

Innovation is at the core of everything we do at AstraZeneca - from our research into effective new medicines to how we run our business.

Our goal is to improve health for patients, bring benefits for stakeholders and deliver long-term shareholder value through continued successful innovation.

### Our innovation:



> Improves health outcomes for patients





> Delivers economic benefits for healthcare systems





> Adds value beyond the medicines





> Contributes to our local communities



In a world where the demand for healthcare continues to grow, the advances made through innovation are vital to address unmet medical need and deliver sustained improvement in healthcare worldwide.



annualreport2012

### AstraZeneca

Welcome to the AstraZeneca Annual Report and Form 20-F Information 2012 (Annual Report). You will find this Annual Report on our website, astrazeneca.com/ annualreport2012

### Strategy

To compete as a global biopharmaceutical business delivering great medicines to patients through innovative science and excellence in development and commercialisation

### Performance

2012 financial performance was defined by significant revenue decline associated with the loss of exclusivity for several products

### Corporate Governance

In addition to the regular programme of meetings for the Board and its Committees 2012 was a busy year with new appointments, a record number of business development deals and our strategic review

### **Financial** Statements

Met or exceeded financial targets as a result of disciplined financial management and lower Reported tax rate

### Additional Information

More information about our business and about being an AstraZeneca shareholder

### Who are we?

An introduction to AstraZeneca, what we do and where we do it, and an overview of our financial and operational performance in 2012

### A year in review

The Chairman and Chief Executive Officer review how we did in 2012 and consider the prospects for 2013 and beyond



### Introduction and overview

- AstraZeneca at a glance
- Chairman's Statement
- Chief Executive Officer's

How do we create sustainable value?

The life-cycle of a medicine and our business model

Investment period

Returns period

P14

### Strategy

- Our business model
- Life-cycle of a medicine
- Our industry
- 20 Our strategy

How does our strategy help us deliver our aims?

Our business model

P16

Our strategy

### **Performance**

- Key Performance Indicators
- **Business Review**
- Therapy Area Review
- 70 Geographical Review
- 74 Risk
- 86 Financial Review

How did we do in delivering our strategy in 2012?

Measuring our performance against the Key Performance Indicators for each of our priorities

How the business performed in 2012

- > Our resources, skills and capabilities
- > Our Therapy Areas
- > Markets around the world in which we operate P30
- > Our finances

P24

The risks that might stop us achieving our strategy and how we manage them

- > Product pipeline
- > Commercialisation and business execution
- > Supply chain and delivery
- > Legal, regulatory and compliance
- > Economic and financial

P74

### **Corporate Governance**

- 106 Board of Directors and Senior Executive Team
- 110 Corporate Governance Report
- 122 Directors' Remuneration Report

How does the way we are managed and paid support the delivery of our strategy?

P106

Corporate Governance Report

Directors' Remuneration Report

The principal role of our Remuneration Committee

is to develop remuneration policies and practices

The Board sets our strategy and monitors progress towards delivering our strategic priorities and meeting our annual plans. In our Corporate Governance Report, introduced by the Chairman, we review the work of the Board and its Committees in 2012 and how we maintain good governance across the Group.

that support the implementation of our business strategy and help create shareholder value over time. The Committee, led by its Chairman, Non-Executive Director John Varley, reports on how it discharged its responsibilities in 2012.

P110

P122

### **Financial Statements**

- 141 Auditor's Report
- 142 Consolidated Statements
- 150 Notes to the Group Financial Statements

**Additional Information** 

- 199 Development Pipeline 203 Shareholder Information
- 206 Corporate Information
- 209 Glossary
- 212 Index

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

### Financial summary

(\$33,591 million in 2011)

Core operating profit down 18% at CER to \$10,430 million (\$13,167 million in 2011)

Reported operating profit down 34% at CER to \$8,148 million (\$12,795 million

ore EPS for the full year decreased by 9% at CER to \$6.41 (\$7.28 in 2011)

Reported EPS for the full year decreased by 29% at CER to \$4.99 (\$7.33 in 2011)

Net cash shareholder distributions decreased by 37% to \$5,871 million including net share repurchases of \$2,206 million (\$9,370 million net cash shareholder distributions including \$5,606 million net share repurchases in 2011)

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 are one of only a handful of companies to span the entire life-cycle of a medicine from discovery, early and late-stage development, to the global commercialisation of primary care, specialty care-led and specialty care medicines. Using these skills and capabilities we can make a real difference to the health of a broad range of patients by delivering great medicines in disease areas where there is unmet medical need.

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.

610,655m

Regional sales US (-21%)

employees in the Americas (27.9%)

Sales and Marketing employees: numbers in Established Markets, such as the US, have fallen, whereas the numbers in Emerging Markets have increased and now represent 53% of the total

Seloken/Toprol-XL

### Our medicines

Our 10 leading medicines by sales value are:

### Cardiovascular

### Atacand

for hypertension and heart failure

2010: \$1,483m 2011: \$1,450m

\$1,009m

### Crestor

for managing cholesterol levels

2010: \$5,691m 2011: \$6,622m

\$6.253m

### \$918m

2010: \$1,210m

2011: \$986m

### Gastrointestinal

### Nexium for acid-reflux

for hypertension, heart failure and angina

> 2010: \$4,969m 2011: \$4,429m

\$3.944m

### Infection

### Synagis

for RSV, a respiratory infection in infants

2010: \$1,038m 2011: \$975m

\$1.038m

\$6,486m

Regional sales Western Europe (-19%)

23,600\*

employees in EMEA (45.6%)

51,700\*

employees worldwide

\$5,080m

Regional sales Established ROW (-14%)

\$5,752m

Regional sales Emerging Markets (+4%)

13,700\*

employees in Asia Pacific (26.5%)

9,800\*

employees work in our R&D organisation and we have 10 principal R&D centres in six countries

10,300°

employees work at our 22 Supply and Manufacturing sites in 16 countries

\* All figures are approximate.

### Neuroscience

### Seroquel IR

for schizophrenia and bipolar disorder

2010: \$4,148m 2011: \$4,338m

2012

\$1,294m

### Seroquel XR

for schizophrenia, bipolar disorder and major depressive disorder

2010: \$1,154m 2011: \$1,490m

2012

\$1,509m

### Oncology

**Zoladex** for prostate and breast cancer

2010: \$1,115m 2011: \$1,179m

2012

\$1,093m

### Respiratory & Inflammation

### **Pulmicort**

for asthma and chronic obstructive pulmonary disease

2010: \$872m 2011: \$892m

201

\$866m

### Symbicort

for asthma and chronic obstructive pulmonary disease

2010: \$2,746m 2011: \$3,148m

2012

\$3,194m

### Overview | AstraZeneca at a glance

### Financial overview Core pre-R&D operating profit Sales **Core operating profit** \$m (-15%) \$m (-16%) \$m (-18%) 27,973 10,430 12 Reported operating profit Net cash flow from Reported pre-R&D \$m (-34%) operating activities \$m operating profit \$m (-25%) 8,148 6,948 12,795 16,812 10,680 Our year in brief February > AstraZeneca March > AstraZeneca and April > Entered into June > David Brennan Targacept decide not to pursue announces an accelerated agreement to acquire retires as CEO regulatory filing on TC-5214 due R&D transformation Ardea and its Phase III > Louis Schweitzer retires to inconclusive Phase III results programme and the end development product as Chairman of the Board of R&D activity at sites in candidate, lesinurad, as a > As anticipated, the Seroquel IR and Leif Johansson starts Sweden (Södertälje) and potential treatment for the patent in the US expired, a number as the new Chairman Canada (Montreal) chronic management of of generic products entered the hyperuricaemia in patients market and our sales declined with gout June > AstraZeneca March > AstraZeneca receives approval April > AstraZeneca agrees from the FDA for FluMist Quadrivalent for with Amgen to jointly enhances its presence the prevention of influenza. This marked develop and commercialise in Asia with the opening the first four-strain influenza vaccine, and of the Zhangjiang Park five monoclonal antibodies the only intra-nasal four-strain vaccine, from Amgen's clinical Regional Hub Headquarters approved by the FDA inflammation portfolio in Shanghai Operational overview **Pipeline Deliver the business** 15% 84 reduction in revenue loss of exclusivity reduction > Some \$4.5 billion of > 84 pipeline projects > Brilinta/Brilique has > Core R&D expense for > Revenue fell by 21% in the US; 19% in Western including 71 in clinical the full vear was down revenue decline was been approved in 88 development, of which countries, launched 11%, despite absorbing Europe; and 14% in related to loss of 11 are in Phase III or Established Rest of in 82 countries and higher costs from exclusivity on several World. Revenue rose by brands in the portfolio. under regulatory review; remains under review spending on in-licensed, 19 withdrawn during in 23 countries. acquired or partnered 4% in Emerging Markets Seroquel IR declined Global sales of projects, as these were by more than \$3 billion; the year \$89 million in 2012 regional losses of more than offset by

restructuring benefits

and lower intangible impairments than

in 2011

\$1 billion

exclusivity for *Atacand*, *Nexium* and *Crestor* 

had a further negative

impact of more than

		Shareholder	distributions	
Core earnings per		Distributions to sha	areholders \$m	
Ordinary Share \$ (-9%)		Diotributions to one	2012	2011 2010
12 6.41		Dividends	3,665	3,764 3,361
11 7.28		Share repurchases <sup>1</sup> Total	2,635 <sup>2</sup> 6,300	6,015 <sup>3</sup> 2,604 <sup>4</sup> 9,779 5,965
10 6.71			6,300	9,779 5,905
		Dividend for 2012	\$ Pence SEK	Payment date
Reported earnings per Ordinary Share \$ (-29%)		First interim dividend	0.90 58.1 6.26	10 September 2012
		Second interim dividend	1.90 120.5 12.08	18 March 2013
		Total	2.80 178.6 18.34	
11 7.33		<sup>2</sup> Share repurchases in 2012, no	mme was suspended effective 1 et of proceeds from the issue of	
10 5.60			et of proceeds from the issue of	share capital equal
			et of proceeds from the issue of	share capital equal
		to \$494 million, were \$2,110 m	nillion.	
August > Expansion of BMS	October > Pa	ascal Soriot	November >	Forxiga approved
diabetes alliance through	starts as CEO		in Europe for t	the treatment
inclusion of the Amylin product portfolio	> Suspension		of Type 2 diab	PELES
> EU gives marketing	repurchase pr	ogramme		
authorisation for Zinforo				
			1 1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1	( = 12
	5			
A S	0		N	D 20
September > AstraZeneo		October > Collaboratio	on	January 2013 > Changes
ranks in the top 7% in the in the Dow Jones Sustaina		with Ironwood in China to co-develop and co-		to the Senior Executive Tea announced
World and European Index		commercialise linaclotic	de	
with a score of 83%				
Business s	shape		People	
	•		-	
\$600m \$1.85		<b>2</b> %	81%	5,500
revenue growth in benefits	red	luction in SG&A	score	reduction in employee
Outinat Ed.	-1.0040 =			No.
> Symbicort, Faslodex, > By the end Onglyza, Iressa, Brilinta/ annual ben		kpenditures in Core G&A were 12% lower	> Our employee engagement score	> Net reduction of some 5,500 employees
Brilique and Seroquel \$1.85 billion	n had th	an 2011, a result of	in our annual FOCUS	since 2011 included
XR combined to deliver been realis \$600 million of revenue the phases		structuring benefits nd spending discipline	survey among all employees	recruitment of approximately 5,700
growth restructuring	ig pa	artially offset by	decreased by three	employees to drive
programme in 2010 and		clusion of amortisation	percentage points	our expansion in
In 2010 and		pense related to the pansion of the	compared with 2011	Emerging Markets, build new capabilities

diabetes alliance with BMS and increased

promotional cost in Emerging Markets and replace leavers



### Dear Shareholder

I am glad I was able to meet a number of you in April 2012 when AstraZeneca held its Annual General Meeting in London. At that meeting you elected me as a Director and it is my privilege to have served as your Chairman since June.

### **Louis Schweitzer and David Brennan**

The day of the AGM was, by any measure, an historic one for your Company. It was the day on which David Brennan announced his decision to retire from AstraZeneca as your Chief Executive Officer. It was also the day on which your previous Chairman, Louis Schweitzer, brought forward the date of his intended retirement to 1 June to coincide with that of David.

Louis had been a Director since 2004 and your Chairman for seven years. During that time he worked tirelessly to ensure that the Board was effective in its task of setting our strategy and overseeing its implementation. We are grateful to him for his efforts on your behalf.

As Chief Executive Officer, David led AstraZeneca with skill, integrity and courage during a period of enormous change for the industry and for the Company in particular. I would like to thank David for his selfless leadership during his six years at the helm.

### **Non-Executive changes**

Part of the strength of any board comes from refreshing and renewing the mix of people sitting around the boardroom table. When I joined the Board, I was pleased that both Graham Chipchase and Geneviève Berger also became Non-Executive Directors. They bring, respectively, in-depth financial and scientific expertise, as well as significant international business experience to our discussions.

Also in April 2012, we said farewell to Michele Hooper who stood down from the Board. We are all grateful for her distinguished contribution to our work and her dedicated service as Chairman of the Audit Committee and senior independent Non-Executive Director. In her place, John Varley took over as senior independent Non-Executive Director and Rudy Markham became Chairman of the Audit Committee.

### A new Chief Executive Officer

Upon my election to the Board I was also appointed Chairman of the Nomination Committee. This enabled me to lead the important process of selecting David Brennan's successor. This was a process that included both internal and external candidates and culminated in the appointment of Pascal Soriot to the Board as the Company's Chief Executive Officer on 1 October.

Pascal joined us from Roche where he had been serving as Chief Operating Officer of the company's pharmaceuticals division. His was a key appointment at an important time for AstraZeneca. The Board is certain that Pascal's leadership qualities, combined with his strategic thinking and extensive

experience in the industry, make him the right person to drive AstraZeneca to success over the coming years. I am confident that Pascal's approach and his track record of delivering results in innovation-driven businesses will be valued by shareholders and employees alike.

Following David's departure, Simon Lowth acted as Interim Chief Executive Officer. The Board and I would like to record our appreciation for his impressive leadership in this period. Supported by a highly capable and committed executive team, Simon maintained the organisation's focus on key business priorities during a period of significant change.

### Sound governance

All the changes I have outlined took place at the same time as AstraZeneca completed a record number of business development deals. We also undertook our annual strategic review, in which Pascal has been fully involved, as well as our regular programme of meetings and business activity. That we have been able to do all this is a tribute both to the sound corporate governance processes we have in place and to the dedication and hard work of my fellow Directors. I am grateful to all of them for the contribution they made in 2012.

### **Challenging times**

We will need to harness all our skills, capabilities and experience if we are to successfully navigate the current harsh climate for the pharmaceutical sector. The world pharmaceutical market is still growing and underlying demographic trends remain favourable to long-term industry growth. However, many of the drivers of demand and supply in the industry are under pressure.

"2012 financial performance was defined by significant revenue decline associated with the loss of exclusivity for several products.

# For 2013, challenging market conditions will persist."

On the demand side, we face increased competition from generic medicines as some of the world's most successful drugs come off patent. In addition, securing recognition (through reimbursement approval) and reward (through favourable pricing and sales) for innovation is becoming more difficult in the face of intensifying pricing pressures, particularly in Established Markets facing rising healthcare costs. On the supply side, the industry faces an ongoing R&D productivity challenge. R&D costs have risen significantly over the past decade, while industry-wide probability of success continues to decline.

### Strategic focus

It is for the reasons outlined above that the outcome of our current strategic review is so important. Our strategy is rooted in our heritage as a company focused on innovative science to deliver great medicines to patients. I firmly believe that it is the path we need to take if we are to remain competitive and return to growth. That path must also include a commitment to the responsible and sustainable development of our business. That is why I was so pleased that we were once again listed in the Dow Jones Sustainability World Index in 2012 and retained our listing on the European Index for the fifth year running.

### Financial performance

We cannot hope to secure our long-term success if we do not meet our financial targets and deliver acceptable levels of return to our owners. Group sales in 2012 were down 15% to \$27,973 million (2011: \$33,591 million) and Reported operating profit was down 34% at \$8,148 million (2011: \$12,795 million). Revenue in the US was down 21% while revenue outside the US was down 11%.

