase in pensions in payment	3.1%	0.9%	3.5%	0.9%	
Discount rate	4.8%	4.1%	5.5%	4.9%	
Long-term rate of return expected at 31 December					
Equities	7.5%	7.4%	8.0%	7.9%	
Bonds	4.5%	3.8%	5.1%	5.0%	
Others	2.8%	3.8%	6.1%	4.7%	
Rate of increase in medical costs (initial rate)	10.0%	9.0%	10.0%	10.0%	

<sup>&</sup>lt;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 2011 and members expected to retire in 2031 (2010: 2010 and 2030 respectively).

	Life ex	Life expectancy assumption for a male member retiring at age				
Country	2011	2031	2010	2030		
UK	22.9	24.7	22.7	24.6		
US	20.0	21.4	19.8	21.3		
Sweden	20.4	22.4	20.4	22.4		
Germany	18.3	21.0	17.9	20.7		

#### 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 2011, 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.

			2011			2010
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Scheme assets Equities	2,221	1,084	3,305	2,437	1,153	3,590
Bonds	2,961	1,382	4,343	2,660	1,124	3,784
Others	506	365	871	52	341	393
Total fair value of scheme assets	5,688	2,831	8,519	5,149	2,618	7,767
Present value of scheme obligations	(7,042)	(4,157)	(11,199)	(6,554)	(3,691)	(10,245)
Past service cost not yet recognised	_	6	6	_	6	6
Deficit in the scheme as recognised						
in the statement of financial position	(1,354)	(1,320)	(2,674)	(1,405)	(1,067)	(2,472)

#### Fair value of scheme assets

			2011			2010
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
At beginning of year	5,149	2,618	7,767	4,853	2,402	7,255
Expected return on scheme assets	340	162	502	305	146	451
Expenses	(7)	-	(7)	(7)	_	(7)
Actuarial (losses)/gains	(4)	35	31	244	(4)	240
Exchange	_	(38)	(38)	(204)	(4)	(208)
Employer contributions	487	246	733	224	245	469
Participant contributions	9	3	12	28	3	31
Benefits paid	(286)	(195)	(481)	(294)	(170)	(464)
Scheme assets' fair value at end of year	5,688	2,831	8,519	5,149	2,618	7,767

The actual return on the plan assets was a gain of \$533m (2010: gain of \$691m).

# Movement in post-retirement scheme obligations

	2011					2010
-	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	(6,554)	(3,691)	(10,245)	(7,055)	(3,591)	(10,646)
Current service cost	(49)	(110)	(159)	(97)	(114)	(211)
Past service (cost)/credit	(32)	(37)	(69)	(39)	106	67
Participant contributions	(9)	(3)	(12)	(28)	(3)	(31)
Benefits paid	286	195	481	294	170	464
Other finance expense	(364)	(175)	(539)	(371)	(172)	(543)
Expenses	7	_	7	7	_	7
Actuarial (loss)/gain	(328)	(444)	(772)	(221)	(65)	(286)
Settlements and curtailments	_	53	53	693	6	699
Exchange	1	55	56	263	(28)	235
Present value of obligations in scheme at end of year	(7,042)	(4,157)	(11,199)	(6,554)	(3,691)	(10,245)

The obligation arises from the following plans:

			2011			2010
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Funded	(7,016)	(3,689)	(10,705)	(6,526)	(3,232)	(9,758)
Unfunded	(26)	(468)	(494)	(28)	(459)	(487)
Total	(7,042)	(4,157)	(11,199)	(6,554)	(3,691)	(10,245)

#### 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 2011, are set out below:

			2011			2010
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Operating profit						
Current service cost	(49)	(110)	(159)	(97)	(114)	(211)
Past service (cost)/credit	(32)	(37)	(69)	(39)	75	36
Settlements and curtailments	-	53	53	693	6	699
Total charge to operating profit	(81)	(94)	(175)	557	(33)	524
Finance expense						
Expected return on post-retirement scheme assets	340	162	502	305	146	451
Interest on post-retirement scheme obligations	(364)	(175)	(539)	(371)	(172)	(543)
Net return	(24)	(13)	(37)	(66)	(26)	(92)
Charge before taxation	(105)	(107)	(212)	491	(59)	432
Other comprehensive income Difference between the actual return and the expected						
return on the post-retirement scheme assets	(4)	35	31	244	(4)	240
Experience (losses)/gains arising on the post-retirement						
scheme obligations	(11)	(10)	(21)	(81)	5	(76)
Changes in assumptions underlying the present value						
of the post-retirement scheme obligations	(317)	(434)	(751)	(140)	(70)	(210)
Actuarial (losses)/gains recognised	(332)	(409)	(741)	23	(69)	(46)

Included in total assets and obligations for the UK is \$388m in respect of members' defined contribution sections of the scheme. Group costs in respect of defined contribution schemes during the year were \$262m (2010: \$228m). During 2011, the Group disposed of Astra Tech (see Note 22) resulting in a curtailment gain of \$44m.

#### **Actuarial gains and losses**

	2011	2010	2009	2008	2007
UK					
Present value of obligations (\$m)	(7,042)	(6,554)	(7,055)	(5,029)	(7,644)
Fair value of scheme assets (\$m)	5,688	5,149	4,853	3,835	6,310
Deficit in the scheme (\$m)	(1,354)	(1,405)	(2,202)	(1,194)	(1,334)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	(4)	244	293	(1,185)	(185)
Percentage of scheme assets	0.1%	4.7%	6.0%	30.9%	2.9%
Scheme obligations					
Amount (\$m)	(328)	(221)	(1,218)	972	114
Percentage of scheme obligations	4.7%	3.4%	17.3%	19.3%	1.5%
Rest of Group					
Present value of obligations (\$m)	(4,157)	(3,691)	(3,591)	(3,591)	(3,348)
Fair value of scheme assets (\$m)	2,831	2,618	2,402	2,013	2,644
Deficit in the scheme (\$m)	(1,326)	(1,073)	(1,189)	(1,578)	(704)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	35	(4)	180	(700)	(24)
Percentage of scheme assets	1.2%	0.2%	7.5%	34.8%	0.9%
Scheme obligations					
Amount (\$m)	(444)	(65)	176	(319)	(18)
Percentage of scheme obligations	10.7%	1.8%	4.9%	8.9%	0.5%
Total					
Present value of obligations (\$m)	(11,199)	(10,245)	(10,646)	(8,620)	(10,992)
Fair value of scheme assets (\$m)	8,519	7,767	7,255	5,848	8,954
Deficit in the scheme (\$m)	(2,680)	(2,478)	(3,391)	(2,772)	(2,038)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	31	240	473	(1,885)	(209)
Percentage of scheme assets	0.4%	3.1%	6.5%	32.2%	2.3%
Scheme obligations					
Amount (\$m)	(772)	(286)	(1,042)	653	96
Percentage of scheme obligations	6.9%	2.8%	9.8%	7.6%	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 \$10m and the amount outstanding at 31 December 2011 was \$1m.

#### Reserves

Included within the retained earnings reserve are accumulated actuarial gains and losses, and related deferred tax balances. Movements on this balance are as follows:

	2011 \$m	2010 \$m	2009 \$m
At 1 January	(1,865)	(1,800)	(1,371)
Actuarial losses	(741)	(46)	(569)
Deferred tax	159	(19)	140
At 31 December	(2,447)	(1,865)	(1,800)

The cumulative amount of actuarial losses before deferred tax recognised in other comprehensive income is \$3,223m (2010: \$2,482m; 2009: \$2,436m).

#### **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.

		2011		2010
	+1%	-1%	+1%	-1%
UK (\$m)	934	(1,088)	937	(1,093)
US (\$m)	229	(262)	203	(232)
Sweden (\$m)	299	(374)	222	(293)
Germany (\$m)	41	(49)	37	(44)
Total (\$m)	1,503	(1,773)	1,399	(1,662)

#### Sensitivity of medical cost assumptions

	Effect of change in medical cost assumption increase/(decrease			
	2011			2010
	+1%	-1%	+1%	-1%
Current service and interest cost of net periodic post-employment medical costs (\$m)	1	(1)	4	(3)
Accumulated post-employment benefit obligation for medical costs (\$m)	10	(10)	10	(11)

# 19 Reserves

#### **Retained earnings**

The cumulative amount of goodwill written off directly to reserves resulting from acquisitions, net of disposals, amounted to \$680m (2010: \$682m; 2009: \$667m) using year end rates of exchange. At 31 December 2011, 36,177 shares, at a cost of \$2m, have been deducted from retained earnings (2010: 57,717 shares, at a cost of \$3m; 2009: 24,178 shares, at a cost of \$1m).

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).

	2011 \$m	2010 \$m	2009 \$m
Cumulative translation differences included within retained earnings Balance at beginning of year	1,798	1,656	1,323
Foreign exchange arising on consolidation	(60)	26	388
Exchange adjustments on goodwill (recorded against other reserves)	(2)	15	13
Foreign exchange differences on borrowings forming net investment hedges	24	101	(68)
Net exchange movement in retained earnings	(38)	142	333
Balance at end of year	1,760	1,798	1,656

# Other reserves

The other reserves arose from the cancellation of  $\mathfrak{L}1,255$ m 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.

#### 20 Share capital of the Company

		Allotted, called-u	up and fully paid
	2011 \$m	2010 \$m	2009 \$m
Issued Ordinary Shares (\$0.25 each)	323	352	363
Redeemable Preference Shares (£1 each – £50,000)	-	_	_
	323	352	363

At 31 December 2011, 1,292,355,052 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 (m)
	2011	2010
At 1 January	1,409	1,451
Issues of shares	11	12
Repurchase of shares	(128)	(54)
At 31 December	1,292	1,409

#### **Share repurchases**

During the year, the Company repurchased 128m Ordinary Shares at an average price of 2932 pence per share (2010: 54m Ordinary Shares at an average price of 3111 pence per share; 2009: nil). These shares were subsequently cancelled.

#### Share schemes

A total of 11m Ordinary Shares were issued during the year in respect of share schemes (2010: 12m Ordinary Shares; 2009: 3m 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 113.

#### Shares held by subsidiaries

No shares in the Company were held by subsidiaries in any year.

#### 21 Dividends to shareholders

	2011 Per share	2010 Per share	2009 Per share	2011 \$m	2010 \$m	2009 \$m
Final	\$1.85	\$1.71	\$1.50	2,594	2,484	2,171
Interim	\$0.85	\$0.70	\$0.59	1,158	1,010	855
	\$2.70	\$2.41	\$2.09	3,752	3,494	3,026

The second interim dividend, to be confirmed as final, is \$1.95 per Ordinary Share and \$2,520m in total. This will be payable on 19 March 2012.

On payment of the dividends, exchange gains of \$3m (2010: gains of \$19m; 2009: gains of \$17m) arose. These exchange gains are included in Note 3.

#### 22 Acquisitions and disposals of business operations

# 2011 disposals

Astra Tech

On 31 August 2011, the Group completed the sale of the Astra Tech business to DENTSPLY International Inc. On the loss of control, the Group derecognised the assets and liabilities of the subsidiary. The surplus arising on the loss of control is recognised in profit. Astra Tech's results were consolidated for the period until disposal and contributed \$386m (2010: \$535m; 2009: \$506m) in revenue and \$16m (2010: \$55m; 2009: \$50m) in profit after tax.

	\$m
Non-current assets	281
Current assets	193
Current liabilities	(104)
Non-current liabilities	(91)
Net book value of assets disposed	279
Fees and other disposal costs	59
Exchange recycled on disposal	(26)
Profit on disposal	1,483
	1,795
Less: Cash held in disposed undertaking	(23)
Net cash consideration	1,772

The gain on disposal of Astra Tech is non-taxable.

#### 22 Acquisitions and disposals of business operations continued

#### 2010 acquisitions

Novexel

On 3 March 2010, AstraZeneca completed the acquisition of Novexel. 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 100% of Novexel's shares for an upfront consideration of \$427m; with additional consideration of up to \$75m becoming 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 the ten-month period post-acquisition to the end of 2010 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

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 on acquisition:

	\$m
Total upfront consideration	427
Cash and cash equivalents included in undertaking acquired	(79)
Net cash consideration	348

In 2011, the contingent consideration of \$50m became fully payable. The fair value of the remaining contingent consideration arising on the Novexel acquisition is nil.

#### 2009 acquisitions

There were no acquisitions or disposals made during the year ended 31 December 2009.

# 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.

#### 23 Financial risk management objectives and policies continued

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 and profit on disposal of Astra Tech). 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 decreased from \$3,653m at the beginning of the year to a net funds position of \$2,849m at 31 December 2011 as a result of our substantial share repurchases in 2011, tax and pension payments made, offset by strong net operating cash inflows and cash received on the disposal of Astra Tech.

#### 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.

In addition to cash and cash equivalents of \$7,571m, fixed deposits of \$3,927m less overdrafts of \$137m at 31 December 2011, the Group has committed bank facilities of \$3.6bn available to manage liquidity. At 31 December 2011, the Group has issued \$1,505m under a Euro Medium Term Note programme and \$7,602m 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 of \$3.6bn mature in October 2012 and were undrawn at 31 December 2011.

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 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	226	2,267	8,975	11,468	(117)	-	(117)	11,351
In one to two years	-	422	385	807	(84)	-	(84)	723
In two to three years	-	1,152	_	1,152	(67)	-	(67)	1,085
In three to four years	-	1,352	_	1,352	(49)	-	(49)	1,303
In four to five years	-	332	_	332	(49)	-	(49)	283
In more than five years	-	9,764	_	9,764	(137)	-	(137)	9,627
	226	15,289	9,360	24,875	(503)	-	(503)	24,372
Effect of interest	(5)	(6,490)	_	(6,495)	503	-	503	(5,992)
Effect of discounting, fair values and issue costs	-	308	_	308	(362)	-	(362)	(54)
31 December 2011	221	9,107	9,360	18,688	(362)		(362)	(18,326)

	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	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

#### 23 Financial risk management objectives and policies continued

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 Medlmmune has been held at fixed rates of interest. The Group uses interest rate swaps and forward rate agreements to manage this mix.

At 31 December 2011, 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 2011 or 2010. At 31 December 2011 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 146.

The majority of surplus cash is currently invested in US Treasury liquidity funds and direct purchases of US Treasury bills earning floating rates of interest. A portion of US Treasury bills have a maturity of greater than 3 months at inception for improved yield.

The interest rate profile of the Group's interest-bearing financial instruments, as at 31 December 2011, 31 December 2010 and 31 December 2009 is set out below. In the case of current and non-current financial liabilities, the classification includes the impact of interest rate swaps which convert the debt to floating rate.

	20		2011			2010			2009
	Total \$m	Fixed rate \$m	Floating rate \$m	Total \$m	Fixed rate \$m	Floating rate \$m	Total \$m	Fixed rate \$m	Floating rate \$m
Financial liabilities Interest-bearing loans and borrowings									
Current	1,990	999	991	125	-	125	1,926	1,790	136
Non-current	7,338	5,215	2,123	9,097	6,242	2,855	9,137	6,340	2,797
	9,328	6,214	3,114	9,222	6,242	2,980	11,063	8,130	2,933
Financial assets Fixed deposits	3,927	_	3,927	1,107	_	1,107	1,466	_	1,466
Cash and cash equivalents	7,571	_	7,571	11,068	_	11,068	9,918	_	9,918
	11,498	_	11,498	12,175	_	12,175	11,384	_	11,384

In addition to the financial assets above, there are \$8,747m (2010: \$7,829m; 2009: \$7,376m) 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 60% of Group external sales in 2011 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 including the principal currencies of Swedish krona (SEK), pounds sterling (GBP), euro (EUR), Australian dollar (AUD), Canadian dollar (CAD), Japanese yen (JPY), Romanian leu (RON) and Russian ruble (RUB). 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 2011, 5.7% of interest-bearing loans and borrowings were denominated in pounds sterling and 10.4% 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 2011, 31 December 2010 and 31 December 2009 along with the underlying gross exposure as defined above.

	GBP \$m	SEK \$m	EUR \$m	AUD \$m	JPY \$m	CAD \$m	RON \$m	RUB \$m
2011	фП	фП	фП	фП	фП	фП	φιιι	фПП
Gross exposure	(1,097)	(785)	588	109	212	102	112	230
Forward exchange contracts	1,097	785	(588)	(109)	(212)	(102)	(112)	(230)
Net exposure	_	_	_	-	_	-	_	_
2010	,							
Gross exposure	732	(806)	478	117	133	33	82	129
Forward exchange contracts	(38)	806	(478)	(117)	(133)	(33)	(83)	(129)
Net exposure	694 <sup>1</sup>	_	_	-	_	_	(1)	_
2009	,							
Gross exposure	(124)	(811)	556	75	197	43	53	91
Forward exchange contracts	124	811	(556)	(75)	(197)	(43)	(53)	(91)
Net exposure	_	_	-	-	_	_	_	_

<sup>&</sup>lt;sup>1</sup> The sterling hedge position as at 31 December 2010 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 2011, with all other variables held constant. Based on the composition of our long-term debt portfolio as at 31 December 2011, a 1% increase in interest rates would result in an additional \$31m 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 2011, 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 and each 1% change in interest rates would have approximately the same effect as the 1% detailed in the table below.

### 31 December 2011

		Interest rates		Exchange rates
	+1%	-1%	+10%	-10%
Increase/(decrease) in fair value of financial instruments (\$m)	654	(777)	(15)	15
Impact on profit: gain/(loss) (\$m)	-	-	(190)	190
Impact on equity: gain/(loss) (\$m)	-	-	175	(175)

#### 31 December 2010

		Interest rates	Exchange rates	
	+1%	-1%	+10%	-10%
Increase/(decrease) in fair value of financial instruments (\$m)	595	(684)	36	(36)
Impact on profit: gain/(loss) (\$m)	_	_	(133)	133
Impact on equity: gain/(loss) (\$m)		_	169	(169)

#### 31 December 2009

		Interest rates		Exchange rates
	+1%	-1%	+10%	-10%
Increase/(decrease) in fair value of financial instruments (\$m)	602	(709)	137	(137)
Impact on profit: gain/(loss) (\$m)	_	_	(134)	134
Impact on equity: gain/(loss) (\$m)	_	_	271	(271)

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.

In the US, sales to three wholesalers accounted for approximately 75% of US sales (2010: three wholesalers accounted for approximately 73%; 2009: three wholesalers accounted for approximately 81%).

The ageing of trade receivables at the reporting date was:

	2011 \$m	2010 \$m	2009 \$m
Not past due	6,249	5,953	5,542
Overdue but renegotiated	-	_	_
Past due 0-90 days	177	104	65
Past due 90-180 days	82	67	75
Past due > 180 days	122	123	100
	6.630	6.247	5.782

	2011 \$m	2010 \$m	2009 \$m
Movements in provisions for trade receivables Balance at beginning of year	81	81	99
Income statement credit	(10)	(1)	(20)
Amounts utilised, exchange and other movements	(5)	1	2
Balance at end of year	66	81	81

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 treasury liquidity funds, US Treasury bills and short-term bank deposits.

The most significant concentration of financial credit risk at 31 December 2011 was \$5,844m invested in three US AAA-rated Treasury funds and \$4,015m 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 15% 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 2011 was \$21m.

#### 24 Employee costs and share 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.

	2011	2010	2009
Employees			
UK	8,700	10,100	10,600
Continental Europe	19,200	20,100	21,200
The Americas	18,000	18,300	19,800
Asia, Africa & Australasia	13,900	13,200	12,300
Continuing operations	59,800	61,700	63,900

Geographical distribution described in the table above is by location of legal entity employing staff. Certain staff will spend some or all of their activity in a different location.

The number of people employed by the Group at the end of 2011 was 57,200 (2010: 61,100; 2009: 62,700).

The costs incurred during the year in respect of these employees were:

	2011 \$m	2010 \$m	2009 \$m
Salaries	4,631	4,837	4,713
Social security costs	783	693	644
Pension costs	490	501 <sup>1</sup>	516
Other employment costs	496	408	560
	6,400	6,439	6,433

<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 \$431m are not included above (2010: \$531m; 2009: \$285m).

The Directors believe that, together with the basic salary system, the Group's employee incentive schemes provide competitive and market-related 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 2011 will be paid in cash, as they were in 2010. 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 was 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.

#### Sweder

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 Performance Share Plan and the AstraZeneca Global Restricted Stock Plan all operate in respect of relevant AstraZeneca employees in Sweden.

#### 24 Employee costs and share plans for employees continued

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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 70 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 charge for share-based payments in respect of share plans is \$153m (2010: \$120m; 2009: \$81m). The plans are equity settled.

#### 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 2011 under the plan was in March, with a further smaller grant in August. 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 2011, except employees of Medlmmune, 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 Medlmmune. 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 120 in the Directors' Remuneration Report.

	Shares '000	WAFV <sup>1</sup> pence	WAFV¹ \$
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
Shares awarded in March 2011	2,964	1427	23.09
Shares awarded in August 2011	127	1421	23.33

<sup>&</sup>lt;sup>1</sup> Weighted average fair value.

#### The AstraZeneca Investment Plan

This plan was introduced in 2010 and approved by shareholders at the 2010 AGM. The main grant of awards in 2011 under the plan was in March, 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 2011, 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 120 of the Directors' Remuneration Report.

	Shares '000	WAFV pence	WAFV \$
Shares awarded in May 2010	76	2575	38.66
Shares awarded in August 2010	15	2904	N/A
Shares awarded in March 2011	95	2853	46.18
Shares awarded in August 2011	3	2841	N/A

#### 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 2011 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.

	Shares '000	WAFV pence	WAFV \$
Shares awarded in March 2010	2,672	2989	44.75
Shares awarded in August 2010	8	3227	49.89
Shares awarded in March 2011	2,706	2853	46.18
Shares awarded in August 2011	54	2841	46.65

#### 24 Employee costs and share plans for employees continued

The AstraZeneca Restricted Share Plan

This plan was introduced in 2008 and provides for the grant of restricted share awards to key employees, excluding Executive Directors. Awards are made on an *ad hoc* basis with variable vesting dates. The plan has been used seven times in 2011 to make awards to 26 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.

	Shares '000	WAFV pence	WAFV \$
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
Shares awarded in January 2011	2	2955	N/A
Shares awarded in February 2011	136	3030	48.55
Shares awarded in March 2011	29	N/A	46.37
Shares awarded in May 2011	14	3052	50.45
Shares awarded in July 2011	21	3026	N/A
Shares awarded in August 2011	27	2841	46.65
Shares awarded in November 2011	10	N/A	49.02

#### 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. All awards of performance shares to US employees in 2010 and 2011 were made under the AstraZeneca Performance Share Plan described above.

	Shares '000	WAFV \$
Shares awarded in March 2009	2,288	16.70
Shares awarded in August 2009	6	23.18

#### 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. This plan was replaced in 2010 by the Global Restricted Stock Plan described above.

	Units '000	WAFV \$
Units awarded in March 2009	1,283	33.39

### The MedImmune, 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 Medlmmune. This plan was used in conjunction with the AstraZeneca Share Option Plan to provide a mix of RSUs and share options. This plan was replaced in 2010 by the Global Restricted Stock Plan described above.

	Units '000	WAFV \$
Units awarded in March 2009	177	33.39

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 grant date fair values of share awards disclosed in this section do not take account of service and non-market related performance conditions.

### **Share option plans**

The charge for share-based payments in respect of share options is \$37m (2010: \$53m; 2009: \$105m) which is comprised entirely of equity-settled transactions. At 31 December 2011, there were options outstanding under the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca Share Option Plan.

#### 24 Employee costs and share plans for employees continued

#### (1) 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.

#### (2) 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 2011, and no further grants will be made. 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.

#### 24 Employee costs and share 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.

		SAYE Schemes	AstraZeneca S	Share Option Plan		1994 Scheme
_	Options	WAEP <sup>1</sup>	Options	WAEP <sup>1</sup>	Options	WAEP <sup>1</sup>
	'000	pence	'000	pence	'000	pence
At 1 January 2009	2.140	2304	52,568	2978	1.285	2934
Options outstanding	2,140	2304	52,508	2976	1,200	2934
Movements during 2009	351	2563	15,246	2281		
Options granted Options exercised	(286)	2258	(2,275)	2213	(317)	2670
Options exercised Options forfeited	(169)	2340		2604	. , ,	2688
Weighted average fair value of options granted during the year	(109)	425	(3,141)	423	(51)	2000
		425		423		
At 31 December 2009	0.000	00.40	00.000	2004	047	0704
Options outstanding	2,036	2349	62,398	2601	917	2734
Movements during 2010	070	0007				
Options granted	276	2907	- (10.11)		(705)	
Options exercised	(455)	2216	(10,144)	2538	(765)	2714
Options forfeited	(183)	2559	(3,189)	2470	(152)	2714
Weighted average fair value of options granted during the year		267				
At 31 December 2010						
Options outstanding	1,674	2455	49,065	2439		
Movements during 2011						
Options granted	397	2551				
Options exercised	(268)	2372	(10,408)	2125	-	
Options forfeited	(116)	2627	(3,435)	2933	_	
Weighted average fair value of options granted during the year		245		-		_
At 31 December 2011						
Options outstanding	1,687	2479	35,222	2484		
		2164		1882		
Range of exercise prices		to 3001		to 3487		
Weighted average remaining contractual life		743 days		1,887 days		
Options exercisable	80	2794	23,556	2598		

<sup>&</sup>lt;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.

	2011	2010	2009
Average share price (pence)	2963	3058	2651
Weighted average exercise price (pence)			
AstraZeneca Share Option Plan	-	_	2281
SAYE Schemes	2551	2907	2563
Expected volatility (%)	20.0	20.0	25.0
Dividend yield (%)	6.0	5.5	4.0
Risk-free interest rate (%)	3.6	2.5	3.7
Expected lives: AstraZeneca Share Option Plan (years)	-	_	6.0
Expected lives: SAYE Schemes (years)	4.5	4.2	4.2

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.