More than 13 percentage points of the revenue decline, approximately \$4.5 billion, was related to loss of exclusivity on several brands in the portfolio. Seroquel IR alone declined by more than \$3 billion, while regional losses of exclusivity for Atacand, Nexium and Crestor accounted for more than \$1 billion. Additionally, the disposals of Astra Tech and Aptium accounted for around 1.7 percentage points of the decline. On the other hand, taken together, Symbicort, Faslodex, Onglyza, Iressa, Brilinta/Brilique and Seroquel XR accounted for more than \$600 million of revenue growth. Additionally, our diabetes alliance with BMS is strengthened by the inclusion of the Amylin portfolio and the approval of Forxiga in Europe.

Reported earnings per share were down 29% to \$4.99. The decline reflects the \$1.08 per share benefit in 2011 from the sale of Astra Tech and higher restructuring costs in 2012.

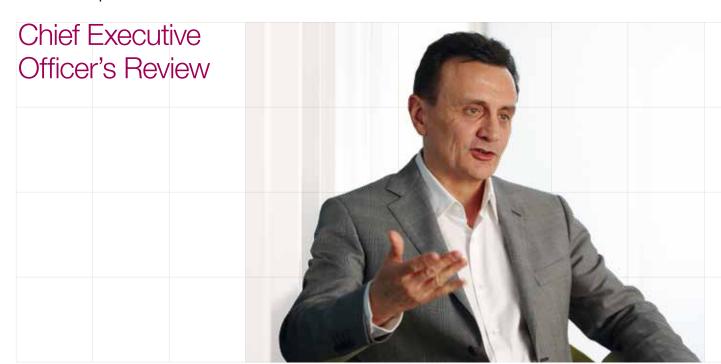
### **Returns to shareholders**

Consistent with our progressive dividend policy, the Board has recommended a second interim dividend of \$1.90. This brings the dividend for the full year to \$2.80 (178.6 pence, SEK 18.34). In 2012, cash distributions to shareholders through dividends totalled \$3,665 million and net share repurchases totalled \$2,206 million. In October, we announced the suspension of our share repurchase programme for 2012 and the Board has decided that no share repurchases will take place in 2013 in order to maintain the flexibility to invest in the business.

### Outlook

We believe challenging market conditions will persist in 2013, including continued government interventions in price. The revenue impact from the loss of exclusivity will also continue to affect our performance. In the context of the ongoing update to our strategy, we have withdrawn the planning assumptions for revenue and margin evolution for the period 2010 to 2014 we outlined in January 2010. We plan to hold a Capital Markets Day in March 2013 to provide a more detailed exposition of our strategic priorities.

Leif Johansson Chairman



I am both excited and honoured to have been asked to lead AstraZeneca. Throughout my career I have had enormous respect for its people and what they have achieved. Since joining in October, I have seen for myself the passion and commitment that exists within the Group to improve the lives of patients around the world.

This level of energy should come as no surprise as our innovative medicines mean that more people than ever before are able to lead longer and healthier lives. As we seek to show throughout this Annual Report, successful pharmaceutical innovation, delivered responsibly, adds value not only for patients and shareholders but also for healthcare systems and the communities in which we work.

### The challenge

Leif has already described in his Chairman's Statement how, in addition to the well-known challenges that confront the pharmaceutical sector, the loss of exclusivity of several of our major brands largely defined AstraZeneca's financial performance in 2012. I believe that our ability to provide an acceptable level of return to you in the years ahead will come from an undiluted focus on delivering great medicines to patients through innovative science and global excellence in development and commercialisation. Underpinning that focus are three priorities: achieving scientific leadership, returning AstraZeneca to growth and making it a great place to work.

In the Strategy section from page 12 of this Annual Report, we talk more about the background to our strategy and the review we are undertaking. For the rest of my Review I want to look at the progress we made towards our goals in 2012, as well as consider some of the setbacks we encountered.

### Scientific leadership

In a research and development-based business such as AstraZeneca, I believe that everything starts with a focus on patients and great science. It is our first priority.

AstraZeneca has a unique combination of scientific capabilities in small molecules, biologics, immunotherapies and antibody engineering. This puts us in a strong position to develop the targeted novel medicines and combinations (such as drug-antibody conjugates) required to meet patient needs in the future. Reviews that we have held with scientific experts outside AstraZeneca have further reinforced my confidence in our underlying science base.

We have much to do to realise our full scientific potential but made some progress in 2012. On the regulatory front, we received approvals in Europe for *Zinforo*, our intravenous antibiotic, *Caprelsa*, our thyroid cancer treatment, and *Forxiga*, a product of our diabetes alliance with BMS. In the US, *FluMist Quadrivalent* was approved, the first four-strain influenza vaccine to be approved by the FDA.

Across the entire pipeline of 84 projects, 39 successfully progressed to the next stage of testing in 2012, including 12 projects into first human testing. Nineteen projects were withdrawn. While we met our target for Phase III investment decisions for the year, we did not meet our value targets for those projects.

To increase the value of our pipeline, we aim to access the best science and molecules regardless of origin. Our portfolio was strengthened during the year by a number of successful business development initiatives. Our collaboration with Amgen encompasses five clinical stage projects in inflammation, including brodalumab, which has already entered Phase III development. In April 2012, we entered into an agreement to acquire Ardea, which added lesinurad, a Phase III project for the treatment of gout, to our portfolio. We also significantly expanded our diabetes alliance with BMS through its acquisition of Amylin.

Overall, we completed a record number of more than 60 important business development deals in 2012 that helped us to strengthen our scientific leadership in key therapeutic areas, expand our pipeline and improve our capabilities. They also helped underpin business growth in both Established and Emerging Markets.

### Return to growth

Our second priority must be to return AstraZeneca to growth. Our performance in 2012 reflected a period of significant patent expiry and tough market conditions globally. Despite the challenges we face, I am excited about AstraZeneca's fundamental strengths, which will be key in returning AstraZeneca to growth.

# "We must focus on delivering great medicines to patients through innovative science and global excellence in development and commercialisation."

Brilinta/Brilique, our treatment for acute coronary syndromes, is now approved in 88 countries and launched in 82. I believe that, while performance since its launch has been disappointing, especially in the US, Brilinta/Brilique has the potential to become a major product for AstraZeneca, given its significant mortality benefits relative to the standard of care. We have moved quickly to improve our sales, marketing and medical support to this important medicine. Early indications from some markets, combined with the favourable profile of this medicine, suggest that we are on the right path.

Taking full advantage of our expanded diabetes alliance with BMS also presents a significant opportunity. With the addition of Amylin products such as *Byetta* and *Bydureon*, we now have treatment options for patients from early stages of Type 2 diabetes to the pre-insulin stage. The launch of the extended portfolio in the US, only a few weeks after we concluded the deal, demonstrates how swiftly we can move to bring a range of treatment options to physicians and their patients.

With our well-established commercial strength, we are in a strong position to bring our medicines to patients in Emerging Markets. Conditions have been tough in Mexico, Brazil and some other markets, but strong growth in countries such as Russia and China shows how much our products are valued in these markets.

### A great place to work

Skilled, committed employees are essential if AstraZeneca is to realise its full potential. Unfortunately, the 2012 global employee survey showed a reduction in the scores in the majority of categories. These scores were disappointing. While they might be regarded as understandable given our challenging environment and the ongoing transformation of the business, my SET colleagues and I are committed to working harder to ensure employees have an improved understanding and confidence in our future direction.

More positively, it was encouraging to see the high level of motivation that exists across AstraZeneca to help us succeed. This was something I witnessed at first hand as I spent time with colleagues on site in the weeks after I joined the organisation. I want to build on this and make AstraZeneca a great place to work – a simplified business that comprises a diverse and talented workforce operating in a high performance culture, which enables us to bring great medicines to patients.

### **Senior Executive Team**

In January 2013, we announced changes to our Senior Executive Team, which were designed to provide sharper management focus, as well as devolving and accelerating decision making. Changes include increased representation of the Company's scientific expertise, product portfolio and key regions. Members of the new SET are shown on pages 108 and 109 and I look forward to working with them all on delivering our strategic goals. As a result

of the changes, two senior roles were eliminated – President of R&D, held by Martin Mackay, and Executive Vice-President, Global Commercial, held by Tony Zook. Both Martin and Tony left their respective roles in January 2013, and I would like to thank them for their contribution and the exemplary leadership they have shown.

### Innovation and growth

In closing, I would like to thank everyone in AstraZeneca for their support and making me feel so welcome. My first three months as Chief Executive Officer confirmed the nature and scale of the challenges we face. Those months also confirmed my view that within the organisation we have both the capabilities and skills necessary to achieve scientific leadership, return to growth and be a great place to work. I am sure that by being true to our mission of bringing innovative medicines to patients we can meet our short- and medium-term goals and thereby deliver our longer term aspirations for the business.

Pascal Soriot
Chief Executive Officer

# Innovation means

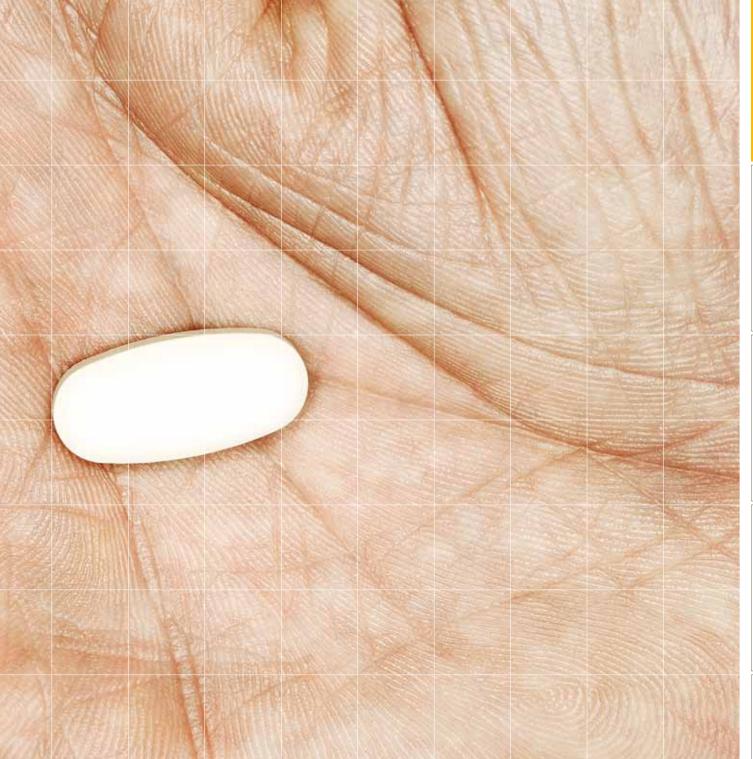


Our innovative medicines are playing a part in increasing survival rates and improving quality of life for patients in important areas of medical need.

For example, *Brilinta/Brilique*, our treatment for acute coronary syndromes, shows a 21% relative reduction in cardiovascular mortality against the current standard of care over a 12 month duration of therapy.

In the UK, the government has announced it is to extend the influenza vaccination programme to all children, recommending use of our nasal spray vaccine, *Fluenz*. Even with moderate vaccination uptake, the UK alone could see around a 40% drop in the number of people affected. That would mean at least 11,000 fewer hospitalisations as a result of influenza and around 2,000 fewer deaths a year.

Innovation is not always about 'breakthrough' discoveries – medical progress can often be delivered just as effectively through incremental improvements.



### Our strategic context

AstraZeneca competes as a global biopharmaceutical business delivering great medicines to patients through innovative science and excellence in development and commercialisation.

### R&D

Creation and acquisition of intellectual property through innovative R&D

Application for patents to protect the intellectual property assets developed in a potential medicine Clinical development programmes to determine safety and efficacy of the potential medicine and generate further intellectual property rights and data for regulatory submissions

In this section, we describe our business model and review the key growth drivers and challenges that the pharmaceutical sector faces.

We then describe AstraZeneca's response to these factors and the ongoing update to our strategy – a strategy that seeks to make a real difference to patient health, deliver long-term value for our shareholders, and add value for our other stakeholders and wider society.

### Our business model

Improving health is one of the toughest challenges facing the world today. Despite all the advances in recent decades, the prevalence of major diseases is on the increase. The world's population is growing and ageing. Health awareness and patients' expectations are rising while healthcare systems everywhere are under pressure. It will take a sustained and significant effort to drive continued progress in healthcare.

As a global biopharmaceutical company, AstraZeneca has a key contribution to make. Our skills and resources are focused on the discovery, development, manufacturing and commercialisation of patent-protected medicines that make a meaningful difference to patients facing some of the world's most serious health challenges: heart disease, diabetes, gastrointestinal disorders, infection,

neurological disorders, cancer, and respiratory and inflammatory conditions. This is the core of our commitment to our stakeholders and society. Successful pharmaceutical innovation, delivered responsibly, improves health for patients, brings benefits to stakeholders and delivers long-term shareholder value.

The process of getting a medicine to market, from initial discovery, through development to approval and launch is risky, costly and time consuming. Of the many thousands of compounds initially analysed, only a few make it through all stages of development. The figure overleaf illustrates the process we follow. Our activities cover the entire life-cycle of a medicine and start with the identification of an unmet medical need, and the scientific search for a potential medicine. The process continues through the phases of clinical trials and drug development, regulatory submission, and a medicine's launch. After launch, our life-cycle management process (including line extensions) is designed to ensure a medicine's continued safe use and to explore its potential for treating other diseases or extending its use into additional patient populations.

As the figure overleaf shows, we work in partnership with others to deliver the highest quality new medicines to market rapidly. For example, we work with those who pay for our medicines and health technology appraisers early on and throughout a

medicine's development to understand where the greatest clinical needs are. As we develop our medicines we gather not only the clinical data required for regulatory approval but also the health economics cost/benefit and 'value-in-use' data required by payers.

An essential element of our business model is the creation and protection of our underlying intellectual property assets. This process is outlined in the diagram above. 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 and for a reasonable period of time. This allows time to generate a return on our investment and to reinvest in new pharmaceutical innovation.

The loss of key product patents has affected a significant proportion of sales in recent years and will continue to do so. A key goal for our planning process is therefore 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.

### Sales and marketing

Period of intellectual property protection for an innovative medicine which allows a return to be made on the investment undertaken Expiry of intellectual property rights and commoditisation of knowledge which typically sees generic versions of a medicine entering a market



### **Distinctive capabilities**

AstraZeneca has clear strengths that allow us to create value for patients and for shareholders:

- > Good underlying science. External opinion leaders confirm that we have strong disease knowledge, research portfolios, and related technology platforms in a number of areas, particularly in oncology, and respiratory and inflammation.
- > Unique scientific capabilities.
  Few pharmaceutical companies in the world, if any, can match the combination of capabilities that we have in small molecules, biologics, immunotherapies and antibody engineering. These capabilities allow us to produce combination therapies (such as drug antibody conjugates and bispecifics) and customisable molecules, both targeted to specific patient populations.
- > Strong therapy area franchises, brands and commercial capability. Over the past decade, we have developed strong commercial franchises that address respiratory, cardiovascular, oncology and neuroscience diseases. We continue to develop these strong therapeutic area positions: for example, *Brilinta/Brilique* and the diabetes portfolio we are commercialising jointly with BMS provide the next phase of development for our cardiovascular and metabolic disease franchise. We have strong commercial capability in developing, marketing and

selling primary care, specialty care-led and specialty care products.

> Strong Emerging Markets presence. We combine global reach with local customer relationships. We do this particularly well in Emerging Markets, where we invested early and where our decentralised approach to sales and marketing has allowed us to develop and act on local customer insight. For example, we are the second largest pharmaceutical company in China by sales.

As we look ahead, the future success of an innovation-driven R&D-based business such as AstraZeneca must be based on the twin foundations of a focus on patients and great science. We are one of only a handful of companies to span the entire life-cycle of a medicine from discovery, early and late-stage development to the global commercialisation of primary care, specialty care-led and specialty care medicines. Using these skills and capabilities we can make a real difference to the health of a broad range of patients in disease areas where there is unmet medical need in more than 100 markets around the world. We also harness these skills and capabilities in partnership with others, such as the relationships we have with BMS and Amgen.

### Health connects us all

We know we cannot deliver on our commitment to improve healthcare on our own. We work closely with others in the healthcare community to understand their needs and challenges, and how we can combine skills and resources to achieve common goals. To be able to do this, people must have confidence in both what we do and how we do it. We know that their trust depends on us acting with integrity and staying true to our core values.

The principles of Courage, Collaboration and Creativity frame our values. They describe what we stand for as a company, and the behaviours we need to demonstrate to achieve our strategic priorities. These values reflect our belief that health connects us all. They guide our actions and shape the culture that underpins our drive for business success.

### Life-cycle of a medicine

We provide medicines that make a real difference in the treatment of some of the world's most serious diseases. The advances made through innovation improve healthcare for more people and make our business model sustainable.

### Increased external collaboration

From the earliest phases in a medicine's development to late-stage or on-market, we work with academia, external clinicians and industry to access the best science. See the Partnering to improve health section from page 31.

### **Customer orientation**

At an early stage we incorporate payer considerations into everything we do to help ensure the economic and therapeutic value of our medicines is understood. See the Driving commercial success section from page 37.

### Operational efficiency

As early as Phase I studies we begin to develop a manufacturing route to ensure the manufacturing process is robust and costs are minimised. See the Supply and Manufacturing section from page 40.







Discovery phase and development phases 10-15 years

### Investment period

**Find potential** 

Identify the unmet

medical need and

research to find a

potential medicine

market opportunity.

Undertake laboratory

that should be potent.

into and well tolerated

Begin the process

of seeking patent protection for the

selective, and absorbed

medicine

Investment in discovery, development and commercialisation of patentprotected medicines.

### **Pre-clinical 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.

### **Phase I studies**

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

### **Phase II studies**

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

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

### 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 seaments in which the medicine will be used.

by the body.

Yet the discovery, development and commercialisation of a medicine is a risky, long and complex process. This is an overview of the life-cycle of a medicine, which demonstrates our business model in practice.

### **R&D** productivity

We are focused on improving the quality and quantity of our R&D which includes reducing function costs and investing in new talent, critical capabilities, as well as partnerships and deals. See the Research and Development section from page 30.

### Global orientation

We are building on our leading position in commercialising medicines in Established Markets by using new sales channels and pursuing further growth in Emerging Markets. See the Sales and Marketing section from page 37.

Note: This is a high level overview of the process and is illustrative only. It is neither intended to, nor does it, represent the life-cycle of any particular medicine or of every medicine discovered and/or developed by AstraZeneca, or the probability of success or approval of any AstraZeneca medicine. For more information see the Research and Development section from page 30.





Launch phase 5-10 years

20+ years

### Returns period

Reinvestment of returns from period of patent protection into next generation of innovative medicines.

### **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 a medicine to regulatory authorities. They decide whether to grant marketing authorisation based on the medicine's safety profile, effectiveness and quality.

### Launch new medicine

Raise awareness of patient benefit and appropriate use.

Clinicians begin to prescribe medicine and patients begin to benefit.

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

### Post-launch research

and development Studies to further understand

the safety profile of the medicine in larger populations.

Work 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.

### Patent expiry and generic entry

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

Additional Information

### Strategy | Our industry



### Our industry

### Introduction

The pharmaceutical industry has doubled in value since 2000, driven by a large number of FDA approvals in the second half of the 1990s and by the increased use of medicines around the world in the wake of global economic growth in that period. Now, many of the drivers of demand and supply in the industry are under pressure.

Nonetheless, as the figure above shows, the world pharmaceutical market grew by 2.5% in 2012. Average revenue growth in Established Markets was 1.5% while that in Emerging Markets was over seven times higher at 11.1%. The top five pharmaceutical markets in the world remained the US, Japan, Germany, France and China, with the US representing 39.3% of global pharmaceutical sales (2011: 38.1%).

On the demand side, underlying demographic trends remain favourable to long-term industry growth. These are outlined below. However, securing recognition (through reimbursement approval) and reward (through favourable pricing and sales) for innovation is becoming more difficult, as there are intensifying pricing pressures, particularly in Established Markets which are facing rising healthcare costs. Our challenge is to work with governments and other payers to ensure they understand the value of pharmaceutical innovation in order for us to achieve adequate commercial returns on our investment. We also face increased competition from generic medicines as some of the world's most successful drugs come off patent. Finally, greater regulatory constraints are being placed on the pharmaceutical industry by governments and those who pay for medicines.

On the supply side, the industry faces an ongoing and significant R&D productivity challenge. R&D costs have risen significantly over the past decade, while industry-wide probability of success from pre-clinical to launch continues to decline. For example, the median large pharmaceutical company success rate for 2007 to 2011 in delivering a compound from pre-clinical studies to launch was 2%. These factors are considered in more detail below.

The industry remains highly competitive. Our competitors are other large researchbased pharmaceutical companies that discover, 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, while some companies have pursued a focused strategy, others have diversified 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.

While most companies continued to pursue their existing strategies in 2012, there were exceptions with some companies moving away from diversification. Key trends across the industry included ongoing efforts to improve R&D innovation and productivity, expansion of geographic scope, especially in Emerging Markets and Japan, and the pursuit of operational efficiency. There was an increase in business development and partnering at all stages of product development, with a continued increase in peer collaboration.

### Growth drivers

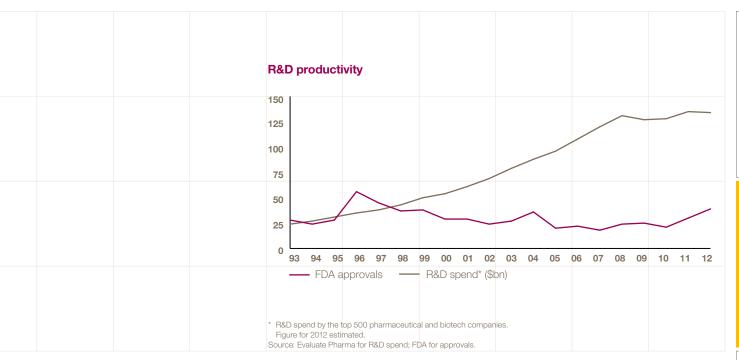
### **Expanding patient populations**

The world population is expected to rise from its current level of some seven billion and 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 between 2000 and 2050, the number of people aged 60 years and over will increase from 605 million to two billion.

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. Developing markets now represent approximately 85% of the world population and over 22% of the world's pharmaceutical revenues. Pharmaceutical revenues in those markets therefore continued to grow faster than those in Established Markets in 2012. As the Estimated pharmaceutical market growth 2011-2016 figure on page 20 shows, we expect this trend will continue.

### Unmet medical need

In most developed markets, ageing populations and certain lifestyle choices such as smoking, a poor diet and lack of exercise drive an increased incidence of non-communicable diseases (NCDs) such as cancer, cardiovascular/metabolic and respiratory diseases which require long-term management. In 2008, almost two-thirds of deaths globally were from NCDs and 80% of those were in lower and middle income countries. For example, in South Asia it is estimated that deaths from NCDs will increase from half to almost three-quarters of all deaths between 2008 and 2030. It is also estimated that nearly one-third 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.

### Advances in science and technology

Innovation leading to new drugs is critical if we are to address 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 2018 predict that of the world's top 100 pharmaceutical products, 49% of sales will come from biologics. This compares with only 34% in 2011 and 17% in 2004. Most pharmaceutical companies now pursue R&D in both small molecules and biologics.

### The challenges R&D productivity

Improving R&D productivity is a critical challenge for the pharmaceutical industry. As shown in the diagram above, global investment in pharmaceutical R&D reached an estimated \$134 billion in 2012, a 94% increase from \$69 billion in 2002. However, the annual growth in R&D spend has slowed in recent years.

The number of new drugs approved by the FDA rose from 30 in 2011 to 39 in 2012. This marks the greatest increase in annual approvals since 2004. However, the average forecast sales from these products five years post-launch is lower than the forecasts for products approved in 2010, reflecting the shift away from broad primary care indications to more specialist drugs.

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 is 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.

The industry is using the full range of innovative technologies to achieve and accelerate product approvals. Additionally, greater emphasis has been placed on demonstrating 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.

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 external partners
- > looking externally for high quality science, technologies, targets, drug candidates, and/or entire drug pipelines.

### Regulatory requirements

Our industry continues to be highly regulated. This reflects public interest in ensuring access to safe, effective and high quality medicines that are responsibly tested, manufactured and commercialised. Given the nature and geographic scope of our business, we maintain important relationships with health authorities worldwide as they assess the safety, efficacy and quality of medicines. These include the FDA in the US, the EMA in the EU, the Japan Pharmaceuticals and Medical Device Agency and the SFDA in China.

In 2012, the US re-authorised the Prescription Drug User Fee Act and the EU continued to implement pharmacovigilance legislation. These measures share the common goals of protecting patient safety, creating greater transparency in the regulatory process throughout a product's life-cycle and taking greater account of the patient perspective in the regulatory process. There is also a global trend, led by the EU, to increase public access to the documentation companies submit to health authorities in support of marketing authorisations.

### Strategy | Our industry

Estimated pharmaceutical sales	- 2016*	
North America \$371.8bn	Latin America <b>\$117bn</b>	Europe (Non EU countries)
Europe (EU countries) <b>\$211.5bn</b>	CIS <b>\$35.5bn</b> Africa	<b>\$21.8bn</b> Middle East <b>\$18bn</b>
South East & East Asia \$194.1bn	\$30.6bn Indian Subcontinent \$29.7bn	Oceania \$16.9bn  * Ex-manufacturer prices at CER. Source: IMS Health.
Japan <b>\$127.4bn</b>		

So far as the development of biosimilars is concerned, health authorities continue to face the challenge of developing robust standards to ensure their safety, effectiveness and quality. For further information on biosimilars, see the Patent expiries and genericisation section below.

Efforts to harmonise regulations globally continue, yet the number of regulations and their impact continue to multiply.

Clinical trials that support the registration of products in a given regulatory jurisdiction must be relevant to a variety of patient demographics. Programmes using foreign clinical trial data also need to meet each individual health authority's requirements and be relevant to their population. Health authorities continue to redefine patient safety assessment processes. In addition, in emerging pharmaceutical markets, health authorities are developing their own individual requirements and safety initiatives.

One impact of the growing complexity and globalisation of clinical studies, and the pressure on industry and healthcare budgets, has been an increase in industry collaborations with health authorities. These are driving innovation and streamlining regulatory processes, as well as defining and clarifying approval requirements for new technology and approaches such as personalised healthcare. They are also accelerating the development of treatments that address public health priorities.

In another trend, health technology assessors and payers are increasingly assessing not only the safety of products but also their relative effectiveness and value. Consequently, there is a heightened interest by health authorities in both comparative clinical effectiveness and the ongoing benefit/risk assessment of medicines after they have been approved. This is resulting in a greater focus on incorporating validated health outcome measures into clinical trials and the development of clinical comparative evidence.

However, it remains the case that when applications are supported by strong data and compelling benefit/risk propositions, regulators are approving drugs that address unmet medical need.

### Pricing pressure

The pricing and reimbursement environment in many markets continues to be highly challenging. Most pharmaceutical sales are 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, including containment of spending on pharmaceuticals, continues to be a focus. A wave of austerity programmes following the current global economic downturn further constrain healthcare providers and tougher economic conditions constrain those patients who pay directly for their medicines. Additional challenges may arise if suppliers and distributors face credit-related difficulties. At the same time, significant extra resources are required by pharmaceutical companies to demonstrate to payers the economic as well as therapeutic value of medicines.

In 2012, pressures on pricing included the implementation of a variety of drug price control mechanisms and other regulatory reforms, as well as the introduction of fixed hospital tariffs which can act as a method of controlling drug costs by incentivising hospitals to choose cheaper generic alternatives over patent-protected medicines.

In the US, the Affordable Care Act has already had a direct impact on healthcare activities despite the fact that many of the healthcare coverage expansion provisions of the Affordable Care Act do not take effect until 2014. For example, in 2010 there was an increase in the mandatory Medicaid rebates. In addition, the pharmaceutical industry, including AstraZeneca, is making prescription drugs more affordable to senior citizens through, for example, helping to close the coverage gap in the Medicare Part D prescription drug programme. The industry continues to work with policymakers and regulators with a view to ensuring that they strike a balance between containing costs, improving outcomes and promoting an environment that fosters medical innovation.

In August 2011, 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 was to take effect on 2 January 2013. Sequestration would have impacted most federal government healthcare programmes with broad reductions in federal government spending. On 3 January 2013, President Barack Obama signed a bill that avoided sequestration. The bill allowed the US Congress and the President an additional two months to address the sequestration challenge. As Congress and the President continue to discuss how to reduce government expenditure, some policymakers may look to the pharmaceutical industry to help achieve the cost savings they seek.

In Europe, governments have issued new legislation on mandatory discounts. clawbacks and referencing rules, driving prices down, especially in the distressed economies of Greece, Portugal and Spain. It has been estimated that in Greece, Ireland, Italy, Portugal and Spain the pharmaceutical industry accommodated price cuts and discounts of more than €7 billion in 2010 and 2011, which amounted to 8% of the industry's turnover in these countries. In Germany, Europe's largest pharmaceutical market, manufacturers are now required to prove the additional benefit of their drugs over existing alternatives. 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.

Elsewhere, in China, the triennial maximum retail drug price review took place in 2012, with more stringent rules being imposed compared with previous rounds of cuts, while in Japan biennial cuts are expected to continue. In Latin America, pricing is increasingly controlled by governments, for example in Colombia and Venezuela.

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 75. The principal aspects of price regulation in our major markets are described further in the Geographical Review from page 70.

### Patent expiries and genericisation

We are in the middle of a period in which 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 access to low price, generic alternatives in many important classes of primary care drugs. For example, in the US in 2012, generics constituted 84% of the market by volume.

Patents only protect pharmaceutical products for a finite period and the expiry or early loss of patents often leads 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. 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 generics 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 and/or availability of this type of settlement agreement.

Biologics have, to date, sustained longer life-cycles than traditional small molecule pharmaceuticals and have faced less generic competition. This is due to a more complex manufacturing process for biologics compared with small molecule medicines. It is also due to the inherent difficulties in producing a biosimilar which, as a biological equivalent, rather than an exact chemical copy, could require additional clinical trials. However, with regulatory authorities in Europe and the US continuing to implement abbreviated approvals pathways for biosimilar versions, innovative biologics are likely to become increasingly subject to competition from biosimilars.

### Strategy | Our strategy

Estimated pharmaceutical market g	growth 2011 to 2016*	
South East & East Asia	Africa <b>10.5%</b>	Europe (Non EU countries)
13.9% Indian Subcontinent 13.3%	Middle East <b>7.5%</b> Japan	2% North America 1.6%
Latin America 13.2% CIS	2.6% Oceania 2.5%	Europe (EU countries) 0.6%
10.5%		* Compound annual growth rate. Source: IMS Health.

### **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.

### Our strategy

AstraZeneca's mission is to make the most meaningful difference to health through great medicines.

Our strategic review has confirmed our belief that biopharmaceuticals remain an attractive business, with strong underlying drivers of demand: expanding and ageing populations, a growing chronic disease burden, and increasing wealth through economic growth, especially in Emerging Markets. While the hurdles to adopting new products have been raised, there remains a willingness to pay for differentiated, innovative medicines.

We further believe that AstraZeneca has the skills and capabilities to take advantage of these opportunities and turn them into long-term value. We will do this by exploiting and further developing our competitive advantage: an innovation and science-led organisation capturing the best of biologics, small molecules, immunotherapies and antibody engineering.