#### 25 Commitments and contingent liabilities

	2011 \$m	2010 \$m	2009 \$m
Commitments			
Contracts placed for future capital expenditure on property, plant and equipment and software development costs not			
provided for in these accounts	190	259	368

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	Years 5 and greater \$m
Future potential research and development milestone payments	2,929	322	596	640	1,371
Future potential revenue milestone payments	3,496	2	28	92	3,374

The table includes all potential payments for achievement of milestones under ongoing research and development arrangements. Revenue-related 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 2011 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 130, 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'). Contingent payments in respect of Prilosec and Nexium will continue until the Second Option is exercised and consummated (as discussed under Second Option below). If AstraZeneca exercises the Second Option in 2012, contingent payments in respect of Prilosec and Nexium will cease in late 2012 or in early 2013, depending on when AstraZeneca consummates the Second Option. If AstraZeneca does not exercise the Second Option in 2012, contingent payments in respect of *Prilosec* and *Nexium* will continue until at least 2017. Contingent payments in respect of the authorised generic version of felodipine will continue until AstraZeneca's third party distribution arrangement ends, currently expected to occur in June 2012. Contingent payments on the other agreement products ceased in 2010 when AstraZeneca consummated the First Option (as discussed under First Option below).

The annual contingent payments on agreement products are expensed as incurred.

#### **Termination arrangements**

The Agreements provided for arrangements and payments under which, subject to the exercise of certain options, the rights and interests in AstraZeneca's activities and products held by Merck immediately prior to the merger would be terminated, including details of:

- > the Advance Payment
- > the Partial Retirement
- > the True-Up
- > the Loan Note Receivable
- > the First Option
- > the Second Option.

#### 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 payment and the Advance Payment (at its undiscounted amount of \$2.8bn). This True-Up amount was settled in an amount equal to \$241m paid 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 exercised 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 then still in development (principally Brilinta and lesogaberan). On 30 April 2010, contingent payments on these products (except for the authorised generic version of felodipine) ceased with respect to periods after this date and AstraZeneca obtained the ability to exploit these products and other opportunities in the Cardiovascular and Neuroscience therapy areas. (Contingent payments on the authorised generic version of felodipine will continue until AstraZeneca's third party distribution arrangement ends, which is currently expected to occur in June 2012.) As detailed in Note 9, the intangible asset relating to lesogaberan 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 purchase Merck's interests in the Merck affiliates that hold the limited partner and other rights referred to above. Exercise of the Second Option would result in the repurchase by AstraZeneca of Merck's interests in Prilosec and Nexium in the US. This option is exercisable by AstraZeneca in May to October of 2012, or in 2017, or if combined annual sales of the two products fall below a minimum amount. If AstraZeneca exercises the Second Option, consummation of the transaction will occur five to six months later. 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 sum of 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% of future US sales of *Vimovo*, with the precise amount dependent on the level of annual sales and the timing of the option exercise, as well as 13 times Merck's average annual 1% profit allocation in the Partnership for the prior three years. 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, *Prilosec*, *Nexium*, *Brilinta*, *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 payment of \$4.271bn less the True-Up amount 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 makes 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 \$50m 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 page 182). Together with the \$1,656m nonrefundable 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 \$40m 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 \$100m 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 in the third quarter of 2010, an impairment of \$128m was recognised. As noted earlier, AstraZeneca has the ability to exercise the Second Option in 2012, 2017 or if combined annual sales of *Prilosec* and *Nexium* fall below a minimum amount. If we do not exercise the Second Option in 2012, this will trigger an impairment review of the non-refundable deposits of \$474m associated with the Second Option. In addition, if it becomes probable that the Second Option will not be exercised, the non-refundable deposits for the product rights available 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 2009, 2010 or 2011

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, 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 29 sites where SMC is likely to incur US Environmental Consequences. AstraZeneca has also given indemnities to third parties for a number of sites outside the US. These environmental liabilities arise from legacy operations that are not currently part of the Group's 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 2011 in the aggregate of \$92m (2010: \$119m; 2009: \$112m), mainly relating to the US. 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, we estimate the potential additional loss for future environmental investigation, remediation, remedial operation and maintenance activity above and beyond our provisions to be, in aggregate, between \$50m to \$90m (2010: \$20m to \$40m; 2009: \$10m to \$25m) which relates solely to the US.

#### 25 Commitments and contingent liabilities continued Legal proceedings

AstraZeneca is involved in various legal proceedings considered typical to its 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 IP rights, the validity of certain patents and competition 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 in this section. We also do not believe that disclosure of the amount sought by plaintiffs, if 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.

While 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 the future incur judgments or insurance settlements that could have a material adverse effect on our results in any particular period.

IP 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 product sales, which could have a material adverse effect on our results. The lawsuits filed by AstraZeneca for patent infringement 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 also involve allegations of non-infringement, invalidity and unenforceability of these patents by the ANDA filers. In the event that the Group is unsuccessful in these actions or the statutory 30-month stay expires before a ruling is obtained, the ANDA filers 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 IP.

Over the course of the past several years, including in 2011, a significant number of commercial litigation claims in which AstraZeneca is involved have been resolved, particularly in the US, thereby reducing potential contingent liability exposure arising from such litigation. Similarly, in part due to patent litigation and settlement developments, greater certainty has been achieved regarding possible generic entry dates with respect to some of our patented products. At the same time, like other companies in the pharmaceutical sector and other industries, AstraZeneca continues to be subject to government investigations around the world.

#### **Patent Litigation**

Arimidex (anastrozole)

#### Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Canada and Russia regarding patent and/or regulatory exclusivity for *Arimidex*.

#### Atacand (candesartan cilexetil)

#### Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Portugal and Canada regarding patent and/or regulatory exclusivity for *Atacand*.

# Atacand Plus (candesartan cilexetil/hydrochlorothiazide) Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Portugal and Canada regarding patent and/or regulatory exclusivity for *Atacand Plus*.

In July 2011, an *Atacand Plus* patent (European patent no. 753301) was revoked by a Technical Board of Appeal at the European Patent Office (EPO).

In Canada, in 2011, AstraZeneca settled notice of compliance proceedings with Pharmascience Inc., Teva Canada Limited and Sandoz Canada, Inc., allowing those companies to enter the Canadian market on 23 September 2012, or earlier, in certain circumstances.

### Crestor (rosuvastatin calcium)

#### US patent litigation/regulatory proceedings

Several defendants appealed the 2010 decision in the US District Court for the District of Delaware finding in favour of AstraZeneca that the substance patent covering the active ingredient in *Crestor* tablets is valid, enforceable and infringed. The parties await the decision of the US Court of Appeals for the Federal Circuit (the Federal Circuit).

AstraZeneca is also engaged in patent litigation in the US District Court for the District of Delaware in which it contends that a §505(b)(2) NDA for rosuvastatin zinc tablets infringes the substance patent and other patents for *Crestor* tablets. The Court has scheduled a trial in this litigation to begin on 24 September 2012.

#### 25 Commitments and contingent liabilities continued

AstraZeneca appealed the 2010 dismissal by the US District Court for the District of Delaware of patent infringement actions brought by AstraZeneca against numerous generic drug manufacturers regarding two method-of-use patents covering *Crestor*. The parties await the decision of the Federal Circuit.

In November 2011, AstraZeneca filed a Citizen Petition with the FDA in respect of *Crestor* requesting the FDA to withhold approval of any generic rosuvastatin drug product that omits from its labelling the diabetes-related warning and adverse reaction information which AstraZeneca was required to include in *Crestor*'s labelling when the FDA approved *Crestor*'s primary prevention of cardiovascular disease indication. The FDA is required to issue a decision by 12 May 2012.

AstraZeneca is also defending a patent infringement lawsuit filed in April 2011 in the US District Court for the District of South Carolina by Palmetto Pharmaceuticals, LLC (Palmetto), which, among other claims, asserts that AstraZeneca's *Crestor* sales induce infringement of a Palmetto patent.

In December 2011, the Federal Circuit affirmed the summary judgment of the US District Court for the Eastern District of Pennsylvania invalidating a Teva Pharmaceutical Industries LTD (Teva LTD) formulation patent, which Teva LTD had alleged was infringed by sales of *Crestor*.

#### Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Australia, Brazil, Canada, Mexico, Portugal and Singapore regarding patent and/or regulatory exclusivity for *Crestor*. Generic drug manufacturers have commenced sales of generic rosuvastatin drug products in Brazil and Mexico.

In Canada, in January 2012, the Federal Court of Canada held a hearing in the patent proceeding involving Pharmascience Inc. The parties await the Court's decision. In 2011, AstraZeneca reached settlements with Mylan Pharmaceuticals Inc. and Ranbaxy Pharmaceuticals Canada Inc. resolving the litigation regarding AstraZeneca's *Crestor* substance patent; and, as part of the agreements, those companies may enter the Canadian market on 2 April 2012, or earlier, in certain circumstances.

In Australia, in November 2011, AstraZeneca was informed that Apotex Pty Ltd. (Apotex) intended to start commercialising its generic rosuvastatin product. AstraZeneca sought and was granted a preliminary injunction. Apotex's motion to vacate the injunction was heard on 31 January 2012. A decision is pending. In January 2012, AstraZeneca instituted proceedings against Watson Pharm Pty Ltd. (Watson) and Actavis Australia Pty Ltd. (Actavis) asserting infringement of various formulation and method patents for *Crestor*. AstraZeneca has applied for interlocutory relief against both Watson and Actavis, pending resolution of the infringement actions. Sandoz has agreed to an undertaking to refrain from launching a product pending decisions on the Apotex, Watson and Actavis injunctions.

#### Entocort EC (budesonide)

#### US patent litigation

AstraZeneca has appealed the 2011 US District Court for the District of Delaware's decision which found that Mylan Pharmaceuticals, Inc.'s generic budesonide product did not infringe AstraZeneca's patent.

#### Losec/Prilosec (omeprazole)

#### US patent litigation

AstraZeneca continues litigation to recover infringement damages against Andrx Pharmaceuticals, Inc., and Apotex Corp. and Apotex Inc.

#### Patent litigation outside the US

In Canada, the AstraZeneca patent infringement proceeding against Apotex Inc. regarding omeprazole capsules and tablets remains pending. Similarly, Apotex Inc's action seeking section 8 damages against AstraZeneca is also pending. The hearing of the damages action is scheduled to begin in March 2012.

## Nexium (esomeprazole magnesium)

#### US patent litigation

In May 2011 and January 2012, AstraZeneca entered into agreements, respectively, with each of Sandoz Inc. (Sandoz) and Lupin Limited (Lupin) settling AstraZeneca's patent infringement actions against those entities. As part of those settlements, Sandoz and Lupin were granted licences to enter the US market with generic esomeprazole magnesium on 27 May 2014, subject to regulatory approval, or earlier, in certain circumstances. As previously disclosed, in 2008, AstraZeneca entered into a settlement agreement with Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited (together Ranbaxy) to settle the Ranbaxy ANDA patent litigation respecting *Nexium*. The settlement agreement allows Ranbaxy to commence sales of a generic version of *Nexium* under a licence from AstraZeneca on 27 May 2014.

In January 2012, AstraZeneca received a Paragraph IV Certification notice letter from Mylan Laboratories Limited (Mylan) stating that it had submitted an ANDA for approval to market esomeprazole magnesium capsules. Mylan alleges non-infringement and/or invalidity of three patents listed in the Orange Book in reference to *Nexium*. AstraZeneca is evaluating Mylan's notice.

In December 2011, AstraZeneca received a Paragraph IV Certification notice letter from Torrent Pharmaceuticals Ltd. (Torrent) stating that it had submitted an ANDA for approval to market esomeprazole magnesium capsules. Torrent alleges non-infringement and/or invalidity of 11 patents listed in the Orange Book in reference to *Nexium*. In January 2012, AstraZeneca commenced a patent infringement action against Torrent in the US District Court for the District of New Jersey.

In June 2011, AstraZeneca received a Paragraph IV Certification notice letter from Hetero Drugs, Ltd. Unit III and Hetero USA Inc. (together, Hetero) stating that it had submitted an ANDA for approval to market esomeprazole magnesium capsules. Hetero alleges non-infringement and/or invalidity of 11 patents listed in the Orange Book in reference to *Nexium*. In July 2011, AstraZeneca commenced a patent infringement action against Hetero in the US District Court for the District of New Jersey.

In February 2011, AstraZeneca also commenced a patent infringement action in the US District Court for the District of New Jersey against Hanmi USA Inc. *et al.* in response to the filing of an NDA under §505(b)(2) for FDA approval to market 20mg and 40mg esomeprazole strontium capsules. The defendant alleges non-infringement or invalidity of 11 patents listed in the Orange Book with reference to *Nexium*.