Our revised strategy is to compete as a global biopharmaceutical business delivering great medicines to patients through innovative science and excellence in development and commercialisation:

- > global in that we believe we combine global reach with local customer relationships and have the ability to meet healthcare needs in both developed and developing markets efficiently and effectively
- > biopharmaceutical in that we will develop both chemical (small molecule) and biological (large molecule) medicines available by prescription, targeting those product categories where medical innovation or brand equity will continue to enable us to make acceptable levels of return on our investments

- > innovative science in that we believe that innovative science must be the foundation for procuring differentiated, novel medicines that benefit patients and for which payers will pay
- > excellence in development and commercialisation in that we believe we have strong commercial franchises and capability in developing, marketing and selling primary care, specialty care-led and specialty care products.

We are currently completing the strategic review that we began in 2012. We plan to hold a Capital Markets Day in March 2013 to provide a more detailed exposition of our strategic priorities.

### **Changes to the Senior Executive Team**

In January 2013, we unveiled changes to our Senior Executive Team that came into immediate effect. Membership of the SET has been expanded to include increased representation of AstraZeneca's scientific expertise, key products and key markets. Changes included the creation of:

- > three senior R&D roles responsible for discovery and early-stage development in small molecules; discovery and early-stage development in biologics; and late-stage development
- > three roles representing the commercial regions: North America; Europe; and International.



A further role will be responsible for global portfolio and product strategy, bridging the R&D and sales organisations. An appointment will be made at a later date.

The new SET structure is designed to provide sharper management focus on our key pipeline assets, product portfolio and key regions, as well as devolving and accelerating decision making. It draws heavily from the leadership talent within AstraZeneca, with the six new members being internal appointments. The full membership of the SET, together with information about individual members and their responsibilities, is shown in the Senior Executive Team section on pages 108 and 109.

### Restructuring

Since 2007, we have undertaken significant efforts to restructure and reshape our business to improve long-term competitiveness.

The first phase was completed in 2009.

The second phase, which featured a significant change programme in R&D, began in 2010. The restructuring actions for this phase of the programme were completed in 2011, at a total programme cost of \$2.1 billion. Headcount changes associated with this phase, involving an estimated 9,000 positions, were also completed. Total annual benefits of \$1.9 billion were to be delivered by the end of 2014 in connection with this phase of the programme, of which \$1.5 billion had been achieved by the end of 2012.

A third phase of restructuring was announced in February 2012. This phase, comprising initiatives across the supply chain, SG&A and R&D, carries an estimated programme cost of \$2.1 billion (approximately \$1.7 billion in cash costs). Restructuring costs of \$1,558 million associated with this third phase were taken in 2012, together with \$261 million that was charged in the fourth quarter of 2011. Most of the remaining costs of approximately \$300 million will be taken in 2013. To date, actions involving around 6,300 of the estimated 7,300 positions to be impacted in connection with this phase of the programme have been completed. When completed, this phase is expected to deliver an estimated \$1.6 billion in annual benefits by the end of 2014, of which approximately \$350 million was realised by the end

These restructuring programmes have been delivering their targeted benefits, and are designed to continue to provide the headroom to make appropriate investments to drive future growth and value, such as Emerging Markets commercial infrastructure and expansion of our research capabilities in biologics.

### Medium-term planning assumptions

We believe challenging market conditions will persist in 2013, including continued government interventions in price. The revenue impact from the loss of exclusivity will also continue to affect our performance. In the context of the ongoing update to our strategy, we have withdrawn the planning assumptions for revenue and margin evolution for the period 2010 to 2014 that we had outlined in January 2010.

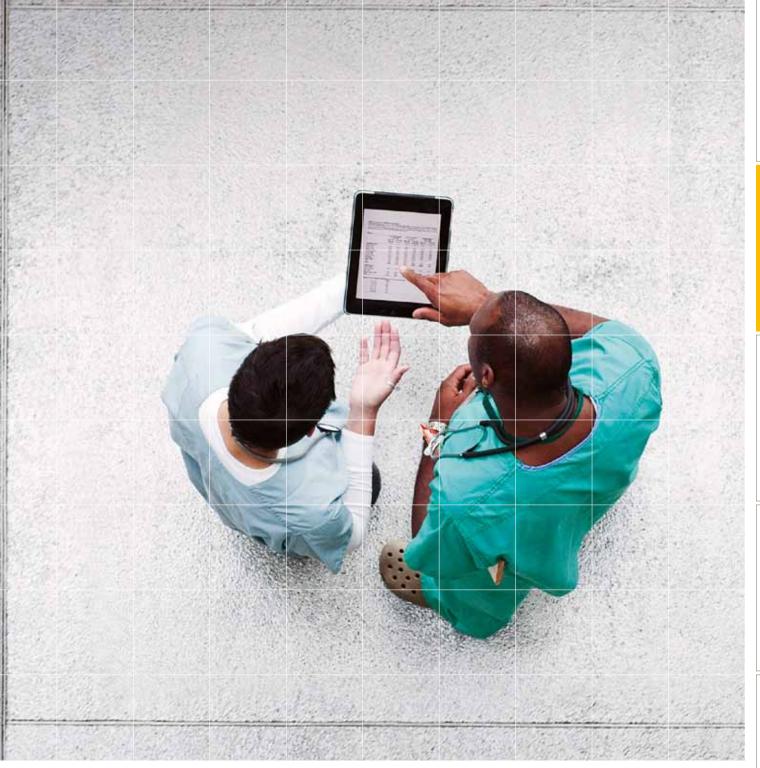
# Innovation means

# enefits for ealthcare s

Healthcare systems around the world are under pressure, working with limited resources to meet the growing demand for healthcare.

Innovative medicines offer benefits that go beyond improving patient outcomes, helping to deliver economic efficiencies and supporting more effective allocation of scarce resources. For example, the introduction of antacid  $H_2$ -receptors followed by proton-pump inhibitors had an almost overnight impact on the cost of surgery by eliminating the need for many gastric operations and follow-up post-operative care. The redundancy of surgical intervention freed up resources to be invested more efficiently elsewhere. The decrease in costs associated with hospital care for cardiovascular diseases is estimated to be almost four times larger than the increase in costs of cardiovascular medicines that deliver improved patient outcomes and overall efficiencies for healthcare systems.

We are working more closely than ever before with the people who pay for healthcare to make sure we can answer their questions about the value of our medicines in delivering better, cost-effective healthcare to patients, including evidence about a medicine's use in the 'real world' once it has been approved.



### Our performance in 2012

In the previous section of this Annual Report, we reviewed our model for creating value, the environment in which we operate and our strategic response, as a global biopharmaceutical business delivering great medicines to patients through innovative science and excellence in development and commercialisation. In this section, we review our progress towards achieving our priorities in 2012.

### Our priorities in 2012

- > Pipeline discovery and development of innovative, differentiated and commercially attractive medicines. We are transforming our R&D organisation to improve productivity and pioneering innovative ways of conducting research. We continue to focus on improving the quantity and quality of R&D output by building industry-leading capabilities in critical areas and being an outward-looking organisation, accessing the best science, regardless of origin.
- > Deliver the business sales and marketing activities focused on the needs of our customers: patients, physicians and payers, and undertaken in the right way. We continue to build on our leading positions in Established Markets, to introduce innovative ways of serving our customers and pursue further growth opportunities in Emerging Markets. We have accelerated our efforts to secure late-stage/on-market product licensing, acquisition and peer collaboration opportunities in order to leverage our global development, resources, and sales and marketing capabilities to bring a broader portfolio of medicines to patients.
- > 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. Given the pressures in the external environment, we continue to simplify the business. Simplification means not only cost reduction, but also streamlining processes and shifting to a more flexible cost base.

- People a talented and diverse workforce with the right capabilities operating in a high performance culture is critical to the successful achievement of our strategic priorities.
- > Responsible business our commitment to enhancing the sustainability of our business by operating responsibly. Our Responsible Business Plan underpins our work and provides the framework for applying integrity and high ethical standards across all our activities.

### 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. Regular reviews are undertaken in order to monitor and assess progress against business and budget targets. During the year we also sought 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 2012 is shown overleaf.

### **Business Review**

This section includes information that fulfils the requirements of a business review under the Companies Act 2006. The Strategy, Corporate Governance, Development Pipeline and Shareholder Information sections from pages 12, 106, 199, and 203, 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 75. 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 disease and the number of individuals who are treated for such a disease.

## Our mission is to make the most meaningful difference to patient health through great medicines

In the remainder of this section, we review our progress in 2012 in terms of:

**Key Performance Indicators** 

P26

how we performed against the indicators by which we measure our success

The resources, capabilities and skills we have within the business and how we use them to ensure a focus on:

Research and Development

the discovery and development

of innovative, differentiated

and commercially attractive

medicines that make a real

difference to the health

of patients

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

Sales and

Marketing

Supply and Manufacturing

> a reliable supply and manufacturing operation that ensures our medicines are where they need to be when they are needed

People

P43

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

Which are supported by:

Intellectual **Property** 

P35

P47

Compliance

Responsible **Business** 

P48

employees acting with integrity a well-functioning system of intellectual property rights

a commitment to acting responsibly and to the sustainable development of our business

Therapy Area Review

our chosen Therapy Areas

Geographical Review

the markets in which we carry out our business

Risk

the risks that might stop us from achieving our strategy and how we manage them

Financial Review

our finances

Our performan	ce in 2012			
These KPIs are subject to review ar	nd changes as part of our ongoing strategy r	eview.		
Priority	KPI	Target		
■ Financial	-			
Met or exceeded targets as a result of disciplined	Revenue	Sustain annual revenues of \$28-\$34 billion		
financial management and	Core pre-R&D operating margin	Sustain Core pre-R&D operating margins of 48%-54%		
lower Reported tax rate	Core EPS	Achieve Core EPS for 2012 in the range \$6.00-\$6.30		
	Reinvestment rate	Reinvest 40%-50% of pre-R&D post-tax cash flows in R&D and capital investments		
	Total shareholder distribution	Provide strong cash returns to shareholders via progressive dividends and periodic share repurchases		
Pipeline				
Major market approvals for Caprelsa, FluMist Quadrivalent, Forxiga, Zinforo	Product approvals	One to two first major market approvals per year that support revenue target for 2014 of \$2-\$4 billion from recent launches, pipeline and in-licensing		
	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		
	Phase III investment decisions	Phase III investment decisions that support value targets for new products		
	Licensing deals/acquisitions	At least 40% of our pipeline sourced from outside our laboratories		
→ Deliver the busin	ess			
Global revenue reduction of 15% largely as a result of loss of exclusivity on <i>Seroquel IR</i> . Key brands grew where we retained exclusivity	Growth of key brands	Drive revenue growth of key brands that retain exclusivity		
	Revenue from new product launches	Revenue in 2014 in the range of \$2-\$4 billion from recent launches, pipeline and in-licensing		
	Emerging Markets sales	25% of revenue in 2014 from Emerging Markets business		

Overview

2011 2012 Commentary \$33,591 million \$27,973 million Missed target by \$27 million, primarily due to adverse exchange rates in 2012 54.2% 53.2% Met target \$7.28 \$6.41 Exceeded target 40% Met target 48% \$2.80 dividend \$2.80 dividend Met target. See the Financial Review from page 86 for more information \$2.2 billion net share repurchases \$5.6 billion net share repurchases Brilinta approved in the US and Marketing authorisation for Caprelsa, We have met our volume target and, with in-licensing, Canada; Caprelsa approved in the US Forxiga and Zinforo granted in the EU; we have built a foundation for new product revenues and positive CHMP opinion in the EU; FluMist Quadrivalent approved by the Axanum approved in the EU; FDA in the US Komboglyze approved in the EU; Fluenz approved in the EU Nexium and Faslodex 500mg Quadrivalent live attenuated influenza On target approved in Japan; dapagliflozin MAA vaccine (MEDI3250) MAA submitted See the Research and Development section from page 30 in September; Nexium OTC and validated by EMA; Complete for more information Response Letter received from the dapagliflozin/metformin IR FDC FDA in the US requesting additional submitted in the EU; Casodex oral clinical data tablet, Nexium Helicobacter pylori, and Arimidex Oral Dispersible Film submitted in Japan Phase III trials started for NKTR-118 Lesinurad entered Phase III clinical On target development following the acquisition and initiation of Phase III programme for CAZ AVI of Ardea. Positive Phase III investment decisions achieved for moxetumomab, and brodalumab 6 out of 9 Phase III/Registration 8 out of 11 Phase III/Registration Met target projects (67%) sourced externally projects (73%) sourced externally 12 out of 24 Phase II projects (50%) 15 out of 25 Phase II projects (60%) sourced externally sourced externally +13% Crestor, +11% Symbicort, -4% Crestor, +5% Symbicort, On target +27% Seroquel XR +4% Seroquel XR Crestor overall +1% in those markets where we retained exclusivity See the Intellectual Property section from page 35 and the Geographical Review from page 70 for more information \$633 million revenue from Onglyza, \$274 million revenue from Onglyza, Meeting this target remains a challenge Vimovo, Brilinta/Brilique, Caprelsa Vimovo, Brilinta/Brilique, Caprelsa, See the Financial Review from page 86 and the Therapy and Axanum Axanum, Zinforo, Bydureon, Byetta Area Review from page 50 for more information and Symlin 17% of revenue from Emerging Markets 21% of revenue from Emerging Markets On target

### Performance | Our performance in 2012 **Target Priority KPI** Business shape Maintain Core gross margin in excess of 80% Met or exceeded targets with Core gross margin continued efficiencies across the organisation Improve cost efficiencies and flexibility Core SG&A costs in Core SG&A costs Procurement savings Procurement savings across all functions Reduced function costs across R&D to support focused R&D cost efficiency R&D portfolio **#** People Achieve global high performing norm rating for employee A decrease in employee Employee engagement engagement by 2014 engagement in the context of a challenging business Leadership communications Further develop our leadership and management environment and the ongoing capabilities transformation of our business Work-life balance Achieve an improvement in the work-life balance of our employees ★ Responsible business Maintained position in the DJSI ranking Maintain position within the DJSI World Index comprising the top 10% of the largest 2,500 companies World Index of the Dow Jones Sustainability Index (DJSI), as Confirmed breaches of external sales Report confirmed breaches of external codes arising from well as the elite European Index external scrutiny and voluntary disclosure by AstraZeneca and marketing codes or regulations Number of audits conducted Expand risk-based programme of responsible procurement audits, across all supplier categories and geographies

Overview

2011	2012	Commentary		
		- · <u> </u>		
82.2%	81.2%	Met target See the Financial Review from page 86 for more information		
1.5% reduction in Core SG&A costs	12.2% reduction in Core SG&A costs	Met target See the Financial Review from page 86 for more information		
Savings of \$487 million	Savings of \$566 million	Exceeded target for 2012 which was \$526 million		
Achieved Core R&D efficiency savings with spend of \$5 billion	A more variable and efficient R&D cost base achieved through accelerated strategy implementation and increased outsourcing	See the Financial Review from page 86 for more information  Met target  See the Research and Development section from page 30 for more information		
84% score	81% score	Meeting this target remains a challenge		
65% score	61% score	Missed target		
67% score	66% score	Missed target  All percentages are the result of our global employee survey (FOCUS), percentage scores are measured on a like-for-like basis using comparable questions/categories from the 201 FOCUS survey		
		See the People section from page 43 for more information		
Top 7% of companies	Top 7% of companies	Met target		
17 confirmed breaches of external sales and marketing regulations or codes globally	10 confirmed breaches of external sales and marketing regulations or codes globally	Met target		
751 audits	482 audits	Audit programme continued. Responsible procurement assessments have been completed on suppliers who account for two-thirds of our spend		
		See the Responsible Business section from page 48 for more information		



### Research and Development

The discovery and development of innovative, differentiated and commercially attractive medicines that make a real difference to the health of patients

"2012 was a productive year for R&D and I look forward to working with the new SET members to improve productivity further in both cost and output, and to build our capabilities in order to restore AstraZeneca to a position of scientific leadership."

Pascal Soriot Chief Executive Officer

4

Four major market approvals – Caprelsa, FluMist Quadrivalent, Forxiga, Zinforo

3

Three positive Phase III investment decisions – lesinurad following the acquisition of Ardea; also moxetumomab and brodalumab

8

Eight out of 11 Phase III/Registration projects (73%) sourced externally

As a research-based biopharmaceutical company, we are committed to applying innovative science and technology to invent, acquire, produce and distribute prescription medicines that make a meaningful difference to people's health around the world. This commitment is at the core of our R&D strategy. It drives our focus to create medicines that are valued by patients and that also recognise the needs of healthcare practitioners, governments, payers and other stakeholders throughout the healthcare system.