#### Patent/regulatory proceedings outside the US

AstraZeneca is involved in proceedings in several countries outside the US regarding patent and/or regulatory exclusivity for *Nexium*, including Australia, Austria, Belgium, Brazil, Canada, China, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Mexico, the Netherlands, Norway, Philippines, Poland, Portugal, Singapore, Slovenia, Sweden, Turkey, Ukraine and the UK. There is generic entry in many European markets. Outside of Europe, Canada is the only major market with generic entry.

In the European Patent Office (EPO), in June and July 2011, the Opposition Division of the EPO revoked EP 1020461 (the '461 patent) (which relates to *Nexium*) and EP 1020460 (which relates to *Nexium i.v.*). AstraZeneca has appealed these decisions.

AstraZeneca initiated infringement proceedings against Consilient Health Limited and Krka, d.d., Novo Mesto in September 2010 in the UK. These companies 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. In July 2011, the injunction was lifted at the request of AstraZeneca. In December 2011, the parties agreed to settle the infringement case but AstraZeneca's undertaking regarding liability remains in effect.

#### 25 Commitments and contingent liabilities continued

In July 2011, the UK High Court held that Ranbaxy (UK) Ltd's generic esomeprazole product does not infringe the *Nexium* esomeprazole magnesium patent (the '461 patent).

In the Netherlands, in July 2011, the District Court of the Hague upheld the validity of the *Nexium* esomeprazole magnesium patent (the '461 patent). This decision has been appealed.

In Finland, the District Court of Helsinki found the *Nexium* esomeprazole enantiomer patent (FI 117755) invalid in December 2011.

In Norway, in March 2011, the Appeal Court upheld the validity of the *Nexium*-related substance patent (NO 307378) and invalidated the *Nexium*-related formulation patent (NO 314125).

#### Nexium i.v. (esomeprazole sodium)

#### US patent litigation

In October 2011, AstraZeneca entered into an agreement with Sun Pharma Global FZE and affiliates (together Sun) to settle the ongoing patent infringement suit against Sun in the US District Court for the District of New Jersey with respect to Sun's ANDA for esomeprazole sodium intravenous formulation. As part of the settlement agreement, AstraZeneca granted Sun a licence to enter the US market with its generic esomeprazole sodium intravenous formulation on 1 January 2014, subject to regulatory approval, or earlier in certain circumstances.

# Pulmicort Respules (budesonide inhalation suspension) US patent litigation

AstraZeneca's consolidated patent infringement lawsuits against various generic companies for infringement of US patents directed to methods of use and the form of active ingredient for *Pulmicort Respules* proceed in the US District Court for the District of New Jersey. The 2010 preliminary injunction against generic defendants, Apotex Inc. and Apotex Corp., remains in place. As previously disclosed, in 2008, AstraZeneca resolved patent litigation with Teva respecting its generic copies of *Pulmicort Respules*, thereby allowing Teva to begin marketing its generic product in December 2009.

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

#### Seroquel (quetiapine fumarate)

#### US regulatory proceedings

In September 2011, AstraZeneca filed a Citizen Petition with the FDA in respect of *Seroquel* requesting the FDA withhold approval of any generic quetiapine drug product which omits from its labelling certain hyperglycemia and suicidality warning language that the FDA required AstraZeneca to include in the *Seroquel* labelling. The FDA is required to issue a decision by 7 March 2012.

#### Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Portugal regarding Seroquel related patents and/or regulatory exclusivity for Seroquel.

#### Seroquel XR (quetiapine fumarate)

#### US patent litigation/regulatory proceedings

AstraZeneca's several patent infringement actions proceeded in the US District Court for the District of New Jersey against various generic drug manufacturers who have filed ANDAs seeking approval to market generic copies of *Seroquel XR* tablets prior to the expiration of AstraZeneca's product patent covering *Seroquel XR*.

In May 2011, the US District Court for the District of New Jersey entered a consent order dismissing the pending patent infringement case against Biovail Laboratories International SRL.

In September 2011, AstraZeneca settled its patent infringement action against Handa Pharmaceuticals, LLC (Handa) by granting Handa a licence to the *Seroquel XR* product patent, effective 1 November 2016, or earlier under certain circumstances.

Also, in September 2011, AstraZeneca filed a Citizen Petition with the FDA in respect of *Seroquel XR* requesting the FDA to withhold approval of any generic quetiapine drug product which omits from its labelling certain hyperglycemia and suicidality warning language that the FDA required AstraZeneca to include in the *Seroquel XR* labelling. The FDA is required to issue a decision by 7 March 2012.

In October 2011, AstraZeneca settled its patent infringement action against Intas Pharmaceutical Ltd. and Accord Healthcare Inc. (collectively, Accord) by granting Accord a licence to the Seroquel XR product patent, effective 1 November 2016, or earlier under certain circumstances.

In October 2011, the US District Court for the District of New Jersey conducted a trial in the patent infringement actions involving the product patent against four of the five remaining defendant generic drug manufacturers. A decision on claims of infringement and invalidity of AstraZeneca's product patent is pending.

#### Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Canada, the Czech Republic, Germany, Hungary, the Netherlands, Portugal, Romania, Spain, Turkey and the UK regarding *Seroquel XR* related patents and/or regulatory exclusivity for *Seroquel XR*. Trials are scheduled in the first quarter of 2012 in the Netherlands, Spain and the UK.

#### Synagis (palivizumab)

#### US patent litigation

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 *Synagis* and/or motavizumab, and that no further royalties are owed under a patent licence MedImmune and PDL signed in 1997. The matter was settled in February 2011. This resulted in the recognition of \$131m credit to operating profit in 2011.

#### Symbicort (budesonide/formoterol)

#### US patent litigation

In December 2011, a complaint alleging patent infringement was filed against AstraZeneca in the US District Court for the Eastern District of Texas by Accuhale LLC (Accuhale). Accuhale is purportedly the owner of US patent no. 5,718,355, which Accuhale alleges is infringed by sales of *Symbicort*. AstraZeneca is evaluating the complaint.

#### Patent litigation outside the US

AstraZeneca is engaged in proceedings related to the validity and/or infringement of AstraZeneca's patents covering *Symbicort* in Turkey.

# Vimovo (fixed dose combination of naproxen and esomeprazole)

#### US patent litigation

In 2011, AstraZeneca and Pozen commenced patent infringement actions in the US District Court for the District of New Jersey against three ANDA challengers seeking approval to market generic copies of *Vimovo* prior to expiry of seven patents listed in the Orange Book including the patent in-licensed from Pozen.

#### 25 Commitments and contingent liabilities continued Zestril (lisinopril)

#### Patent/regulatory proceedings outside the US

As previously disclosed, 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 Canada against Apotex, Inc. (Apotex), alleging infringement of Merck Group's lisinopril patent. In 2010, after having established Apotex's liability, AstraZeneca and the Merck Group initiated proceedings to recover damages. That damages matter proceeded in 2011.

#### Zomig (zolmitriptan)

#### Patent/regulatory proceedings outside the US

AstraZeneca is engaged in proceedings in Canada and Portugal regarding patent and/or regulatory exclusivity for *Zomig*.

#### **Product Liability Litigation**

#### 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 Japanese patients. In November 2011, the Tokyo High Court reversed the Tokyo District Court's decision and ruled that neither AstraZeneca, nor the Japanese Ministry of Health, Labour and Welfare, had any liability for the *Iressa* product liability claims filed in the Tokyo District Court. The plaintiffs have appealed the Tokyo High Court decision to the Japanese Supreme Court.

AstraZeneca is awaiting a ruling from the Osaka High Court on AstraZeneca's appeal of the February 2011 Osaka District Court decision, which ordered AstraZeneca to pay approximately \$670,000, plus interest.

#### Nexium (esomeprazole magnesium)

Since April 2011, AstraZeneca has been named as a defendant in product liability lawsuits brought by plaintiffs alleging bone deterioration, loss of bone density and/or bone fractures caused by *Nexium* and/or *Prilosec* in the US. Currently, there are five served cases involving 101 plaintiffs.

#### Seroquel (quetiapine fumarate)

With regard to Seroquel product liability litigation in the US, which primarily relates to diabetes and/or other related injuries, as of 31 January 2012, AstraZeneca was aware of approximately 25 claims that have not been settled in principle. As of 31 January 2012, pursuant to court-ordered mediation, AstraZeneca has reached agreements in principle on monetary terms, subject to various subsequent conditions, approvals and agreement on non-monetary terms, with the attorneys representing 28,575 claimants. The mediation process is ongoing with regard to other currently unsettled claims.

In Canada, four putative class actions remain pending in the provinces of British Columbia, Alberta, Ontario and Quebec, alleging that AstraZeneca failed to provide adequate warnings in connection with an alleged association between *Seroquel* and the onset of diabetes. AstraZeneca is awaiting an appellate ruling on the dismissal of the Quebec action. A decision on class certification in the Ontario action is pending.

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.

With regard to insurance coverage for the substantial legal defence costs and settlements that have been incurred in connection with the *Seroquel* product liability claims (which now exceed the total amount of insurance coverage available), disputes continue with insurers about the availability of coverage under insurance policies. These policies have aggregate coverage limits of \$300m. No insurance receivable can be recognised under applicable accounting standards at this time.

#### **Commercial Litigation**

#### Nexium (esomeprazole magnesium)

Of the various putative class actions in the US alleging that AstraZeneca's promotion, advertising and pricing of *Nexium* to physicians, consumers and third party payers was unfair, unlawful and deceptive, only two cases remain pending. In the Massachusetts State Court case, a bench trial has been set to commence on 9 October 2012. The Delaware State Court case has been stayed since May 2005.

#### Seroquel (quetiapine fumarate)

Of the various state laws actions generally alleging that AstraZeneca made false and/or misleading statements in marketing and promoting *Seroquel*, AstraZeneca remains in litigation with the Attorneys General of Montana, New Mexico, South Carolina, Utah and Mississippi. In 2011, AstraZeneca reached settlement agreements in principle with the Attorneys General of the states of Arkansas and Alaska, and provisions have been taken.

In March 2011, the Eleventh Circuit Court of Appeals affirmed the November 2008 dismissal of a putative nationwide third party payer class action lawsuit which alleged that AstraZeneca promoted *Seroquel* for off-label uses and as superior to lower-cost alternative medicines. No further appeals were taken.

#### Synagis (palivizumab)

In September 2011, AstraZeneca's biologics unit, MedImmune, filed a declaratory judgment action against Abbott International, LLC (Abbott) in the Circuit Court for Montgomery County, Maryland seeking a declaratory judgment related to a contract dispute between the parties as to when the transfer price of *Synagis* would revert to a lower amount (the Reversion Event). Abbott moved to dismiss the action and MedImmune filed its opposition. A hearing on the motions has been set for 9 February 2012.

In September 2011, Abbott filed a parallel action in the Illinois State Court for breach of contract and for a declaratory judgment regarding the Reversion Event. Medlmmune filed a motion to dismiss the action and Abbott filed a motion seeking to deposit the 'disputed funds' in escrow. Both Medlmmune's motion to dismiss and Abbott's motion for escrow were heard on 19 January 2012. A ruling on those motions is expected by mid-February 2012.

#### Toprol-XL (metoprolol succinate)

AstraZeneca is defending against anti-trust claims in the US regarding the listing and enforcement of patents protecting *Toprol-XL*, brought by both direct purchasers and end-payers. In 2011, AstraZeneca paid \$35.75m in aggregate in connection with agreements to settle the claims of the putative class of direct purchasers and those plaintiffs who have opted-out of that class. A provision has been taken. AstraZeneca continues to defend against the remaining claims alleged by end-payers.

#### Other Commercial Litigation

### Verus Pharmaceuticals litigation

In June 2011, the US Court of Appeals for the Second Circuit affirmed the trial court's dismissal of Verus Pharmaceuticals Inc.'s lawsuit, which had alleged breaches of several related collaboration agreements to develop novel paediatric asthma treatments.

## 25 Commitments and contingent liabilities continued

#### Average Wholesale Price litigation

Of the various lawsuits against AstraZeneca and other pharmaceutical manufacturers involving allegations that, by causing the publication of allegedly inflated wholesale list prices, defendants caused entities to overpay for prescription drugs, AstraZeneca remains in litigation with the Attorneys General of the states of Kentucky, Louisiana, Oklahoma, Utah and Wisconsin. In 2011, AstraZeneca settled the cases brought by the Attorneys General of the states of Alaska, Idaho, Illinois, Kansas and Mississippi, and those settlement amounts have been paid. A provision has been taken.

AstraZeneca is currently pursuing an appeal before the Commonwealth of Kentucky Court of Appeals, seeking to reverse the judgment against it in the case brought by the Attorney General of Kentucky and the corresponding award of damages and penalties. Following the underlying 2009 trial, a Kentucky jury found AstraZeneca liable under the Commonwealth of Kentucky's Consumer Protection and Medicaid Fraud statutes and awarded \$14.72m in compensatory damages and \$100 in punitive damages. The trial court subsequently awarded an additional \$5.4m in statutory penalties. No provision has been recognised.