We invest in high quality science while developing a learning-based culture which is built on high standards of leadership, ethics and transparency.

### 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.

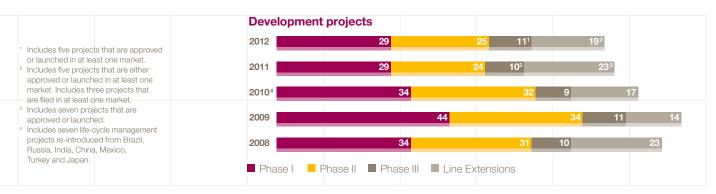
In 2012, we continued our research focus on six Therapy Areas: Cardiovascular, Gastrointestinal, Neuroscience, Infection, Oncology and Respiratory & Inflammation. Early R&D efforts are conducted by our small molecules (Innovative Medicines) and biologics R&D groups, which are responsible for discovery and development up to and including Proof of Concept. Our Global Medicines Development (GMD) organisation progresses products through late-stage development, registration and ongoing post-launch development activities. The GMD organisation provides

a consistent, global platform dedicated to conducting trials for small molecules and biologics. It is accountable for delivering the regulatory packages to support launches of new medicines that have a positive benefit/risk profile 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.

In February 2012, as part of our accelerated R&D strategy, we created a virtual neuroscience Innovative Medicines unit (Virtual iMed) made up of a team of approximately 40 scientists conducting discovery and development externally through a network of partners in academia and industry. The team is based in our major neuroscience hubs - US (Cambridge, Massachusetts) and the UK (Cambridge) and works closely with partners such as the Karolinska Institute in Sweden (Stockholm). The implementation of the Virtual iMed has resulted in the end of R&D activity at two sites that focused on neuroscience: in Sweden (Södertälje) and in Canada (Montreal). For more information about the Virtual iMed please see the Neuroscience section of the Therapy Area Review at page 61.

### **Development pipeline**

Our pipeline includes 84 projects of which 71 are in the clinical phase of development. As shown in the Development projects chart below, we now have a total of 29 projects in Phase I, 25 projects in Phase II, 11 projects in late-stage development, either in Phase III or under regulatory review, and we are running 19 significant life-cycle management projects.



### **Development projects**

During 2012, across the clinical portfolio, 36 projects successfully progressed to their next phase (including 12 projects entering first human testing). The Pipeline delivery table overleaf summarises the milestones for products in development passed in 2012. Ten projects have successfully completed development activities and have now been launched in all relevant major markets. Nineteen projects were withdrawn in 2012. One project was withdrawn following failure to obtain the required regulatory or marketing approvals for the product candidate or the facilities in which it is manufactured and 17 projects were withdrawn following poorer than anticipated safety or efficacy results. One project was withdrawn due to the anticipated completion of the collaboration which supported that project. For more information about our pipeline, including discontinued and completed projects, see the Therapy Area Review and Development Pipeline section from page 50 and page 199 respectively. For information about the risks inherent in the clinical phase of development, please see the Principal risks and uncertainties section from page 75.

### Portfolio quality

Our focus continues to be on identifying key candidate medicines that have the highest potential to deliver technical and commercial success. This includes an annual assessment of our early portfolio projects. 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 quality approach focuses on ensuring that every project in our pipeline has been assessed against a valid biological target, has sufficient exposure to demonstrate an effect on the disease, and has a strong efficacy and safety profile in the intended patient population.

Our Portfolio Investment Board (PIB) plays an important role in maintaining portfolio quality. It continuously evaluates our projects with the goal of maximising the value of our R&D investments. More detail relating to the PIB's responsibilities can be found in the Corporate Governance Report on page 119.

For more information about our pipeline, including discontinued and completed projects, see the Development Pipeline section from page 199.

### Our R&D approach

As demonstrated by the Life-cycle of a medicine diagram on page 14, our R&D activities span the entire life-cycle of a medicine. Our approach brings together drug discoverers and developers within each Therapy Area 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 model is designed to promote accountability and scientific knowledge-sharing within therapeutic areas. In addition, our 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.

### Partnering to improve health

We know that we cannot address the challenges of healthcare alone and scientific innovation does not exist solely within our own research laboratories. By engaging with partners across the healthcare delivery spectrum, we can stimulate more creativity and better develop medicines and solutions for patients. Our collaboration efforts have resulted in a combination of internally and externally sourced compounds throughout our portfolio, which include development partnerships with biotechnology firms, research institutions and other pharmaceutical companies. We aim to source at least 40% of our pipeline from outside our laboratories and we continued to deliver against this KPI in 2012 with external partnerships positively impacting our pipeline including:

- > A collaboration with Amgen to jointly develop and commercialise five monoclonal antibodies from Amgen's clinical inflammation portfolio including brodalumab.
- > The acquisition of Ardea and their Phase III development product candidate, lesinurad, as a potential treatment for the chronic management of hyperuricaemia in patients with gout.

- > An expansion of the diabetes alliance with BMS in connection with BMS's acquisition of Amylin and the potential development and commercialisation of Amylin's portfolio of products related to diabetes and other metabolic diseases, with a primary focus on a franchise of glucagon-like peptide 1 agonists (GLP-1 agonists) for the treatment of Type 2 diabetes. This includes Byetta (exenatide injection) and Bydureon (exenatide extended release for injectable suspension), both of which are approved for use in the US, Europe and Japan, and Symlin (pramlintide acetate), an injected amylin analogue, which is approved in the US.
- > An innovative research alliance that brings four leading academic research laboratories together with AstraZeneca to study a major risk factor for Alzheimer's disease, the apolipoprotein E4 genotype (ApoE).
- > The acquisition of a portfolio of neuroscience assets from Link Medicine Corporation, a privately held biopharmaceutical company developing potential new treatments for a range of neurodegenerative diseases.
- > A collaboration with the diagnostics division of Roche to develop companion diagnostics for selected products in development across all AstraZeneca Therapy Areas.
- > A worldwide exclusive licensing agreement with Ardelyx in respect of their NHE3 inhibitor programme for the treatment of complications associated with end-stage renal disease (ESRD) and chronic kidney disease (CKD).
- > A collaboration with Ironwood to co-develop and co-commercialise linaclotide in China. Linaclotide is a guanylate cyclase-C (GC-C) agonist for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).
- > A collaboration in China with WuXi AppTec to develop and commercialise MEDI5117, a biologic for autoimmune and inflammatory diseases.

### Performance | Business Review

&D spend analysis		
2012	2011	2010
scovery and early development (%) 60	56	73
te-stage development (%) 40	44	27
re R&D costs¹ (\$m) 4,452	5,033	4,219
Reported expenditure in our R&D organisation was \$5.2 billion (2011: \$5.5 billion; 2010: \$5.3 billion).		

### Pipeline delivery

Milestone	Product	2012 Achievement
Key pipeline progressions (Phase III starts and first regulatory filings)	Brodalumab	Phase III programme has commenced for brodalumab in psoriasis.
Major market approvals	Zinforo (ceftaroline fosamil)	European marketing authorisation for <i>Zinforo</i> , a new intravenous cephalosporin antibiotic, for the treatment of adult patients with complicated skin and soft tissue infections (CSSTI) or community acquired pneumonia (CAP).
	Caprelsa (vandetanib)	European marketing authorisation for <i>Caprelsa</i> for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. <i>Caprelsa</i> is the first approved treatment for advanced MTC in Europe.
	FluMist Quadrivalent (influenza vaccine live, intra-nasal)	FDA approval for <i>FluMist Quadrivalent</i> in the prevention of influenza. This marks the first four-strain influenza vaccine approved by the FDA.
	Forxiga (dapagliflozin)	European marketing authorisation for Forxiga tablets for the treatment of Type 2 diabetes, as an adjunct to diet and exercise, in combination with other glucose-lowering medicinal products including insulin, and as a monotherapy in metformin intolerant patients.

- > A collaboration with the Cancer Research Institute and the Ludwig Institute for Cancer Research to advance the research of immunotherapy in cancer. Specifically, the research will focus on clinical trials to test novel combinations of immunotherapies, including three investigational MAbs.
- > A strategic alliance with Isis
  Pharmaceuticals, Inc. (Isis) for the
  discovery and development of novel
  generation antisense therapeutics against
  five cancer targets, which includes a
  licence to develop and commercialise
  ISIS-STAT3RX, a drug Isis is currently
  evaluating in an early clinical trial in
  patients with advanced lymphomas.

We continue to search for opportunities to advance science and public health through research collaborations and partnerships. Initiatives that we announced in 2012 include the following:

- > A collaboration with other pharmaceutical and biotechnology companies working alongside public partners in the NewDrugs4BadBugs research programme (part of the European Commission's Action Plan Against the Rising Threats from Antimicrobial Resistance) which is intended to boost the current industry-wide faltering discovery and development of new antibiotics.
- > A collaboration along with six other pharmaceutical companies and four research institutions, working with the Bill & Melinda Gates Foundation, with

- a goal to speed the discovery of essential new treatments for tuberculosis (TB).
- > Formation of a non-profit organisation called TransCelerate BioPharma Inc., along with nine other major pharmaceutical companies, to accelerate the development of new medicines by solving common challenges (initially) related to clinical study execution.
- > Continued activities to meet our commitment to health research through our ongoing efforts with organisations such as the European Innovative Medicines Initiative aimed at improving tools, technologies and methodologies. We have actively shared knowledge through collaborations with the UK Medical Research Council and the World Intellectual Property Organisation (WIPO) for Neglected Tropical Diseases (NTDs). More information concerning NTDs can be found in the Therapy Area Review in the Infection section on page 58.

### Investing in capabilities

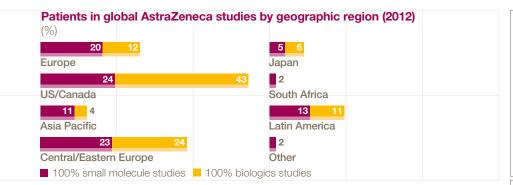
A component of our R&D strategy is strengthening four core capabilities. In 2010, we announced an investment of more than \$200 million over five years to develop capabilities in the areas of payer partnering, personalised healthcare, predictive science and clinical design. We have made significant progress in building these skills both internally and through external collaborations, and they are now fully integrated into most of our development programmes.

### **Our resources**

At the end of 2012, our R&D organisation comprised approximately 9,800 people at 10 principal centres in six countries. In February 2012, we announced an acceleration of our R&D transformation originally announced in 2010. This included initiatives to cease R&D activities at our site in Sweden (Södertälje), and close our laboratories in Canada (Montreal), France (Reims) and the US (Mountain View, California) in 2012. These initiatives have impacted a total of approximately 2,200 positions across the R&D organisation.

Our approach to implementing such change is outlined in the Managing change in our organisation section on page 45. Further details are also set out in the Our strategy section from page 20.

Our current R&D geographic footprint includes four main small molecule facilities in: the UK (Alderley Park and Macclesfield); Sweden (Mölndal); and the US (Waltham, Massachusetts). We also have a clinical development facility in Japan (Osaka). Our principal sites for biologics and vaccines are in the US (Gaithersburg, Maryland) and in the UK (Cambridge). Our Wilmington, Delaware site in the US focuses on latestage development across the entire therapeutic portfolio. Our strategic expansion in Emerging Markets continues and includes the ongoing growth of our research facilities in China (Shanghai) and India (Bangalore).



In 2012, there was Core R&D expenditure of \$4.5 billion in our R&D organisation (2011: \$5 billion; 2010: \$4.2 billion). In addition, \$5,228 million was spent on acquiring product rights (such as in-licensing) (2011: \$189 million; 2010: \$1,017 million) and we invested approximately \$791 million on the implementation of our R&D restructuring strategy. The allocations of spend by early development and late-stage activities are presented in the R&D spend analysis table opposite.

### **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 third parties.

### Clinical trials†

Our commitment: to deliver consistently high standards of ethical practice and scientific conduct in all our trials worldwide and to public transparency on registration and results of all clinical trials, whether positive or negative.

**Our objective:** to be recognised as an industry leader in the publication and sharing of clinical trial information.

We conduct clinical trials at multiple sites in several different countries/regions as shown in the chart above. 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 procedure for gaining informed consent is 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.

All our clinical studies are conceptually designed and finally interpreted in-house but a percentage of them are run for us by contract research organisations (CROs). In 2012, around 31% of patients in our small molecule studies and around 87% of patients in our biologics studies were monitored by CROs on our behalf. We contractually require CROs to work to our global standards and we conduct risk-based audits to monitor compliance.

### Animal research†

**Our commitment:** to embrace, promote and embed scientific and technical best practice in animal research.

Our objective: to drive continuous improvement internally and engage with external providers on the implementation of AstraZeneca global standards for non-human primate housing and care. These include the following targets:

- > roll-out of AstraZeneca Good Statistical Practice (GSP) global standard and associated compliance monitoring
- > more than 80% of external providers of AstraZeneca non-human primate research studies are operating to AstraZeneca standards.

We remain committed to minimising our use of animals in our research without compromising the quality of the research data. 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'. To support our drive for

continuous improvement, we work both within AstraZeneca and the wider scientific community to share the 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 pre-clinical 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 2012, we used approximately 304,000 animals in-house (2011: 381,000). In addition, approximately 14,000 animals were used by external CROs on our behalf (2011: 17,000). Against our 2012 target of more than 80%, 85% of our externally-placed non-human primate studies met AstraZeneca standards in 2012. We will continue to progress towards our 2013 target of 100% of our studies being conducted in facilities meeting AstraZeneca required standards.

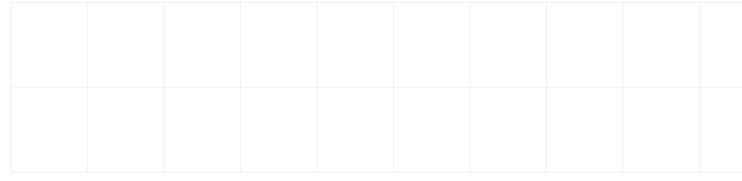
The welfare of the animals we use continues to be a top priority and our Bioethics Policy applies worldwide. We routinely have inspections by government authorities of our internal animal research facilities. External CROs that conduct animal studies on our behalf are required to comply with our global standards and we undertake audits to ensure our expectations are being met.

During 2012, we developed, launched and began implementation of standard operating procedures and guidance documents to underpin our new GSP global standard, developed in 2011. These apply to our internal animal research and the launch included extensive training programmes for relevant scientists, technical staff and managers across the organisation.

† Extract from 2012 Responsible Business Plan.

Further information on AstraZeneca's approach to responsible business can be found in the Responsible Business section from page 48 and on our website, astrazeneca.com/responsibility.

### Performance | Business Review



### Patient safety<sup>†</sup>

**Our commitment:** the safety of the patients who take our medicines is of fundamental importance to us.

Our objective: to enhance pharmacovigilance awareness – including the use of collaborative programmes to share and use our knowledge and best practice in order to improve reporting and patient safety in developing countries.

All drugs have potential side effects and we aim to minimise the risks and maximise the benefits of each of our medicines throughout the whole life-cycle of a medicine. 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 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.

A pharmacovigilance awareness programme was developed in 2012 and circulated to marketing companies, together with guidance about how the information should be shared with regulatory authorities in readiness for external enquiry. One such opportunity arose when SFDA (the Chinese health authority) met UMC (WHO Uppsala Monitoring Centre) and we were able to share our experience and thoughts around signal management.

We have an experienced, in-house team of clinical patient safety professionals 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 Chief Medical Officer has overall accountability for the benefit/risk profiles of the products we have in development and those on the market. He provides medical oversight and ensures that appropriate risk assessment processes are in place to enable informed decisions to be made about safety as quickly as possible.

† Extract from 2012 Responsible Business Plan.

Further information on AstraZeneca's approach to responsible business can be found in the Responsible Business section from page 48 and on our website, astrazeneca.com/responsibility.

### **Clinical trial transparency**

AstraZeneca has a long-standing commitment to making information about our clinical research publicly available to enhance the scientific understanding of how our medicines work and in the medical interest of patients. By the end of 2012, we had registered 2,050 clinical trials and posted the results of 1,360 trials on a range of public websites including our own dedicated clinical trials website, astrazenecaclinicaltrials.com.

We publish information on the registration and results of all new and ongoing AstraZeneca-sponsored clinical trials for all products in all phases, including marketed medicines, drugs in development and drugs whose further development has been discontinued. We post results, irrespective of whether they are favourable or unfavourable to AstraZeneca.

- > Our disclosure policy goes beyond legal requirements, which currently require publication for Phase II studies onwards only.
- > From 15 January 2013, we are voluntarily disclosing the research protocol for our clinical trials on astrazenecaclinicaltrials.com once a manuscript relating to an investigational or approved product is published in a peer-reviewed medical journal.

These disclosure requirements are set out in our Bioethics Policy and compliance is mandatory across the Group.

We consider requests for patient-level data from other parties on a case-by-case basis, following consistent criteria to establish if, and how, the information provided will be used for valid scientific purposes and to benefit patients.

Calls for 'open access' to clinical data raise complex practical, legal and ethical issues around full disclosure of patient information. Decision makers, as well as academia and industry, have a duty to consider all the implications that could arise from such proposals. These include ensuring scientific rigour, safeguarding patient privacy and protecting innovation and medical progress. We are engaging with regulators, legislators, industry, and medical and scientific bodies to discuss the issues raised by the proposals to routinely publish full clinical trial and patient data so we can collectively identify practicable solutions that deliver real benefits to medical science and patients.

Overview

# Intellectual Property A well-functioning system of intellectual property rights

"A period of patent protection is essential in allowing us to achieve a return on our investment in innovation. Our challenge is to refresh our portfolio of patented products and offset the impact when that protection is lost."

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 before product launch. Therefore, we 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 typically 20 years from the 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, when including PTE, cannot exceed 15 years (EU) or 14 years (US) from the first marketing authorisation.

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 75.

# Patent expiries

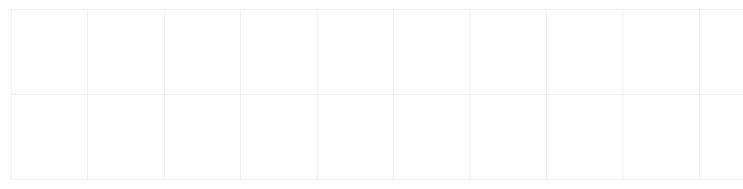
The tables overleaf set out certain patent expiry dates and sales for our key marketed products. The expiry dates relate to the basic substance patent relevant to that product unless indicated otherwise. The expiry dates shown include any PTE and Paediatric Exclusivity periods.

# 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 products, 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

# Performance | Business Review



to secure marketing approval or if patent protection has not been secured, has expired or has been lost, then RDP may be the sole IP right protecting a product from copying, as generics should not be allowed to rely on AstraZeneca's data to support the generic product's approval or marketing until the RDP right has expired.

# **Compulsory licensing**

Compulsory licensing (the over-ruling of patent rights to allow patented medicines to be manufactured and sold by other parties) is increasingly being included in the access to medicines debate. We recognise the right of developing countries to use the flexibilities in the World Trade Organization's Agreement on Trade-Related Aspects of

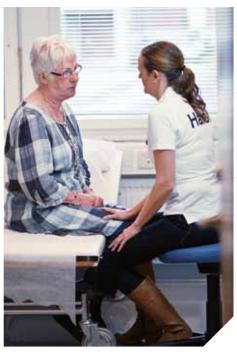
Intellectual Property Rights (TRIPS) (including the Doha amendment) in certain circumstances, such as a public health emergency. We believe that this should apply only when all other ways of meeting the emergency needs have been considered and where healthcare frameworks and safeguards are in place to ensure that the medicines reach those who need them.

### Patent expiries for our key marketed products

		US	revenue (\$m)	
Key marketed products*#	US patent expiry	2012	2011	2010
	Expired	150	182	216
Crestor	2016	3,164	3,074	2,640
Losec/Prilosec	Expired	30	38	47
Nexium	2015 <sup>1</sup>	2,272	2,397	2,695
Pulmicort	2019 <sup>2</sup> ( <i>Respules</i> ) 2018 ( <i>Turbuhaler</i> formulation) 2019 ( <i>Turbuhaler</i> device)	233	279	305
Seloken/Toprol-XL	Expired	320	404	689
Seroquel IR	Expired	697	3,344	3,107
Seroquel XR	2017 (formulation) <sup>3</sup>	811	779	640
Symbicort	2014 (combination), 2023 (formulation), 2026 (pMDI device)	1,003	846	721
Synagis	2015 (composition), 2023 (formulation)	611	570	646
Zoladex	2021 (safety syringe)	24	39	46

				EU, Canada	and Japan rever	iue (\$m)4
Key marketed products*#	EU patent expiry <sup>5</sup>	Canadian patent expiry	Japanese patent expiry	2012	2011	2010
Atacand	Expired	Expired	n/a	463	799	837
Crestor <sup>6</sup>	2017 <sup>7</sup>	Expired	2017	2,090	2,534	2,201
Losec/Prilosec	Expired	Expired	Expired	484	660	660
Nexium	2014	2014	2018 <sup>8</sup>	648	1,042	1,422
Pulmicort	2018 (Respules) 2018 (Turbuhaler formulation)	2018 ( <i>Respules</i> ) 2018 ( <i>Turbuhaler</i> formulation)	2018 (Respules) 2018 (Turbuhaler formulation)	300	344	353
Seloken/Toprol-XL	Expired	Expired	Expired	139	163	169
Seroquel IR	Expired	Expired	Expired	357	651	705
Seroquel XR	2017 (formulation) <sup>9</sup>	2017 (formulation)	n/a	527	562	401
Symbicort	2018 (formulation) 2019 ( <i>Turbuhaler</i> device)	2018 (formulation) 2019 ( <i>Turbuhaler</i> device)	2017 (combination) 2018 (formulation) 2019 ( <i>Turbuhaler</i> device)	1,728	1,822	1,621
Synagis	2015 (composition)	2015 (composition)	2015 (composition)	427	405	392
Zoladex	2021 (safety syringe)	2021 (safety syringe)	2021 (safety syringe)	638	733	718

- \* Patents are or may be challenged by third parties. Generic products may be launched 'at risk' and our patents may be revoked, circumvented or found not to be infringed. See the Principal risks and uncertainties section from page 75. 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.
- <sup>2</sup> Date includes Paediatric Exclusivity. A licence agreement with Teva permits their ongoing sale in the US of a generic version from December 2009.
- <sup>3</sup> Licence agreements with various generics companies allow launches of generic versions of Seroquel XR in the US from 1 November 2016 or earlier upon certain circumstances, subject to regulatory approval.
- Aggregate revenue for the EU, Canada and Japan.
- 5 Expiry in major EU markets.
- <sup>6</sup> Crestor is covered by a range of patents, including substance, formulation and use patents. Crestor patent coverage is not uniform across countries. Granted PTEs mean that a Crestor substance patent remains in force in several major markets after the standard patent term expired in 2012. However, this substance patent is not in force in a number of countries, such as Australia, Brazil, Mexico, Russia and China.
- A substance patent and PTE with expiry in 2017 is in force in most major EU markets.
- Includes PTE. Re-examination period (similar to data exclusivity) ends July 2019.
- 9 AstraZeneca is engaged in numerous patent revocation proceedings regarding Seroquel XR patents and further adverse court rulings, in addition to those seen in Germany and the UK, are possible.



# Sales and Marketing

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

"As anticipated, our performance in 2012 was impacted by a series of patent expiries. I will be working with the new commercial SET members to invest in key growth platforms which are essential if the Group is to return to revenue growth."

Pascal Soriot Chief Executive Officer

\$4.5bn

Some \$4.5 billion of revenue decline was related to loss of exclusivity on several brands in the portfolio, with the largest impact from *Seroquel IR* 

\$600m

Symbicort, Faslodex, Onglyza, Iressa, Brilinta/Brilique and Seroquel XR accounted for more than \$600 million revenue growth

4%

Emerging Markets revenue rose by 4% and included 17% revenue growth in China, offset by weak performance in Mexico, Brazil, Turkey and India If we are to improve the health of patients around the world, we need to ensure that the right medicines are available and help improve access to them. To that end, our global sales and marketing organisation is active in over 100 countries. At the end of 2012, it comprised approximately 30,200 employees. As well as building on our leading positions in commercialising our medicines in the US and Other Established Markets, we continue to increase our ability to serve customers in Emerging Markets including China, Brazil, Mexico and Russia.

We work to ensure success in serving customers in individual markets by having highly accountable local leaders who understand their markets and have a strong focus on business growth. This extensive network is supported by our Global Sales and Marketing 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**

Driving commercial success requires us to maximise the value of our portfolio across the whole life-cycle of a medicine. 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 that customers value and which meet their needs.

For an overview of this process, see the Life-cycle of a medicine diagram on page 14.

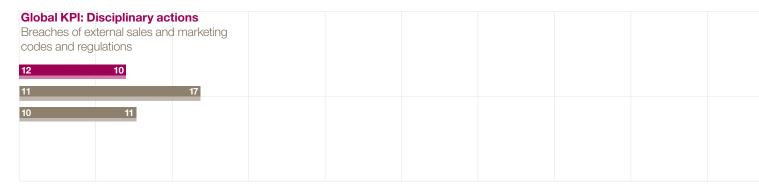
Activities in 2012 focused on ensuring continued commercial excellence of key products in our established patented portfolio, such as Crestor, Seroquel XR and Symbicort, driving growth in developing markets and accelerating the commercialisation of recently launched products. Brilinta/Brilique has now been approved for use in hospitalised ACS patients in 88 countries, is reimbursed in 29, available in 33 patient pay markets and commercially launched in 82. Other recently launched products include Caprelsa, Zinforo and Forxiga. In the US, we also started promotion of Bydureon, Byetta and Symlin, the Amylin diabetes products that are part of our expanded diabetes alliance with BMS.

### Working in partnership

Our commitment to collaboration is outlined in the Partnering to improve health section from page 31. This approach is further evidenced by our global collaboration agreement, announced in April 2012, with The Medicines Company, which has a strong network in interventional cardiology. In May, their salesforce began supporting *Brilinta* in the US, complementing our own efforts.

In August, we entered into an agreement with Pfizer pursuant to which Pfizer acquired the exclusive global rights to market *Nexium* for approved OTC indications. We will continue to manufacture and market the prescription product, as well as supply Pfizer with the OTC product.

# Performance | Business Review



# Global strategies tailored to meet local needs

We focus on developing global strategies tailored to meet local needs and recognise that our commercial capabilities 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. In 2012, this effort included completing the regional consolidation of our Commercial organisation announced in 2011. Our streamlined operating model includes integrating our smaller local marketing companies into area clusters, allowing them to benefit from global resources while staying local and concentrating on meeting local customer needs.

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. Our footprint continues to evolve to reflect declining sales in Established Markets and increasing sales in Emerging Markets. For example, in 2012 we enhanced our presence in Asia with the opening of the Zhangjiang Park Regional Hub Headquarters in Shanghai.

# Changing customer needs

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.

Historically, our commercial model has been based on the use of face-to-face marketing techniques. This is now changing to reflect the changing profile of the prescribers of our medicines. For example, primary care physicians tend to be younger on average than previously, a greater proportion is female, and more work part-time. Primary care physicians want to interact with pharmaceutical companies in different ways. Driven by experience from innovative approaches piloted and implemented in North America and Europe, we have changed the way we work. Improvements include the introduction of office-based sales teams, which include physicians and dedicated customer service staff, and expanded use of digital channels. These selling channels have now been rolled out in more than 30 countries and across a range of products. Evidence to date suggests these channels are appreciated by those who use them and are an efficient and effective way of driving value for our business. We are accelerating the roll-out and adoption of the new model in the majority of markets in which we operate.

### **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 medicines to the patients that need them. Therefore, we work with payers and healthcare providers to understand their priorities and requirements and generate evidence regarding how our products offer value and support costeffective healthcare delivery.

# Increasing access to healthcare<sup>†</sup> Our commitment: to increase access to healthcare for under-served patient populations in a sustainable way.

**Our objective:** to roll-out our access to healthcare strategy within the business and further develop the framework for implementation, including non-financial performance indicators for monitoring our performance across all our initiatives.

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. Increasing that availability and increasing access to healthcare for under-served patient

	Number of pe	
Action taken	2012	201 <sup>-</sup>
Removed from role <sup>1</sup>	188	214
Formal warning	685	570
Guidance and coaching	1,808	97
Total	2,681	1,758

populations in a sustainable way is a significant global challenge and, in March 2012, we announced our access to healthcare strategy to help in that process. The strategy framework is explained on our website, astrazeneca.com/responsibility. It seeks to take account of the different barriers to healthcare around the world and is tailored locally to meet the needs of different patient populations. We are pursuing a range of initiatives, including broadening affordability of our medicines, across these populations to understand what works best and in what context.

During the year, we rolled out our access to healthcare framework within our Global Sales and Marketing Organisation to support further development of our existing approach and to enable us to capture ongoing 'broadening affordability' commercial initiatives. For example, our work to expand patient access to healthcare in countries such as Brazil, Romania and Ukraine continues with a range of different commercial approaches being adopted. In China, we are pursuing our strategy to reach patients in the broader market, beyond the big hospitals in the big cities, by developing new commercial channels for reaching emerging hospitals and community health centres. Best practice will be shared and replicated. In addition, in 2012, we acquired Guangdong BeiKang Pharmaceutical Company Limited, a generics manufacturing company in China which gave us access to a portfolio of injectable medicines used to treat infections. First launches are planned for 2013 and underscore 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. You can read more about our strategy and the access initiatives we have under way on our website, astrazeneca.com.

We are making progress on the development of non-financial indicators for monitoring our performance and these are included in our 2013 Responsible Business Plan.

# Sales and marketing ethics†

**Our commitment:** to deliver consistently high ethical standards of sales and marketing practice worldwide.

**Our objective:** to focus on ensuring compliance with our Ethical Interactions Policy and report on the:

- > number of confirmed breaches of external sales and marketing codes
- > number of instances of failure to meet our standards in the Global Commercial Organisation, including contract staff
- > number of corrective actions for breaches of our Code of Conduct or supporting policies by Commercial employees, including contract staff.

During 2012, we continued to provide training for employees on our global standards that govern the way that we conduct our business around the world. 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 network of nominated signatories who review our promotional materials against all applicable requirements. Additionally, in 2012, audit professionals have conducted compliance audits of a selection of our marketing companies.

As shown in the Global KPI: Disciplinary actions chart opposite, we identified a total of 10 confirmed breaches of external sales and marketing regulations or codes globally in 2012 (17 in 2011). There were 1,932 instances, including contract staff, of failure to comply with AstraZeneca's Code of Conduct and global policies in our Global Commercial Organisation, the majority of which were minor (1,292 in 2011, including external breaches). We believe that the movement in both numbers reflects our enhanced management oversight and compliance monitoring.

As shown in the Corrective actions table above, in relation to these breaches (and it is important to note that a single breach can involve more than one person failing to meet the standards required), we removed 188 people from their role, formally warned 685 people and provided further guidance or coaching on our policies for 1,808 people. The most serious breaches are raised with the Audit Committee.

# 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 selfreporting 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.

† Extract from 2012 Responsible Business Plan.

Further information on AstraZeneca's approach to responsible business can be found in the Responsible Business section from page 48 and on our website, astrazeneca.com/responsibility.



# Supply and Manufacturing

A reliable supply and manufacturing operation that ensures our medicines are where they need to be when they are needed

'The supply of high quality medicines to patients around the world continues to be at the forefront of our strategy. The increasingly challenging regulatory environment, providing access to Emerging Markets and maintaining supply in an increasingly volatile market all represent an opportunity to think about supply to the patient in a more differentiated way."