#### Medco qui tam litigation (Schumann)

AstraZeneca has been named as a defendant in a lawsuit filed in Federal Court in Philadelphia under the *qui tam* (whistleblower) provisions of the federal and certain state False Claims Acts alleging overpayments by federal and state governments resulting from alleged improper payments intended to influence the formulary status of *Prilosec* and *Nexium* to Medco and its customers. 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 US government's decision not to intervene in the case. AstraZeneca's motion to dismiss for lack of jurisdiction remains pending.

#### Average Manufacturer's Price qui tam litigation (Streck)

AstraZeneca is one of several manufacturers named as a defendant in a lawsuit filed in the US Federal Court in Philadelphia under the *qui tam* (whistleblower) provisions of the federal and certain state False Claims Acts alleging inaccurate reporting of Average Manufacturer's Prices to the Centers for Medicaid and Medicare Services. The action was initially filed in October 2008 but remained under seal until May 2011, following the US government's decision not to intervene in the case with regard to certain manufacturers, including AstraZeneca. In December 2011, the manufacturer defendants filed a joint motion to dismiss the complaint.

#### 340B Class Action litigation

In March 2011, the US Supreme Court reversed a decision of the US Court of Appeals for the Ninth Circuit and held that covered entities under the 340B programme do not have enforceable rights to sue as third party beneficiaries of the Pharmaceutical Pricing Agreement. The putative class action suit filed by the County of Santa Clara on behalf of similarly situated California counties and cities was thereby dismissed.

#### Drug importation and 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 March 2011, the Superior Court of California granted the defendants' motion for summary judgment. In April 2011, the plaintiffs appealed.

#### 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 sales specialists employed by the Group in California. 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 Code. The US District Court for the Central District of California granted summary judgment in favour of AstraZeneca. The plaintiff has filed a Notice of Appeal with the Ninth Circuit Court of Appeals in California. The case is currently stayed.

In November 2010, a separate group of plaintiffs' counsel filed a nationwide collective action in the US District Court for the Southern District of Indiana against AstraZeneca, alleging violations of federal wage-and-hour law for non-payment of overtime wages. The plaintiff voluntarily dismissed the case with prejudice in March 2011.

In January 2011, a third group of plaintiffs' attorneys filed a separate nationwide collective action against AstraZeneca, alleging that AstraZeneca violated federal wage-and-hour law by failing to pay overtime compensation to pharmaceutical sales representatives across the country. The court has stayed the case pending a decision from the US Supreme Court in Christopher v. Smithkline Beecham Corp., Case No. 11-204, which is addressing similar issues in the pharmaceutical sales context.

#### Government investigations/proceedings

Except as otherwise noted, the precise parameters of the following 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.

#### Losec/Prilosec (omeprazole) European Commission case

AstraZeneca is awaiting a ruling on the cross-appeals from the General Court of the EU's judgment regarding the European Commission's 2005 Decision fining AstraZeneca €60m (reduced to €52.5m by the General Court) for abuse of a dominant position regarding omeprazole. An oral hearing took place on 12 January 2012.

# Nexium (esomeprazole magnesium) European Commission investigation

The European Commission investigation into alleged practices regarding *Nexium* and alleged breaches of EU competition laws, which commenced in November 2010, remains pending.

#### **Dutch Competition Authority investigation**

The Dutch National Competition Authority (NMa) investigation into alleged practices regarding *Nexium* and alleged breaches of both Dutch and EU competition laws is ongoing. In December 2011, the investigation team issued a report alleging foreclosure of generic versions of certain proton pump inhibitors. The file has now been passed to the Legal Department of the NMa.

#### US FTC Civil Investigative Demand

AstraZeneca has completed its response to the 2008 Civil Investigative Demand from the US Federal Trade Commission seeking information regarding the *Nexium* patent litigation settlement with Ranbaxy Laboratories Ltd.

#### Department of Justice/Attorney General of Texas investigation

AstraZeneca has received a subpoena from the Department of Justice and a Civil Investigative Demand issued by the Attorney General of Texas in connection with an investigation of the possible submission of false or otherwise improper pricing information for certain formulations of *Nexium* to the Centers for Medicare and Medicaid Services (CMS).

#### Other government investigations/proceedings 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 cooperating with these inquiries. AstraZeneca is investigating indications of inappropriate conduct in certain countries, including China.

## **25 Commitments and contingent liabilities** continued Serbia

In August 2011, AstraZeneca UK Limited's Representative Office in Belgrade, Serbia was served with a criminal indictment alleging that local employees of AstraZeneca and several other pharmaceutical companies who are also named defendants in the indictment, made allegedly improper payments to physicians at the Institute of Oncology and Radiology of Serbia. AstraZeneca filed a number of preliminary procedural objections asking the Serbian criminal court to dismiss the indictment against the Representative Office and those objections were granted in November 2011. The Serbian prosecutor then amended and re-served the indictment and, in December 2011, AstraZeneca asked the Court again to dismiss the indictment.

#### Korea

In September 2011, the Korean Fair Trade Commission (KFTC) announced administrative fines against AstraZeneca and five other pharmaceutical companies as a result of the third and final wave of its investigation into alleged unfair trade practices related to interactions between the local pharmaceutical industry and Korean healthcare providers. AstraZeneca was fined KRW 1,512m (\$1.24m), but was not referred to the public prosecutor for criminal proceedings. The KFTC's final investigation report was provided to AstraZeneca in November 2011 and alleges that AstraZeneca induced prescriptions through improper marketing to physicians in 2006 and 2007, yet recognises that such alleged unfair conduct stopped in 2007 after AstraZeneca voluntarily implemented an improved and effective compliance programme across its business.

# Other US Attorney's Offices and/or State Attorneys' General investigations

The US Attorney's Offices in Alabama, Delaware and Texas are conducting investigations related to sales and marketing activities potentially involving more than one product, including *Crestor* and *Seroquel XR*, in response to the filing of *qui tam* (whistleblower) lawsuits.

The US Attorney's Office for the District of Delaware, Criminal Division, is conducting an investigation relating to AstraZeneca's relationship with Medco and sales of *Nexium*, *Plendil*, *Toprol-XL* and *Prilosec*.

In November 2006, AstraZeneca was notified of an inquiry by the US Attorney's Office for the Eastern District of Pennsylvania regarding whether a payment made by AstraZeneca to Advance PCS was taken into account when calculating best price. In December 2011, the matter was resolved in principle with CMS and the Department of Justice.

In June 2011, MedImmune received a demand from the US Attorney's Office for the Southern District of New York requesting certain documents related to the sales and marketing activities of *Synagis*. In July 2011, MedImmune received a similar court order to produce documents from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit. MedImmune is coordinating with the Government offices to provide the appropriate responses and cooperate with any related investigation.

#### 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. As accruals can be built up over a long period of time but the ultimate resolution of tax exposures usually occurs at a point in time and given the inherent uncertainties in assessing the outcomes of these exposures (which sometimes can be binary in nature), we could in future periods experience adjustments to these accruals that have a material positive or negative effect on our results in any particular period.

Transfer pricing and other international tax contingencies. The total net accrual included in the Group Financial Statements to cover the worldwide exposure to transfer pricing audits is \$649m, a reduction of \$1,661m compared to 2010 primarily due to the agreement announced in March 2011, referred to below.

In March 2011, AstraZeneca announced that HM Revenue & Customs in the UK and the US Internal Revenue Service agreed the terms of an Advance Pricing Agreement regarding transfer pricing arrangements for AstraZeneca's US business for the period from 2002 to the end of 2014, and a related valuation matter arising on integration of the legacy Astra and legacy Zeneca US businesses in 2000 following the global AstraZeneca merger in 1999. Based on these agreements, AstraZeneca paid a net amount of \$1,133m during 2011 to resolve all US transfer pricing and related valuation matters for all periods from 2000 to the end of 2010 and this net amount reflects expected US tax payments and updated estimates of corresponding tax refunds in other jurisdictions. As a consequence of this agreement, AstraZeneca released a portion of the provision related to these matters resulting in a benefit to earnings in the year of \$520m.

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.

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 \$375m (2010: \$565m); 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 \$1,672m relating to a number of other tax contingencies, an increase of \$243m 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 material 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 \$291m (2010: \$608m). Interest is accrued as a tax expense.

#### 26 Leases

Total rentals charged to profit were as follows:

	2011	2010	2009
	\$m	\$m	\$m
Operating leases	215	212	198

The future minimum lease payments under operating leases that have initial or remaining terms in excess of one year at 31 December 2011 were as follows:

<u> </u>	2011 \$m	2010 \$m	2009 \$m
Obligations under leases comprise: Not later than one year	92	161	132
Rentals due after more than one year:			
Later than one year and not later than five years	178	242	208
Later than five years	122	103	131
	300	345	339
	392	506	471

#### 27 Statutory and other information

	2011 \$m	2010 \$m	2009 \$m
Fees payable to KPMG Audit Plc and its associates:			
Group audit fee	2.4	2.3	2.4
Fees payable to KPMG Audit Plc and its associates for other services:			
The audit of subsidiaries pursuant to legislation	5.5	6.5	6.6
Other services pursuant to legislation	2.4	3.3	2.9
Taxation	0.9	1.1	1.0
All other services	2.5	0.1	0.7
Fees payable to KPMG Audit Plc in respect of the Group's pension schemes:			
The audit of subsidiaries' pension schemes	0.6	0.6	0.5
	14.3	13.9	14.1

Other services pursuant to legislation include fees of \$1.9m (2010: \$2.4m; 2009: \$2.3m) 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 third party royalty agreements, an audit in connection with the disposal of Astra Tech, and advisory services supporting management in their development of competency and development frameworks for staff, and in their outsourcing arrangements for the provision of IT infrastructure.

#### **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.

	2011 \$000	2010 \$000	2009 \$000
Short-term employee benefits	19,973	21,925	20,784
Post-employment benefits	2,155	1,793	2,080
Termination benefits	-	-	3,639
Share-based payments	16,064	11,563	12,547
	38,192	35,281	39,050

Total remuneration is included within employee costs (see Note 24). Further details of Directors' emoluments are included in the Directors' Remuneration Report from pages 113 to 128.

#### **Subsequent events**

On 2 February 2012, AstraZeneca announced new restructuring initiatives to further reduce costs and increase business flexibility.

## **Principal Subsidiaries**

At 31 December 2011	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	D.I.:	100	
NV AstraZeneca SA	Belgium	100	Marketing
AstraZeneca Dunkerque Production SCS AstraZeneca SAS	France	100	Manufacturing
	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	Netherlands	100	Marketing
LLC AstraZeneca Pharmaceuticals	Russia	100	Marketing
The Americas			
AstraZeneca do Brasil Limitada	Brazil	100	Manufacturing, marketing
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
AZ (Wuxi) Trading Co. Limited	China	100	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 235 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 2011.

## 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 2011 set out on pages 193 to 197. 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 auditor

As explained more fully in the Preparation of the Financial Statements and the Directors' Responsibilities Statement set out on page 140, 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 2011.
- > 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 matter

We have reported separately on the Group Financial Statements of AstraZeneca PLC for the year ended 31 December 2011.

#### **Jimmy Daboo**

Senior Statutory Auditor

For and on behalf of KPMG Audit Plc, Statutory Auditor Chartered Accountants 15 Canada Square, London, E14 5GL

2 February 2012

# **Company Balance Sheet** at 31 December

#### AstraZeneca PLC

	Notes	2011 \$m	2010 \$m
Fixed assets Fixed asset investments	1	23,421	25,232
Current assets Debtors – other		1	1
Debtors – amounts owed by Group undertakings		1,937 1,938	3,558 3,559
Creditors: Amounts falling due within one year Non-trade creditors	2	(3,217)	(194)
Interest-bearing loans and borrowings	3	(1,749)	
Net current (liabilities)/assets		(4,966)	(194) 3,365
Total assets less current liabilities		20,393	28,597
Creditors: Amounts falling due after more than one year Amounts owed to Group undertakings	3	(283)	(283)
Interest-bearing loans and borrowings	3	(6,714)	(8,486)
Net assets		(6,997) 13,396	(8,769) 19,828
Capital and reserves Called-up share capital	6	323	352
Share premium account	4	3,078	2,672
Capital redemption reserve	4	139	107
Other reserves	4	2,983	3,020
Profit and loss account	4	6,873	13,677
Shareholders' funds	5	13,396	19,828

\$m means millions of US dollars.

The Company Financial Statements from page 193 to 197 were approved by the Board on 2 February 2012 and were signed on its behalf by

**David R Brennan Simon Lowth** Director 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 are presented on pages 142 to 191 and have been prepared in accordance with International Financial Reporting Standards as adopted by the EU and as issued by the IASB and in accordance with the Group Accounting Policies set out on pages 146 to 149.

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 25 (IAS 32) 'Financial Instruments: Presentation Classification of Rights Issues', Abstract 47 'Extinguishing Financial Liabilities with Equity Instruments' and 'Improvements to Financial Reporting Standards 2010' (November 2010) during the year. The adoptions had no impact on the net results or net assets of the Company.