**David Smith** Executive Vice-President, Operations & IS

81.2%

Sustained Core gross margin in excess of 80%

\$566m

Procurement savings of \$566 million, representing a 7% reduction

\$417m

Capital investment of \$417 million in supply and manufacturing facilities

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. Where efficiencies can be achieved, we continue to consider using outsourced production but our strategy is to retain the final stages of the production cycle in-house. This balance is designed to give us product integrity and quality assurance while affording us cost efficiency and volume flexibility.

We progressed two key production facilities during 2012 in China (Taizhou) and Russia (Vorsino), which will enable us to supply our products to both markets locally. These sites are intended to commence phased commercial production in 2014. The work is led by our global engineering group who put a strong focus on carrying out these projects fully in line with our ethical and safety standards. This work was recognised externally in 2012 with the Shell health, safety, security and environment (HSSE) award for embedding an HSSE culture in our Emerging Markets projects.

# Product quality and supply chain

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.

Notwithstanding our efforts, during 2012 we experienced disruptions to our supply chain resulting from the implementation in February 2012 of an enterprise resource planning IT system in our facilities in Sweden (Södertälje and Gärtuna). This change was

necessary, due to the legacy systems reaching the end of their life-cycle. At launch the implementation encountered some unexpected difficulties and we put in place a team with representatives from different parts of the organisation to manage the situation so that impact on patients would be minimised and markets were kept informed. The underlying problems have now been resolved and production levels returned to normal in September. We estimate that the negative revenue impact for the year resulting from this disruption was approximately 1%.

Supply from our site in India (Bangalore) was also disrupted for a period of time following a voluntary recall of products that we determined did not meet our global quality standards. Remediation actions have been implemented.

### **Continuous improvement**

Lessons learned from the supply chain disruptions in 2012 have been shared across the Group as part of our continuous improvement programme. This programme allows us to improve our systems and minimise the impact of our activities on the environment. We focus on what adds value to our customers and patients, as well as waste elimination. The 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.

Year         internal audits         external audits         geographic region 2012           2012         44         438         Asia Pacific         143           2011         64         687         Europe         182           2010         35         13         Americas         129           Middle East & Africa         28	Supplier aud	its			
2011     64     687     Europe     182       2010     35     13     Americas     129       Middle East & Africa     28	Year				Number of audits by geographic region 2012
2010         35         13         Americas         129           Middle East & Africa         28	2012	44	438	Asia Pacific	143
Middle East & Africa 28	2011	64	687	Europe	182
	2010	35	13	Americas	129
Total 482				Middle East & Africa	28
				Total	482

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, in recent years, have applied them to the whole of our supply chain. This has led to improvements in quality, lead times and overall equipment effectiveness. In 2012, we continued to establish more efficient processes, with experts from our global supply chain organisation providing cross-functional support throughout the business.

# Regulation and compliance

Facilities and processes for manufacturing medicines must observe rigorous standards of quality. They are subject to inspections by regulatory authorities to ensure compliance with prescribed standards. Regulatory 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 44 independent inspections from 22 different regulatory authorities in 2012. 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 and approaches to product registration, both at national and international levels, through our membership of industry associations. For example, in the EU we continue to provide input into the Falsified Medicines Directive, which came into force in January 2013 and starts to take effect in stages from July 2013. We have taken steps to ensure that our supply chains can comply with the Falsified Medicines Directive. In the US, we contributed to debates concerning Supply Chain Security and the prevention of Drug Shortages.

Our supply and manufacturing strategy is based on our commitment to maintaining the highest ethical standards while complying with internal policies, and laws and regulations. We achieve this by placing compliance responsibility with line managers who are supported by dedicated compliance teams. Independent assurance is provided by our GIA function.

# Managing 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.

As part of our overall risk management, we carefully consider the timing of investment with a view to ensuring 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.

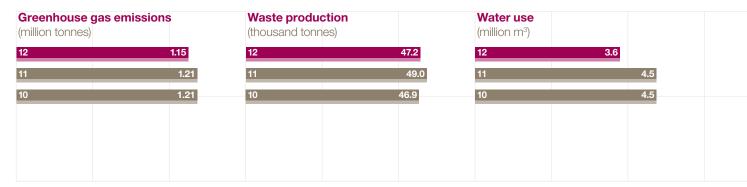
# Our resources

Capital expenditure on supply and manufacturing facilities totalled approximately \$417 million in 2012 (2011: \$388 million; 2010: \$333 million). This included expenditure on two production facilities, in China (Taizhou) and Russia (Vorsino), which will enable us to supply

our products to both markets locally. In addition to these two facilities, our principal small molecule manufacturing facilities are in the UK (Avlon and Macclesfield), Sweden (Snäckviken, Gärtuna, Södertälje), the US (Newark, Delaware and Westborough, Massachusetts), France (Reims and Dunkerque), Japan (Maihara), Australia (North Ryde), China (Wuxi), Indonesia (Jakarta), Egypt (Cairo), India (Bangalore), 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, Australia and the UK.

At the end of 2012, approximately 10,300 people at 22 sites in 16 countries were working on the manufacture and supply of our products. This total includes some 770 permanent and 110 seasonal people who 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.

# Performance | Business Review



# Working with suppliers†

**Our commitment:** to integrate AstraZeneca ethical standards into our procurement activities and decisions worldwide.

Our objective: to monitor compliance through our ongoing assessment and programmes with focus on areas experiencing highest challenges; to address challenges with our suppliers and promote improvement through collaboration.

Our Global Responsible Procurement 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. The process is based on an escalating set of risk-based due diligence activities, applied in a pragmatic way. The same initial assessment process is used for all suppliers and more detailed, focused assessments are then made, relevant to the service provided. Since the programme began in 2009, we have completed 5,661 assessments of new and existing suppliers, which accounts for approximately two-thirds of our spend on suppliers.

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 2012, we continued our audit activity with 482 audits across 52 countries (751 audits in 2011) as set out in the table on the previous page.

Forty-three percent of suppliers audited demonstrated standards that met our expectations, with a further 53% implementing improvements to address minor 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. During 2012, we removed eight suppliers from our supply chain.

# Environmental impact<sup>†</sup>

Our commitment: to minimise the environmental impact of our operations by reducing the carbon footprint and natural resource demands of our own and our suppliers' business activities.

Our targets for 2012<sup>‡</sup> included reducing: > operational greenhouse gas footprint to 890 kilo tonnes CO<sub>2</sub> e/yr

- > hazardous waste to 0.70 tonnes/\$m sales and non-hazardous waste to 0.52 tonnes/employee
- > water use to 4.0 million m<sup>3</sup>.

Our SHE strategy and associated objectives and targets for 2011 to 2015 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 work to reduce our greenhouse gas emissions by, among other things, improving our energy efficiency and pursuing lower-carbon alternatives to fossil fuels at our sites. We strive to ensure 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 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% from our 2011 levels by 2015. In 2012, our gross greenhouse gas emissions (from all sources) totalled 1.15 million tonnes (41 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 from our 2011 levels. 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 2012, our total waste was 47,000 tonnes with a tonnes/\$m index of 1.7.

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% from our 2011 levels by 2015, we now have water conservation plans at our largest sites. In 2012, our water use was 3.6 million m³ with a m³/\$m index of 130.

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 and to its ultimate disposal. Further information is available on our website, astrazeneca.com/responsibility, including environmental risk assessment data for our medicines.

- † Extract from 2012 Responsible Business Plan.
- Further information on AstraZeneca's approach to responsible business can be found in the Responsible Business section from page 48 and on our website, astrazeneca.com/responsibility.
- ‡ The following figures have been revised from those previously published to incorporate our biologics capabilities into our targets.



# People

A talented and diverse workforce with the right capabilities operating in a high performance culture that enables us to bring great medicines to patients

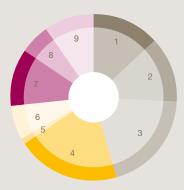
"The reduction in scores in our employee survey was disappointing, if understandable given our business challenges. We must redouble our efforts to make AstraZeneca a great place to work – one that leverages the deep commitment and passion of our people and enables us to operate nimbly, decisively and collaboratively."

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

81%

Engagement score fell by three percentage points to 81%

# **Employees by geographical area** (%)



### EMEA 45.6

- 1 UK 13.1
- 2 Sweden 12.8
- 3 Other EMEA 19.7

### Americas 27.8

- 4 US 20
- 5 Canada 1.2
- 6 Other Americas 6.6

# Asia Pacific 26.6

- 7 China 11.3
- 8 Japan 5.6
  - 9 Other Asia Pacific 9.7

With approximately 51,700 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 that we believe are critical: acquiring and retaining key capabilities and talent; further developing leadership and management capabilities; further improving the strength and diversity of the talent pipeline; and managing employee engagement while building a high performance culture. Managing significant change in the organisation's workforce is also something to which considerable management attention continues to be directed. We use a range of metrics to track progress against these priorities, many of which are reported regularly to the SET.

# Acquiring and retaining key capabilities and talent

During 2012, we hired approximately 5,700 permanent employees to fuel the expansion of our business in Emerging Markets, to continue to build the new capabilities required to implement our strategy successfully and to replace leavers. We have successfully attracted key talent to supplement critical capabilities across the business and to refresh our leadership pipeline in key areas.

With our focus on business growth in Emerging Markets, the composition of our global workforce continued to change, as shown in the Sales and Marketing workforce composition figure overleaf. For example, in 2012, 1,800 of the new recruits joined AstraZeneca in China. We continue to deploy a range of innovative approaches to help us achieve our ambitious growth plans in these markets and to ensure that we have an attractive employer brand and strong reputation globally.

Compared with a level of 6.7% in 2011, the level of voluntary employee turnover across AstraZeneca increased to 7.3% in 2012 and now stands at the average for the pharmaceutical sector. We have continued to invest significant management time to minimise the risks to the business posed by employee turnover, particularly in markets where conditions are most volatile. This has included regular reporting to the SET of resignation rates in total, by SET area and by key markets using the global HR platform being deployed across all markets as part of a transformation of the HR function. In addition, specific steps have been taken to retain key people and talent within our business. For example, regular risk assessments and retention plans are in place in respect of key individuals.

# Performance | Business Review



# 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 AstraZeneca. 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 that 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. We complement our leadership capabilities with a set of manager accountabilities, which define what we expect from our managers. These manager accountabilities are further enabled across all markets through the deployment of our global HR platform.

Alongside judicious hiring of new leaders into critical senior roles, the development of an internal pipeline of future global leaders is a high priority. We identify individuals with the potential for more senior and complex roles. These talent pools provide succession candidates for a range of leadership roles across AstraZeneca. 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.

Changes to the Senior Executive Team announced in January 2013 included the promotion of six internal candidates and demonstrate our commitment to the development of senior leaders.

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<sup>†</sup>

**Our commitment:** to build an inclusive, open and trusting organisation embracing the skills, knowledge and unique ability of our employees.

**Our objective:** to accelerate diversity and inclusion appropriately throughout the business, build accountability and track progress. Our target for 2015 is to improve female representation:

- > at senior manager level and above from 38% (2010) to 43% (2015)
- > in the global talent pool from 33% (2010) to 38% (2015).

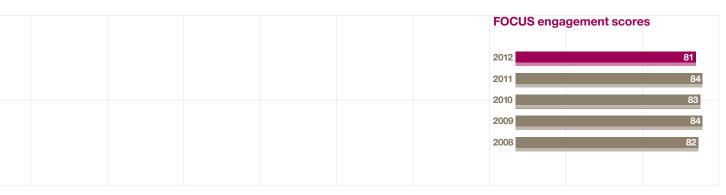
Our global workforce provides a diversity of skills, capabilities and creativity, and we value the benefits that such diversity brings to our business. We aim to foster a culture of respect and fairness where individual success depends solely on ability, behaviour, work performance and demonstrated potential. As we continue to reshape our organisation and geographic footprint, our 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. Within this context, we support the representation of women at the highest

levels in our business. Women make up 50% of our global workforce, giving us a real opportunity to develop female leaders. Indeed, there are currently three women on our Board (25%) and, below Board level, women account for 40% of senior management.

Under the leadership of a global Diversity & Inclusion steering group chaired by a member of the SET and comprising senior leaders from across the business and geographies, we are driving change in three key areas: 'leadership & management capability'; 'transparency in talent management & career progression'; and 'work-life challenges'. In March 2012, we launched our Global Insight Exchange programme as a direct result of the work of the steering group. This programme, which consists of peer-to-peer mentoring of over 30 'learning pairs' of identified talent from different functional areas and geographies within our organisation, is designed to accelerate the development of our leadership culture and talent pipeline through the exchange of diversity of thought and experience. In addition, we track gender representation at different levels of the organisation and country of origin representation of our senior leaders to measure progress over the medium term.

### **Driving employee engagement**

We use a variety of global leadership communication 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 third year in a row our annual global employee survey (FOCUS) included an open text feedback mechanism, with around 25,000 comments made on a variety of topics.



In 2012, 91% of our employees participated in the survey, which measures levels of employee engagement and considers the effectiveness of our organisational, leadership and management capabilities, and satisfaction in terms of employees' working environment. Our employee engagement score decreased by three percentage points this year and our leadership communications and work-life balance scores also decreased. The survey took place at a challenging time for the Group and the scores were disappointing. We remained ahead of external pharmaceutical industry norms in areas such as motivation, willingness to put in more effort than would normally be expected, line management, and operating with integrity and ethics. However, we recognise that we have more work to do in important areas, such as strategic understanding and reducing organisational complexity, to ensure AstraZeneca is a great place to work. Local leadership teams have also identified actions designed to target any concerns specific to their organisational area.

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 111). Managers across AstraZeneca are accountable for working with their teams to develop individual and team performance targets, and for ensuring that employees 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 performance-related bonus and incentive plans. AstraZeneca also encourages employee share ownership by offering the opportunity to participate in various employee share plans, some of which are described in the Directors' Remuneration Report from page 122 and also in Note 24 to the Financial Statements from page 179.

### Human rights<sup>†</sup>

**Our commitment:** to respect and promote international human rights in our operations and our sphere of influence.

**Our objective:** to ensure that human rights considerations are appropriately integrated into our policies, processes and practices.

As reported in 2011, we have carried out labour reviews in 106 countries in which we have employees. The reviews focused on International Labour Organization (ILO) core areas, including freedom of association and collective bargaining, child labour, discrimination, working hours and wages. The framework for the review was provided by an adaptation of the employment section of the Danish Institute for Human Rights assessment tool for pharmaceutical companies, which was developed with our industry's help and launched in 2010. Results showed that our practices are generally consistent across all countries, based on our mandate that our global standards are applied when external national standards do not meet our minimum requirements. Some gaps to ILO standards have been identified and are being addressed as part of the review of our Global People Policy, which is planned for 2014.

# Managing change

Recruitment in our Emerging Markets continues to be accompanied by headcount reductions in our Established Markets 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. The net effect of these changes since the end of 2006 has been to reduce our total headcount by some 15,100 from 66,800 to 51,700. This decrease includes a reduction of 2,600 positions in 2010, 5,000 in 2011 and a further 6,300 in 2012, which resulted from our business change plans announced since 2010.

We are 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. Further details are set out in the Our strategy section from page 20.

† Extract from 2012 Responsible Business Plan.

Further information on AstraZeneca's approach to responsible business can be found in the Responsible Business section from page 48 and on our website, astrazeneca.com/responsibility.

# Performance | Business Review

Vehicle collision	s		Lost tin	ne injury/illness	
Year	Collisions/ million km	Target	Year	Lost time injury/illness rate/ million hours worked	Target
2015		5.6	2015		1.91
2012	7.43	7.1	2012	2.01	2.38
2011	8.73	7.7	2011	1.96	2.49

# Managing employee relations

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.

Early in 2012, we implemented our Global Employment Standards, which are linked to our Global People Policy. Our Global Employment Standards serve to provide common and consistent expectations concerning the way in which our employees will be managed globally and cover matters including attendance, employee concerns, flexible working, leaving AstraZeneca, misconduct, performance improvement, redeployment and redundancy, and work-life balance.

### Safety, health and wellbeing<sup>†</sup>

Our commitment: to promote a safe, healthy and energising work environment in which our people, and those from third parties working closely with us, are able to express their talents, drive innovation and improve business performance.