The Amendments to FRS 29 (IFRS 7) 'Disclosures – Transfers of Financial Assets' has 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 subs		
	Shares \$m	Loans \$m	Total \$m	
Cost and net book value at 1 January 2011	16,465	8,767	25,232	
Transfer to current assets	-	(1,747)	(1,747)	
Capital contribution	(38)	-	(38)	
Exchange	_	(25)	(25)	
Amortisation	-	(1)	(1)	
Cost and net book value at 31 December 2011	16,427	6,994	23,421	

A list of principal subsidiaries is included on page 191.

#### 2 Non-trade creditors

	2011 \$m	2010 \$m
Amounts due within one year Short-term borrowings (unsecured)	14	12
Other creditors	170	169
Amounts owed to Group undertakings	3,033	13
	3,217	194

#### 3 Loans

	Repayment dates	2011 \$m	2010 \$m
Amounts due within one year Interest-bearing loans and borrowings (unsecured)			
US dollars			
5.4% Callable bond	2012	1,749	-
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
5.4% Callable bond	2014	749	749
5.9% Callable bond	2017	1,744	1,744
6.45% Callable bond	2037	2,716	2,718
Euros 5.125% Non-callable bond	2015	969	993
Pounds sterling			
5.75% Non-callable bond	2031	536	535
		6,714	8,486
		0044	0010

	2011 \$m	2010 \$m
Loans or instalments thereof are repayable:		
After five years from balance sheet date	5,279	5,280
From two to five years	1,718	1,742
From one to two years	-	1,747
Within one year	1,749	_
Total unsecured	8,746	8,769

All loans are at fixed interest rates. Accordingly the fair values of the loans will change as market rates change. However, since the loans are held at amortised cost, changes in interest rates and the credit rating of the Company do not have any effect on the Company's net assets.

#### 4 Reserves

	Share premium account \$m	Capital redemption reserve \$m	Other reserves \$m	Profit and loss account \$m	2011 Total \$m	2010 Total \$m
At beginning of year	2,672	107	3,020	13,677	19,476	22,927
Profit for the year	_	-	_	2,961	2,961	2,043
Dividends	_	_	_	(3,752)	(3,752)	(3,494)
Amortisation of loss on cash flow hedge	_	_	_	2	2	1
Share-based payments	_	_	(37)	_	(37)	98
Share repurchases	_	32	_	(6,015)	(5,983)	(2,591)
Issue of AstraZeneca PLC Ordinary Shares	406	_	_	_	406	492
At end of year	3,078	139	2,983	6,873	13,073	19,476
Distributable reserves at end of year	_	-	1,841	6,873	8,714	15,518

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 2011, \$6,873m (31 December 2010: \$13,677m) 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 2011 is \$1,142m (31 December 2010: \$1,179m) in respect of cumulative share-based payment awards. These amounts are not available for distribution.

#### 5 Reconciliation of movement in shareholders' funds

	2011 \$m	2010 \$m
At beginning of year	19,828	23,290
Net profit for the financial year	2,961	2,043
Dividends	(3,752)	(3,494)
Amortisation of loss on cash flow hedge	2	1
Share-based payments	(37)	98
Issue of AstraZeneca PLC Ordinary Shares	409	494
Repurchase of AstraZeneca PLC Ordinary Shares	(6,015)	(2,604)
Net decrease in shareholders' funds	(6,432)	(3,462)
Shareholders' funds at end of year	13,396	19,828

Details of dividends paid and payable to shareholders are given in Note 21 to the Group Financial Statements on page 170.

#### 6 Share capital

	Allotted, called	l-up and fully paid
	2011 \$m	2010 \$m
Issued Ordinary Shares (\$0.25 each)	323	352
Redeemable Preference Shares (£1 each – £50,000)	-	_
	323	352

At 31 December 2011, 1,292,355,052 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 (m)	\$m
At 1 January 2011	1,409	352
Issues of shares	11	3
Repurchase of shares	(128)	(32)
At 31 December 2011	1,292	323

#### **Share repurchases**

During the year, the Company repurchased 128m Ordinary Shares at an average price of 2932 pence per share (2010: 54m Ordinary Shares at an average price of 3111 pence per share).

#### Share schemes

A total of 11m 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 include the *Seroquel* product liability litigation; the *Seroquel* Attorney General commercial litigation; the *Nexium* product liability litigation; and the *Symbicort* freedom to operate lawsuit (Accuhale LLC v. AstraZeneca) each of which are described more fully in Note 25 to the Group Financial Statements.

#### **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 cooperating with these inquiries. AstraZeneca is investigating indications of inappropriate conduct in certain countries, including China.

#### **European Commission investigation**

The European Commission investigation into alleged practices regarding *Nexium* and alleged breaches of EU competition laws, which was commenced in November 2010, remains pending.

#### **European Commission case**

AstraZeneca is awaiting a ruling on the cross-appeals from the General Court of the EU's judgment regarding the European Commission's 2005 Decision fining AstraZeneca €60m (reduced to €52.5m by the General Court) for abuse of a dominant position regarding omeprazole. An oral hearing took place on 12 January 2012.

#### **Dutch Competition Authority investigation**

The Dutch National Competition Authority (NMa) investigation into alleged practices regarding *Nexium* and alleged breaches of both Dutch and EU competition laws is ongoing. In December 2011, the investigation team issued a report alleging foreclosure of generic versions of certain Proton Pump Inhibitors. The file has now been passed to the Legal Department of the NMa.

#### 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 2011 and 2010.

## **Group Financial Record**

For the year ended 31 December	2007 \$m	2008 \$m	2009 \$m	2010 \$m	2011 \$m
Revenue and profits					
Revenue	29,559	31,601	32,804	33,269	33,591
Cost of sales	(6,419)	(6,598)	(5,775)	(6,389)	(6,026)
Distribution costs	(248)	(291)	(298)	(335)	(346)
Research and development	(5,162)	(5,179)	(4,409)	(5,318)	(5,523)
Selling, general and administrative costs	(10,364)	(10,913)	(11,332)	(10,445)	(11,161)
Profit on disposal of subsidiary	-	_	_	_	1,483
Other operating income and expense	728	524	553	712	777
Operating profit	8,094	9,144	11,543	11,494	12,795
Finance income	959	854	462	516	552
Finance expense	(1,070)	(1,317)	(1,198)	(1,033)	(980)
Profit before tax	7,983	8,681	10,807	10,977	12,367
Taxation	(2,356)	(2,551)	(3,263)	(2,896)	(2,351)
Profit for the period	5,627	6,130	7,544	8,081	10,016
Other comprehensive income for the period, net of tax	342	(1,906)	(54)	25	(546)
Total comprehensive income for the period	5,969	4,224	7,490	8,106	9,470
Profit attributable to:	·	•	· · · · · · · · · · · · · · · · · · ·		-
Equity holders of the Company	5,595	6,101	7,521	8,053	9,983
Non-controlling interests	32	29	23	28	33
	<del>-</del>				
Earnings per share Earnings per \$0.25 Ordinary Share (basic)	\$3.74	\$4.20	\$5.19	\$5.60	\$7.33
Earnings per \$0.25 Ordinary Share (diluted)	\$3.73	\$4.20	\$5.19	\$5.57	\$7.30
Dividends	\$1.75	\$1.90	\$2.09	\$2.41	\$2.70
-	Ψιιιο	ψ1.00	Ψ2.00	Ψ2.11	<u> </u>
Return on revenues Operating profit as a percentage of revenues	27.4%	28.9%	35.2%	34.5%	38.1%
Ratio of earnings to fixed charges	15.6	13.5	19.9	24.0	28.5
Take of carrings to mod charges				2.10	
At 31 December	2007 \$m	2008 \$m	2009 \$m	2010 \$m	2011 \$m
	φπ	φιιι	φιτι	φιτι	Ç.III
Statement of Financial Position Property, plant and equipment, goodwill and intangible assets	29,649	29,240	29,422	28,986	27,267
Other investments	299	605	446	535	543
Deferred tax assets	1,044	1,236	1,292	1,475	1,514
Current assets	16,996	15,869	23,760	25,131	23,506
Total assets	47,988	46,950	54,920	56,127	52,830
Current liabilities	(15,218)	(13,415)	(17,640)	(16,787)	(15,752)
Non-current liabilities		(17,475)		, , ,	
Net assets	(17,855)	,	(16,459)	(15,930)	(13,606)
	14,915	16,060	20,821	23,410	23,472
Share capital	364	362	363	352	323
Reserves attributable to equity holders	14,414	15,550	20,297	22,861	22,923
Non-controlling interests	137	148	161	197	226
Total equity and reserves	14,915	16,060	20,821	23,410	23,472
	2007	2008	2009	2010	2011
For the year ended 31 December	\$m	\$m	\$m	\$m	\$m
Cash flows					
Net cash inflow/(outflow) from:	7.510	0.740	11 700	10.600	7 004
Operating activities	7,510	8,742	11,739	10,680	7,821
Investing activities	(14,887)	(3,896)	(2,476)	(2,340)	(2,022)
Financing activities	6,051	(6,362)	(3,629)	(7,220)	(9,321)
	(1,326)	(1,516)	5,634	1,120	(3,522)

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.

# **Development Pipeline**

## at 31 December 2011

Throughout the development process, we strive to obtain patent protection consistent with our patent process (as described in the Intellectual Property section from page 34). However, until marketing approval in individual countries is obtained, it is not possible to accurately predict the maximum period of product protection available from any such patents. While the most significant uncertainties for development pipeline products progressing to launch are meeting development targets and obtaining regulatory marketing approvals (as detailed in the Risk section from page 129), the date and language of any actual marketing approval will crucially determine the length of Patent Term Extension and the full range, if any, of pending patents that will protect the marketed product. Further details of possible periods of patent, RDP and related IP protections which may protect pipeline products once marketed are included on page 35.

#### **Line Extensions**

				Date		Estimate	ed Filing	
Compound	Mechanism	Area Under Investigation	Phase	Commenced Phase	US	EU	Japan	Emerging
Cardiovascular								
Axanum	proton pump inhibitor + low dose aspirin FDC	low dose aspirin associated peptic ulcer in high risk CV patients	III		Withdrawn	Launched	1H 2013	Filed
Brilinta/ Brilique PEGASUS-TIMI	ADP receptor antagonist	outcomes study	III	4Q 2010	2014	2014	2014	2014
Crestor#	statin	outcomes in subjects with elevated CRP	III		Launched	Launched		Filed
dapagliflozin/metformin FDC#	SGLT2 inhibitor + metformin FDC	diabetes	III	3Q 2007		3Q 2012		
dapagliflozin#	SGLT2 inhibitor	diabetes – add on to DPP-IV	III	1Q 2010		3Q 2012		
dapagliflozin#	SGLT2 inhibitor	diabetes – add on to insulin and add on to metformin LT data	III	2Q 2008		3Q 2012		
dapagliflozin#	SGLT2 inhibitor	diabetes – in patients with high CV risk – Study 18 and 19 data	III	1Q 2013		3Q 2013		
Kombiglyze XR <sup>™</sup> / Komboglyze <sup>™</sup> FDC <sup>#*</sup>	DPP-IV inhibitor + metformin FDC	diabetes	III		Launched	Approved		Approved
Onglyza <sup>TM</sup> SAVOR-TIMI#	DPP-IV inhibitor	outcomes study	III	2Q 2010	2016	2016		2016
Gastrointestinal								
Entocort	glucocorticoid steroid	Crohn's disease and ulcerative colitis	III		Launched	Launched	2014	TBC
Nexium	proton pump inhibitor	peptic ulcer bleeding	III		Filed**	Launched		Launched
Nexium	proton pump inhibitor	GERD	III		Launched	Launched	Launched	Launched
Infection								
FluMist/Fluenz	live, attenuated, intranasal influenza virus vaccine	influenza	III		Launched	Approved		Launched
Neuroscience								
Diprivan#	sedative and anaesthetic	conscious sedation	III			Launched	2H 2013	Launched
EMLA#	local anaesthetic	topical anaesthesia	III			Launched	Approved	Launched
Oncology								
Faslodex	oestrogen receptor antagonist	high dose (500mg) 2nd line advanced breast cancer	III		Launched	Launched	Launched	Launched
Faslodex	oestrogen receptor antagonist	1st line advanced breast cancer	III		2016	2016	2016	2016
Iressa	EGFR tyrosine kinase inhibitor	1st line EGFR mut+ NSCLC	III			Launched	Launched	Launched
Iressa	EGFR tyrosine kinase inhibitor	treatment beyond progression	III			2015	2015	2015
Respiratory & Inflamma	ation							
Oxis	long-acting B₂ agonist	COPD	III			Launched	Filed	
Symbicort	inhaled steroid/long-acting $\ensuremath{\beta_2}$ agonist	asthma/ COPD	III		1H 2013			
Symbicort	inhaled steroid/long-acting ß <sub>2</sub> agonist	COPD	III		Launched	Launched	Filed	Launched
Symbicort	inhaled steroid/long-acting B <sub>2</sub> agonist	SMART	III			Launched	Filed	Launched

<sup>#</sup> Partnered product.
\* Kombiglyze XR™ US; Komboglyze™ FDC EU.

<sup>\*\* 2</sup>nd CRL received in June 2011.

## **Development Pipeline**

#### **NCEs**

### Phase III/Registration

				Date				
Compound	Mechanism	Area Under Investigation	Phase	Commenced Phase	US	EU	Japan	Emerging
Cardiovascular								
Brilinta/Brilique	ADP receptor antagonist	arterial thrombosis	III		Launched	Launched	1H 2013	Launched
dapagliflozin#	SGLT2 inhibitor	diabetes	III	3Q 2007	Filed*	Filed	1H 2013	Filed
Infection		-						
CAZ AVI# (CAZ104)	beta lactamase inhibitor/ cephalosporin	serious infections	**	1Q 2012		2014	2014	2014
Q-LAIV Flu Vac*** (MEDI-3250)	live, attenuated, intranasal influenza virus vaccine (quadrivalent)	seasonal influenza	III	1Q 2009	Filed	4Q 2012		
Zinforo# (ceftaroline)	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections	III	1Q 2007		Filed		Filed
Neuroscience		-						
NKTR-118#	oral peripherally-acting opioid antagonist	opioid-induced constipation	III	2Q 2011****	2H 2013	2H 2013		
TC-5214#	neuronal nicotinic channel modulator	major depressive disorder (adjunct)	III	2Q 2010	3Q 2012	2015		
Oncology								
Caprelsa (vandetanib)	VEGFR/EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer	III		Launched	Filed	2014	Filed
Ranmark™# (denosumab)	anti-RANKL MAb	bone disorders stemming from bone metastasis	III				Approved	
Respiratory & Inflamn	nation							
fostamatinib#	spleen tyrosine kinase (SYK) inhibitor	rheumatoid arthritis	III	3Q 2010	2H 2013	2H 2013		2H 2013

Partnered product.
 CRL received in January 2012. See page 61 of the Therapy Area Review for more information.
 Phase III dosing expected in 1Q 2012.
 supplemental Biologics License Application (sBLA) in US, MAA in EU.
 Enrolment began in 1Q 2011.

#### **NCEs** Phases I and II

				Date ——		Estimated	Filing	
Compound	Mechanism	Area Under Investigation	Phase	Phase	US	EU	Japan	Emerging
Cardiovascular								
AZD2927	ion channel blocker/inhibitor	atrial fibrillation	II	4Q 2011				
AZD4017	11BHSD	glaucoma	II	1Q 2011				
AZD2820#	melanocortin receptor type 4(MC4r) partial agonist peptide	obesity	I	2Q 2011				
				,	ı			
tralokinumab (CAT-354)	anti-IL-13 MAb	ulcerative colitis	ı	2Q 2011				
Infection					'			
AZD9773#	anti-TNF-alpha polyclonal antibody	severe sepsis	II	1Q 2008				
CXL# (CEF104)	beta lactamase inhibitor/ cephalosporin	MRSA	II	4Q 2010				
AZD5099	gyrase B	serious infections	ı	2Q 2011	,			
AZD5847	oxazolidinone antibacterial inhibitor	tuberculosis	ı	4Q 2009				
MEDI-534	RSV/PIV-3 vaccine	RSV/PIV prophylaxis		2Q 2005				
MEDI-550	pandemic influenza virus vaccine		ı	2Q 2006				
MEDI-557	anti-RSV MAb -	RSV prevention in high-risk						
	extended half-life	adults (COPD/CHF/other)		3Q 2007				
MEDI-559	paediatric RSV vaccine	RSV prophylaxis	ı	4Q 2008				
Neuroscience								
AZD2423	CCR2b antagonist	chronic neuropathic pain	II	4Q 2010				
AZD3480#	alpha4/beta2 neuronal nicotinic receptor agonist	Alzheimer's disease	II	3Q 2007				
AZD6765	NMDA receptor antagonist	major depressive disorder	II	3Q 2007				
TC-5214#	neuronal nicotinic channel modulator	major depressive disorder (monotherapy)	II	1Q 2011				
AZD1446#	alpha4/beta2 neuronal nicotinic receptor agonist	Alzheimer's disease	I	4Q 2008				
AZD3241	myeloper-oxidase (MPO) inhibitor	Parkinson's disease	I	2Q 2007				
AZD3839#	beta-secretase (BACE) inhibitor	Alzheimer's disease	I	3Q 2011				
AZD5213	histamine-3 receptor antagonist	Alzheimer's disease/ADHD	ı	2Q 2010				
MEDI-578	anti-NGF MAb	OA pain	- 1	1Q 2010				
Oncology					,			
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	4Q 2011				
AZD8931	erbB kinase inhibitor	breast cancer chemo. combi./ solid tumours	II	2Q 2010				
fostamatinib#*	spleen tyrosine kinase (SYK) inhibitor	haematological malignancies	II	1Q 2012				
MEDI-575#	anti-PDGFR-alpha MAb	NSCLC/glioblastoma	II	4Q 2010				
selumetinib# (AZD6244) (ARRY-142886)	MEK inhibitor	solid tumours	II	4Q 2006				
tremelimumab#	anti-CTLA4 MAb	solid tumours	II	3Q 2004				
AZD1480	JAK1, 2 inhibitor	solid tumours	1	2Q 2009		·		
AZD2014	TOR kinase inhibitor	solid tumours	1	1Q 2010				
AZD3514	androgen receptor down-regulator	prostate cancer	I	3Q 2010				
AZD5363#	AKT inhibitor	solid tumours	I	4Q 2010				
AZD8330# (ARRY-424704)	MEK inhibitor	solid tumours	I	1Q 2007				
MEDI-551#	anti-CD19 MAb	haematological malignancies	1	2Q 2010				
MEDI-565#	anti-CEA BiTE	solid tumours	ı	1Q 2011				
MEDI-573#	anti-IGF MAb	solid tumours	I	1Q 2009				
MEDI-3617#	anti-ANG-2 MAb	solid tumours	I	4Q 2010				
moxetumomab pasudotox# (CAT-8015)	anti-CD22 recombinant immunotoxin	haematological malignancies	I	2Q 2007				
olaparib	PARP inhibitor	solid tumours	1	4Q 2008				
selumetinib# (AZD6244)	MEK/AKT inhibitor	solid turnours	<u>'</u>	4Q 2008 4Q 2009				

<sup>#</sup> Partnered product.
\* Added to pipeline table after starting Phase II in January 2012.

## **Development Pipeline**

#### **NCEs**

#### Phases I and II continued

				Date		Estimated F	Filing	
Compound	und Mechanism Area Under Investigation		Phase	Commenced —— Phase	US	EU	 Japan	Emerging
Respiratory & Inflamm	ation							
AZD1981	CRTh2 receptor antagonist	asthma/COPD	II	3Q 2005				
AZD2423	CCR2b antagonist	COPD	II	4Q 2010				
AZD5069	CXCR2	COPD	II	4Q 2010				
AZD5423	inhaled SEGRA	COPD	II	4Q 2010				
AZD8683	muscarinic antagonist	COPD	II	4Q 2010				
benralizumab# (MEDI-563)	anti-IL-5R MAb	asthma/COPD	II	4Q 2008				
mavrilimumab# (CAM-3001)	anti-GM-CSFR MAb	rheumatoid arthritis	II	1Q 2010				
MEDI-8968#	anti-IL-1R MAb	COPD	II	4Q 2011				
sifalimumab# (MEDI-545)	anti-IFN-alpha MAb	SLE	II	3Q 2008				
tralokinumab (CAT-354)	anti-IL-13 MAb	asthma	II	1Q 2008				
AZD2115	MABA	COPD	1	1Q 2011				
MEDI-546#	anti-IFN-alphaR MAb	scleroderma	I	3Q 2009				
MEDI-551#	anti-CD19 MAb	scleroderma	I	2Q 2010		,		
MEDI-570#	anti-ICOS MAb	SLE	I	2Q 2010				

<sup>#</sup> Partnered product.

### Discontinued projects between 27 January 2011 and 31 December 2011

NCE/Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
Cardiovascular			
NCE	AZD1656	Safety/Efficacy	diabetes
NCE	AZD5658	Safety/Efficacy	diabetes
NCE	AZD6714	Safety/Efficacy	diabetes
NCE	AZD7687	Safety/Efficacy	diabetes
NCE	AZD8329	Safety/Efficacy	diabetes
Neuroscience	'		
NCE	AZD2066	Safety/Efficacy	major depressive disorder
NCE	AZD2066	Safety/Efficacy	chronic neuropathic pain
NCE	AZD3043	Economic	short acting sedative/anaesthetic
NCE	TC-5619	Economic	cognitive disorders in schizophrenia
Oncology			
NCE	AZD1152	Economic	haematological malignancies
NCE	AZD2461	Safety/Efficacy	solid tumours
NCE	AZD7762	Safety/Efficacy	solid tumours
NCE	AZD8055	Safety/Efficacy	range of tumours
NCE	olaparib (AZD2281)	Safety/Efficacy	serous ovarian cancer
NCE	Recentin	Safety/Efficacy	NSCLC
NCE	zibotentan (ZD4054)	Safety/Efficacy	castrate resistant prostate cancer
Infection			
NCE	AZD9742	Safety/Efficacy	MRSA
NCE	motavizumab	Regulatory	early and late treatment of RSV in paeds > 1 year
Respiratory & Inflammation			
NCE	AZD3199	Economic/Regulatory	asthma/COPD
NCE	AZD9819	Economic	COPD
NCE	MEDI-528	Safety/Efficacy	asthma

#### Comments

As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

# **Shareholder Information**

#### AstraZeneca PLC share listings and prices

	2007	2008	2009	2010	2011
Ordinary Shares in issue – millions					
At year end	1,457	1,447	1,451	1,409	1,292
Weighted average for year	1,495	1,453	1,448	1,438	1,361
Stock market price – per Ordinary Share					
Highest (pence)	2984	2888	2947	3385	3194
Lowest (pence)	2093	1748	2147	2732	2543.5
At year end (pence)	2164	2807	2910.5	2922	2975

#### Percentage analysis of issued share capital at 31 December

By size of account No. of Ordinary Shares	2007 %	2008 %	2009 %	2010 %	2011 %
1 – 250	0.5	0.5	0.5	0.5	0.6
251 – 500	0.7	0.7	0.7	0.6	0.7
501 – 1,000	0.9	0.9	0.8	0.8	0.8
1,001 – 5,000	1.3	1.2	1.1	1.1	1.2
5,001 – 10,000	0.2	0.2	0.2	0.2	0.2
10,001 – 50,000	1.0	1.0	1.1	1.0	1.0
50,001 – 1,000,000	12.9	13.6	13.0	12.8	13.8
Over 1,000,000¹	82.5	81.9	82.6	83.0	81.7

<sup>&</sup>lt;sup>1</sup> Includes Euroclear and ADR holdings.

At 31 December 2011, the Company had 119,435 registered holders of 1,292,355,052 Ordinary Shares. At 31 December 2011, there were approximately 209,000 holders of ADRs representing 8.6% of the issued share capital of the Company and 136,000 holders of Ordinary Shares held under the Euroclear Services Agreement representing 15.3% 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 2011, under AstraZeneca's share repurchase programme, which was introduced in 1999, 127.4 million Ordinary Shares were repurchased and subsequently cancelled at a total cost of \$6,015 million, representing 9.9% of the total issued share capital of the Company at 31 December 2011. The average price paid per share in 2011 was 2932 pence. This brings the total number of Ordinary Shares repurchased to date since the beginning of the repurchase programme in 1999, to 557.4 million Ordinary Shares (at an average price of 2767 pence per Ordinary Share) for a consideration, including expenses, of \$26,717 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 10.7 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 New York Stock Exchange (NYSE). The table below sets out, for 2010 and 2011, the reported high and low share prices of the Company, on the following bases:

#### **Shareholder Information**

- > For shares listed on the LSE the reported high and low middle market closing quotations are derived from the Daily Official List.
- > For shares listed on the SSE the high and low closing sales prices are as stated in the Official List.
- > For ADSs listed on the NYSE the reported high and low sales prices are as reported by Dow Jones (ADR quotations).

			Ordinary LSE		ADS		Ordinary SSE
		High (pence)	Low (pence)	High (US\$)	Low (US\$)	High (SEK)	Low (SEK)
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
	- Quarter 3	3385.0	3051.5	53.41	47.05	382.2	345.0
	- Quarter 4	3359.0	2922.0	53.50	45.80	354.7	309.3
2011	- Quarter 1	3073.5	2801.5	49.38	45.40	320.6	289.0
	- Quarter 2	3194.0	2895.0	52.40	46.60	328.5	294.2
	- Quarter 3	3166.5	2543.5	51.08	40.95	324.5	269.3
	- Quarter 4	3080.5	2731.5	49.89	42.53	319.0	293.7
	– July	3166.5	2973.0	51.08	48.51	324.5	309.0
	- August	2950.5	2543.5	48.26	40.95	304.1	269.3
	- September	2916.0	2738.5	46.69	42.64	305.1	284.0
	- October	3080.5	2814.5	49.89	43.86	319.0	299.5
	- November	2976.5	2731.5	47.88	42.53	316.2	293.7
	- December	2975.0	2883.0	46.34	45.15	318.2	307.0

#### Major shareholdings

At 2 February 2012, 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	7.87
Invesco Limited	72,776,277	6 October 2009	5.67
Axa SA	56,991,117	3 February 2009	4.44
Investor AB	51,587,810	2 February 2012	4.02
Legal & General Investment Management Limited	57,675,232	5 August 2010	4.50

<sup>&</sup>lt;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.

		Percentage of issued share capit		d share capital
Shareholder	2 Feb 2012	27 Jan 2011	28 Jan 2010	29 Jan 2009
BlackRock, Inc.	7.87	7.18	6.94	-
Invesco Limited	5.67	5.18	5.01	_
Axa SA	4.44	4.06	3.92	4.90
Investor AB	4.02	3.67	3.55	4.38
Legal & General Investment Management Limited	4.50	4.10	4.64	4.09
Capital Research and Management Company	-	_	_	4.92
Wellington Management Co., LLP		-	-	4.18
Barclays PLC		_	_	4.26

ADSs evidenced by ADRs issued by JPMorgan, as depositary, are listed on the NYSE. At 2 February 2012, the proportion of Ordinary Shares represented by ADSs was 8.66% of the Ordinary Shares outstanding.

Number of registered holders of Ordinary Shares at 2 February 2012:

> In the US 766 > Total 119,039

Number of record holders of ADRs at 2 February 2012:

> In the US 2,165 > Total 2,176

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 2 February 2012, 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	533,235	0.04

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 2012 to 2 February 2012, 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 190).

#### Options to purchase securities from registrant or subsidiaries

(a) At 2 February 2012, options outstanding to subscribe for Ordinary Shares were:

Number of s	Subscription ares price (pence)	Normal expiry date
36,077,128	1882 – 3487	2012 - 2019

The weighted average subscription price of options outstanding at 2 February 2012 was 2496 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
1,552,569	1882 – 3487	2012 – 2019

(c) Included in paragraph (b) are options granted to individually named Directors. Details of these option holdings at 31 December 2011 are shown in the Share option plans table on page 127.

During the period 1 January 2012 to 2 February 2012, 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 2011, payable on 19 March 2012, is 17 February 2012 and the ex-dividend date is 15 February 2012.

The record date for the first interim dividend for 2012, payable on 10 September 2012, is 10 August 2012.

Future dividends will normally be paid as follows:

First interim: Announced in July and paid in September. Second interim: Announced in February 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 2012 will be published on 26 April 2012 and results in respect of the first six months of 2012 will be published on 26 July 2012.

#### **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 material UK and US federal income tax consequences of ownership of Ordinary Shares or ADRs held as capital assets by the US resident holders described below 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 holders' particular circumstances and tax consequences applicable to US resident holders subject to special rules (such as certain financial institutions, entities treated as partnerships for US federal income tax purposes, persons whose functional currency for US federal income tax purposes is not the US dollar, tax-exempt entities, or persons holding Ordinary Shares or ADRs in connection with a trade or business conducted outside of the United States). US resident holders are urged to consult their tax advisers regarding the UK and US federal income tax consequences of the ownership and disposition of Ordinary Shares or ADRs in their particular circumstances.

This summary is 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 American depository shares 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 American depository shares, may be taking actions that are inconsistent with the claiming, by US holders of American depository shares, of foreign tax credits for US federal income tax purposes. Such actions would also be inconsistent with the claiming of the reduced tax rates, described below, applicable to dividends received by certain non-corporate US resident holders. Accordingly, the availability of the reduced tax rates for dividends received by certain non-corporate US resident holders could be affected by actions that may be taken by parties to whom ADRs are pre-released.

For purposes of this summary, the term 'US resident holder' means a beneficial owner of Ordinary Shares or ADRs that is, for US federal income tax purposes, a citizen or resident of the US, a corporation (or other entity taxable as a corporation) created or organised in or under the laws of the US, any state in the US or the District of Columbia, or an estate or trust the income of which is subject to US federal income taxation regardless of its source.

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 holder 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 holders 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 holders, 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 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 taxable at favourable US federal income tax rates, up to a maximum rate of 15%. US resident holders 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 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 or other permanent establishment.

A US resident holder 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 holders 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 holders 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 2011. 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 holders.

#### Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the US or through certain US-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the US resident holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the US resident holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding. The amount of any backup withholding from a payment to a US resident holder will be allowed as a credit against the holder's US federal income tax liability and may entitle the holder to a refund, provided that the required information is supplied to the IRS on time.

Certain US resident holders who are individuals, or are controlled by individuals, may be required to report information relating to securities issued by non-US persons, generally on IRS Form 8938, subject to certain exceptions (including an exception for securities held through US financial institutions). US resident holders should consult their tax advisers regarding their reporting obligations with respect to the Ordinary Shares or ADRs.

#### **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 domiciled shareholder, the Ordinary Shares or ADRs will generally not be subject to UK inheritance tax unless the settlor, at the time of settlement, was a UK national, or 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. 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**

The following information relating to average and spot exchange rates used by AstraZeneca is provided for convenience:

	SEK/US\$	US\$/GBP
Average rates (statement of comprehensive income, statement of cash flows)		
2009	7.6552	1.5496
2010	7.2504	1.5453
2011	6.5059	1.5996
End of year spot rates (statement of financial position)		
2009	7.1636	1.6072
2010	6.7511	1.5422
2011	6.9050	1.5443

# **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 to form a new company called Syngenta AG.

The Group owns and operates numerous R&D, production and marketing facilities worldwide. Its corporate office is 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 2011, the Company had 1,292,355,052 Ordinary Shares and 50,000 Redeemable Preference Shares in issue. The Ordinary Shares represent 99.98% and the Redeemable Preference

Shares represent 0.02% 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 2011 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 Ma	rkets	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 and 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
	Iceland*		Georgia*	Laos*	South Africa
	Ireland		Hungary	Malaysia	
	Italy		Kazakhstan*	Philippines	
	Luxembourg*		Latvia*	Singapore	
	Netherlands		Lithuania*	South Korea	
	Norway		Macedonia*	Sri Lanka*	
	Portugal		Poland	Taiwan	
	Spain		Romania*	Thailand	
	Sweden		Russia	Vietnam*	
	Switzerland		Serbia and 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\*, Kuwait\*, Oman\*, Qatar\* and UAE.
Maghreb means Algeria, Morocco and Tunisia\*.

The above table is not an exhaustive list of all the countries in which AstraZeneca operates.

#### **US** equivalents

Terms used in this Annual Report	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
Loans	Long-term debt
Prepayments	Prepaid expenses
Profit	Income
Profit and loss account	Income statement/consolidated statement of comprehensive income
Share premium account	Premiums paid in excess of par value of Ordinary Shares
Short-term investments	Redeemable securities and short-term deposits

<sup>\*</sup>IMS Health, IMS Midas Quantum Q3 2011 data is not available or AstraZeneca does not subscribe for IMS Health quarterly data for these countries.

## Glossary

The following abbreviations and expressions have the following meanings when used in this Annual Report:

**Abbott** – Abbott Pharmaceuticals PR Ltd. with respect to *Certriad* and Abbott Laboratories, Inc. with respect to *Crestor*.

Accord - Accord Healthcare, Inc.

**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 2011.

**API** – active pharmaceutical ingredient.

Articles - the Articles of Association of the Company.

ASA - acetylsalicylic acid.

Astellas - Astellas Pharma, Inc.

**Astra** – Astra AB, being the company with whom the Company merged in 1999.

Astra Tech – Astra Tech AB.

AstraZeneca - the Company and its subsidiaries.

AZIP - AstraZeneca Investment Plan.

BMS - Bristol-Myers Squibb Company.

**Board** – the Board of Directors of the Company.

Bureau Veritas – Bureau Veritas UK Limited.

**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.

**Company** or **Parent Company** – AstraZeneca PLC (formerly Zeneca Group PLC (Zeneca)).

Complete Response Letter (CRL) – 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 51.

Daiichi Sankyo - Daiichi Sankyo Company, Limited.

**Dainippon Sumitomo** – Dainippon Sumitomo Pharmaceuticals Co., Limited.

**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.

**ECG** – electrocardiagram.

**EMA** – the European Medicines Agency.

EMEA - Europe, Middle East and Africa.

**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.

**EFPIA** – European Federation of Pharmaceutical Industries and Associations.

**GAAP** – Generally Accepted Accounting Principles.

GDP - gross domestic product.

GERD - gastro-oesophageal reflux disease.

**GIA** – AstraZeneca's group internal audit function.

**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.

**GSK** - GlaxoSmithKline plc.

Handa - Handa Pharmaceuticals, LLC.

HealthCore - HealthCore Inc.

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.

IP – intellectual property.

IT – information technology.

IS - information services.

**KPI** – key performance indicator.

**krona or SEK** – references to the currency of Sweden.

**Lean** – means enhancing value for customers with fewer resources.

**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.

**NDA** – a new drug application to the FDA for approval to market a new medicine in the US.

NCE - new chemical entity.

NERD - non-erosive reflux disease.

**NGO** – non-governmental organisation.

**n/m** – not meaningful.

Novartis - Novartis Pharma A.G.

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 (PTE)** – 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. The analogous right in the EU is a supplementary protection certificate (SPC).

PDUFA - Prescription Drug User Fee Act.

Pfizer - Pfizer, Inc.

**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.

PhRMA - Pharmaceutical Research and Manufacturers of America.

 $\boldsymbol{pounds}$  sterling, £, GBP, pence or  $\boldsymbol{p}$  – references to the currency of the UK.

Pozen - Pozen Inc.

**Proof of Concept** – data demonstrating that a candidate drug results in a clinical change on an acceptable endpoint or surrogate in patients with the disease.

PSP - AstraZeneca Performance Share Plan.

PUD - peptic ulcer disease.

**QT prolongation** – a biomarker of ventricular tachyarrhythmias measured by ECG.

**R&D** – research and development.

**Redeemable Preference Share** – a redeemable preference share of £1 each in the share capital of the Company.

**Regulatory Data Protection** – see the Intellectual Property section from page 34.

**Regulatory Exclusivity** – any of the IP rights arising from generation of clinical data and includes Regulatory Data Protection (as explained in the Intellectual Property section from page 34), Paediatric Exclusivity and Orphan Drug status.

Responsible Business Plan – the plan described in the Responsible Business section from page 47, further details of which can be found at our website, astrazeneca.com/responsible/management-and-measurement/responsible-business-plan.

Rigel - Rigel Pharmaceuticals, Inc.

**RSV** – respiratory syncytial virus.

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.

**SHE** – Safety, Health and Environment.

SFDA - State Food and Drug Administration of China.

SG&A costs - selling, general and administrative costs.

**Six Sigma** – a rigorous and disciplined methodology that uses data and statistical analysis to measure and improve a company's operational performance by identifying and eliminating defects.

**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.

SOP - AstraZeneca Share Option Plan.

Targacept - Targacept, Inc.

Teva - Teva Pharmaceuticals USA, Inc.

TKI - Tyrosine Kinase Inhibitors.

**TSR** – total shareholder return, being the total return on a share over a period of time, including dividends reinvested.

 $\boldsymbol{\mathsf{UK}}$  – the United Kingdom of Great Britain and Northern Ireland.

UK Bribery Act - means the UK Bribery Act 2010.

**UK Corporate Governance Code** – the 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.

 $\ensuremath{\mathbf{WHO}}$  – the World Health Organization, the United Nations' specialised agency for health.

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Important information for readers of this Annual Report

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 130 of this Annual Report. Nothing in this Annual Rep

Inclusion of reported performance, Core financial measures and constant exchange rate growth rates
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 2011 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 2011; 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 53 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

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.

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

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 ™ sign and include: Abraxane™, a trade mark of Abraxis BioScience, LLC.; Cubicin™, a trade mark of Cubist Pharmaceuticals, Inc.; CytoFab™, a trade mark of Protherics Inc.; Kombiglyze XR™ and Komboglyze™, trade marks of Bristol-Myers Squibb Company; Lipitor™, a trade mark of Pfizer Ireland Pharmaceuticals; Onglyza™, a trade mark of Bristol-Myers Squibb Company; Ranmark™, a trade mark of Dalichi Sankyo Company Limited; and Teflaro™, a trade mark of Forest Laboratories, Inc.



This report is printed on Heaven 42 which is FSC® certified virgin fibre. The pulp is a mix, partly bleached using an Elemental Chlorine Free (ECF) process and partly bleached using a Totally Chlorine Free process. Printed in the UK by Pureprint using its alcofree® and pureprint® environmental printing technology, and vegetable inks were used throughout. Pureprint is a CarbonNeutral® company. Both manufacturing mill and the printer are registered to the Environmental Management System ISO14001 and are Forest Stewardship Council® chain-of-custody certified.

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This Annual Report is also available on our website, astrazeneca.com/annualreport2011