Our targets for 2012 included:

- > 0 fatalities
- > combined lost time injury/illness rate per million hours worked of 2.38
- > 7.1 collisions per million kilometres driven.

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 AstraZeneca business. Driver safety targets are included in regional and local scorecards. Performance is monitored centrally to assess progress and identify areas for improvement. In 2012, we missed our annual target for collisions per million kilometres driven. We remain on track to achieve our 2015 target.

We regret that during 2012, two members of the public were killed in two separate road traffic accidents involving AstraZeneca drivers in Russia and Turkey. Detailed investigations into both accidents have been carried out. For the Russian accident, an action plan was formulated to respond to the findings of the investigation and those actions are being tracked. The investigation report for the Turkish accident, which occurred in October, has not yet been finalised. Learning from the investigations into both accidents will be shared widely across the Group.

In 2012, the lost time injury/illness rate increased by 3% from 2011. However, we remain on track to achieve our 2015 target of a 25% reduction in the lost time injury/illness rate from the 2010 baseline, with an overall 21% reduction achieved so far.

Work-related stress has been a particular focus for us in recent years; in 2012 we achieved a significant (59%) reduction in the number of reportable cases compared to 2011. We are continuing our efforts in this area, using a risk-based approach, including wellbeing risk assessment tools, to identify high-risk areas and target interventions effectively.

Further information on AstraZeneca's approach to responsible business can be found in the Responsible Business section from page 48 and on our website, astrazeneca.com/responsibility.

<sup>†</sup> Extract from 2012 Responsible Business Plan.

Overview

Compliance
Employees acting with integrity

"If people are to have confidence in AstraZeneca, we must be trusted as an organisation. That trust is built on all employees acting with integrity in everything that they do on a daily basis – and feeling able to raise concerns about possible breaches of our Code of Conduct and our Global Policies."

Katarina Ageborg Chief Compliance Officer

Our Global Compliance function has been established to drive and embed a culture of ethics and integrity within our organisation.

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
- > providing key stakeholders with assurance and effective reporting of material issues.

These priorities are closely aligned to the Group's strategy and reflect our drive to strengthen our efforts for oversight at all levels of our business, including risk management relating to external parties and anti-bribery/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. In March 2012, we created a Group Compliance Council, with membership drawn from Global Compliance and from the other specialist compliance functions, whose purpose is to co-ordinate our compliance activities.

When a potential compliance breach is identified, an internal investigation is undertaken by appropriate staff from our Global Compliance, HR and/or Legal teams. When appropriate, external advisers are engaged to conduct and/or advise on investigations. Should the investigation conclude that an actual 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 110.

### **Code of Conduct**

Our Code of Conduct (the Code) is at the core of our compliance programme and applies worldwide to all full- and part-time AstraZeneca Directors, officers, employees and temporary staff. It has been translated into over 40 languages and each employee has access to an electronic copy. It provides clear direction as to how our commitment to honesty and integrity is to be realised in consistent actions across all areas of the business. Compliance with the Code is mandatory and every employee receives training on it. 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. The Code is regularly reviewed and updated to take account of 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 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 them and report the outcome of such investigations to the Audit Committee, as appropriate.

In 2012, 194 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 2011, the number of reports through equivalent channels was 222. This decrease is in the context of a significant increase in management and 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 HR, Legal or Compliance, as recommended in the Code and reinforced in the 2012 Code training.

As with the Code, our Global Policies apply to all companies within 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.



# Responsible Business

A commitment to acting responsibly and to the sustainable development of our business

"Being a responsible business is not an optional extra. Despite the challenges we face as a business, we remain committed to acting responsibly and our sustainable development. In this way we can continue to be valued for what we do and trusted for the way we do it."

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

In this section, we describe our approach to delivering business success responsibly. Summary information about our commitment and performance in key areas is integrated into the relevant sections of this Annual Report, while further information about these and other areas is available on our website, astrazeneca.com/responsibility.

# Introduction

At AstraZeneca, we are dedicated to the discovery, development and commercialisation of prescription 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, improves health for patients, brings benefits to stakeholders and delivers long-term shareholder value.

In the Strategy section from page 12, we describe our approach to creating value across the life-cycle of a medicine, our distinctive capabilities and our strategy.

All these efforts are underpinned by our commitment to being a responsible company, working with integrity and delivering sustainable business development that adds value for our stakeholders. To that end, our responsible business objectives are aligned to, and support delivery of, our business strategy. Our Responsible Business Plan is our framework for managing our commitments and includes objectives, targets and KPIs that are agreed across the Group, taking account of external stakeholder insights and internal reputational risk assessment. The Responsible Business Plan puts at the top of the agenda those areas most impacted by our business strategy, which are as follows:

- > R&D: Underpinning our accelerated drive for innovation with sound R&D ethics worldwide (see page 33).
- > Patient safety: Maintaining a strong focus on patient safety in everything we do, minimising the risks and maximising the benefits of all our medicines throughout R&D, and after launch (see page 34).
- > Access to healthcare: As we expand our geographic footprint, exploring ways of increasing access to healthcare for more people, tailored locally to different patient needs (see page 38).
- > Sales and marketing: Working to consistent global standards of ethical sales and marketing practices in all our markets as we work to restore growth (see page 39).
- > Diversity and inclusion: Working to ensure that diversity in its broadest sense is reflected in our leadership and people strategies (see page 44).
- > Human rights: Continuing to develop and embed a consistent approach to human rights across all our worldwide activities (see page 45).
- > Employee safety, health and wellbeing: Promoting the safety, health and wellbeing of all our people worldwide as we continue to drive a high performance culture and achievement of our business goals (see page 46).
- > Working with suppliers: Only working with suppliers who have standards consistent with our own as we increase our outsourcing to drive business efficiency (see page 42).
- > The environment: Managing our impact on the environment, across all our operations, with a particular focus on carbon emissions, waste and water use (see page 42).

> Community investment: Making a positive contribution to our local communities around the world, through community support programmes consistent with improving health and promoting science (see page opposite).

A core element of our business strategy is value-creating business development activity that strengthens our pipeline and accelerates growth. This includes targeted acquisitions. When we acquire companies we aim to work with them to align standards of responsible business and incorporate the companies into the setting of targets and measurement of performance. This process can take time. Thus, for example, responsible business data relating to Ardea, acquired in June, is not incorporated in this Annual Report.

# **Benchmarking**

As expectations of stakeholders evolve, we continue to engage with them and use the feedback to inform the development of our responsible business strategy and risk management planning.

We also 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, we were once again listed in the 2012 World Index (the top 10% of the largest 2,500 companies). We also retained our listing on the DJSI STOXX - European index (the top 20% of the 600 largest European companies) for the fifth year running (one of only four pharmaceutical companies to do so out of 14 assessed). We achieved a total score of 83% (2011: 85%) compared with a sector best score of 87% (2011: 87%). We increased individual scores for nine out of 22 criteria for 2012 (compared to 14 out

Overview

of 23 criteria in 2011) including marketing practices, supply chain management and human capital development. While these scores are encouraging, we lost ground in some areas including innovation management and health outcomes contribution. To better understand these lower scores, we commissioned an in-depth external benchmark survey and the analysis will be used to inform our improvement planning.

# Responsible business governance

The Board is responsible for our responsible business framework and Non-Executive Director, 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.

Our Responsible Business Council (the Council) is chaired by our Executive Vice-President of Human Resources & Corporate Affairs, and members include senior leaders from each relevant SET area. Its 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
- > managing and monitoring the annual process of setting responsible business objectives and targets recorded in the Responsible Business Plan, as well as reviewing performance against KPIs
- > appropriate policy positions to support AstraZeneca's business objectives and reputation management.

The Council is supported by a Responsible Business Working Group (the Working Group) of SET area representatives. 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.

### **External assurance**

Bureau Veritas has provided external assurance on the responsible business information contained within this Annual Report on pages 33-34, 38-39, 42, 44-46 and below, and of the performance related content of the Responsibility section of our website. Based on the evidence provided and subject to the scope, objectives and limitations defined in the full assurance statement, nothing has come to the attention of Bureau Veritas causing them to believe that the responsible business information included within this Annual Report is materially misstated. The full assurance statement, which contains detailed scope, methodology, overall opinion and recommendations can be found on our website, astrazeneca.com/responsibility. 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.

### Community investment<sup>†</sup>

Our commitment: to meet our responsibility as a global corporation to support the wider community, maximising the benefit of our investment for all stakeholders, through focused investment and by embracing current best practice.

Our objective: to extend the geographic reach of our Young Health Programme (YHP). Our target was to have 15 YHP country programmes running by the end of 2012 with a total target reach of 500,000 adolescents by 2015.

In 2012, we spent a total of \$1.18 billion (2011: \$1.06 billion\*) on community investment 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 \$1.12 billion (2011: \$938 million). We also donated products worth over \$5.8 million, valued at average wholesale price, to charitable organisations Americares and Direct Relief International.

Our global community investment strategy focuses on two key areas, healthcare in the community and science in education. In 2012, we continued to expand our YHP country programme. This 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 currently have 15 country programmes under way around the world.

Through YHP, we have reached over 250,000 young people in communities across five continents with health information. Over 3,000 of these young people have been trained to share this health information with their peers and with the community, and over 2,700 frontline health providers have completed training programmes in adolescent health. We are on track to meet our Clinton Global Initiative commitment to reach 500,000 young people by the end of 2015. Initial findings from the Wellbeing of Adolescents in Vulnerable Environments study being undertaken by Johns Hopkins Bloomberg School of Public Health as part of YHP were presented at the World Health Summit in Berlin, Germany in October. As part of our best practice sharing, our dedicated online resource (younghealthprogrammeYHP.com) enables those working with young people to access information and resources created by the YHP partners.

Our support for science education takes a number of forms. For example, in 2011, we entered a three year partnership with Career Academies UK to support increased participation by 16 to 19-year-olds in Science, Technology, Engineering and Maths (STEM) subjects, with a target that one-third of Career Academies have a STEM theme by the 2014/15 academic year. By the 2012/13 academic year, the proportion was almost one-quarter, representing 48 Career Academies. Our work with Career Academies UK complements the involvement we have had since 2003 with the STEM ambassador programme.

- † Extract from 2012 Responsible Business Plan. Further information on AstraZeneca's approach to responsible business can be found above and on our website, astrazeneca.com/responsibility.
- \* Figures re-stated to correct product donation data capture error in 2011.

# Therapy Area Review

As outlined in the Strategy section from page 12, we are one of only a handful of companies to span the entire life-cycle of a medicine from discovery, early and late-stage development to the global commercialisation of primary, specialty care-led and specialty care medicines.

This process is summarised in the Life-cycle of a medicine diagram on page 14, and in the subsequent Business Review section from page 30, we explore how we apply our resources, skills and capabilities to the various elements of that process in furtherance of our business strategy.

This Therapy Area Review contains information about the six Therapy Areas in which our efforts are focused: Cardiovascular, Gastrointestinal, Infection, Neuroscience, Oncology, and Respiratory & Inflammation. For each research area we review our pipeline from early projects through to launched brands. 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 2012 focus and key developments relating to our marketed medicines and how they are designed to make a meaningful difference for patients. We also report 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.

This Therapy Area Review reflects the range of our activities. This includes the work of our small molecule and biologics groups, responsible for discovery and development projects up to and including Proof of Concept, as well as our Global Medicines Development (GMD) organisation, which progresses products through late-stage development, registration and post-launch development activities. This Therapy Area Review also draws on the expertise of our Commercial organisation which ensures our science is connected with our customers' needs. We embed customer insights into our R&D strategy based on our interactions with healthcare providers, patients, regulators and payers. This approach helps us to prioritise resources and optimise our portfolio, thereby delivering medicines that customers value and which meet their needs. While the focus of this Therapy Area Review is on our key marketed products, many of our other established products are key to certain markets within Emerging Markets and, taken together, represent an important part of AstraZeneca's business.

For a list of all our potential new products and product life-cycle developments, see the Pipeline by Therapy Area table opposite 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 36.

Indications for each product described in this Therapy Area Review may vary from country to country and local prescribing information should be referred to for country-specific indications for any particular product.

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 75.

# **Sales by Therapy Area**

		2012					2010
	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m
Cardiovascular	9,531	(7)	(4)	10,212	9	5	9,403
Gastrointestinal	4,852	(12)	(11)	5,536	(9)	(11)	6,088
Infection and other*	1,715	(8)	(7)	1,856	(15)	(15)	2,176
Neuroscience	3,923	(46)	(44)	7,204	7	5	6,704
Oncology	3,489	(6)	(3)	3,705	(8)	(12)	4,045
Respiratory & Inflammation	4,415	(1)	2	4,468	9	6	4,099
Other businesses**	48	n/m	n/m	610	(19)	(22)	754
Total	27,973	(17)	(15)	33,591	1	(2)	33,269

<sup>\*</sup> Represents all other pharmaceutical product sales that are not in our six Therapy Areas.

<sup>\*\*</sup> Represents sales by Aptium Oncology of \$48m (2011: \$224m; 2010: \$219m) and Astra Tech of \$nil (2011: \$386m; 2010: \$535m). The last portion of Aptium was sold in July. Astra Tech was sold to DENTSPLY International Inc. on 31 August 2011.

Key – showing movements in 2012

- Addition
- No change
- + Progression
- New filing
- Approved/launched

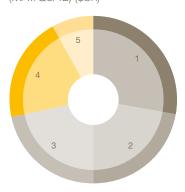
Kombiglyze XR in the US; Komboglyze FDC in the EU.

# Cardiovascular

# \$183.8bn

Wordwide market value

# Therapy area world market (MAT/Q3/12) (\$bn)



- 1 High blood pressure 51.15
- 2 Diabetes 40.97
- 3 Others 39.8
- 4 Abnormal levels of blood cholesterol 37.25
- 5 Thrombosis 14.59

# Our marketed products



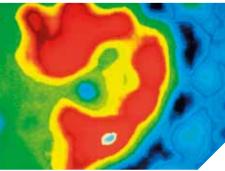
>Atacand<sup>2</sup> (candesartan cilexetil) is an angiotensin II antagonist used for the 1<sup>st</sup> line treatment of hypertension and symptomatic heart failure.

- >**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.
- >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.
- >**Brilinta/Brilique** (ticagrelor) is an oral antiplatelet for the treatment of acute coronary syndromes (ACS).

# Diabetes

- >Forxiga<sup>4</sup> (dapagliflozin) is a selective and reversible inhibitor of human sodium-glucose co-transporter 2 (SGLT2 inhibitor) indicated as an adjunct to diet and exercise as a once daily oral medication to improve glycaemic control in adult patients with Type 2 diabetes mellitus as add on combination therapy or as monotherapy in metformin-intolerant patients.
- >Komboglyze<sup>4</sup> (saxagliptin and metformin HCl) 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>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>4</sup> (saxagliptin) is a DPP-IV inhibitor used for the treatment of Type 2 diabetes.
- >**Byetta**<sup>4</sup> (exenatide injection) is an injectable medicine indicated to improve blood sugar (glucose) control along with diet and exercise in adults with Type 2 diabetes mellitus
- > Bydureon<sup>4</sup> (exenatide extended release injectable suspension) is an injectable medicine indicated to improve blood sugar (glucose) along with diet and exercise in adults with Type 2 diabetes mellitus.
- >**Symlin**<sup>4</sup> (pramlintide acetate) is an injected amylin analogue for the treatment of Type 1 and Type 2 diabetes in patients with inadequate glycaemic control on meal-time insulin.





- <sup>1</sup> Licensed from Shionogi & Co. Ltd.
- <sup>2</sup> Licensed from Takeda Chemicals Industries Ltd.
- Licensed from Merck.
- Co-developed and co-commercialised with BMS.

Our financial pe	rforman	ce													
			World		US		Wester	n Europe		Establisl	ned ROW		Emerging	Markets	Prior year
		Reported growth	CER	Sales	Reported	Sales	Reported	CER	Sales	Reported	CER		Reported	CER	World
2012	\$m	growth %	growth %	\$m	growth %	\$m	growth %	growth %	\$m	growth %	growth %	Sales \$m	growth %	growth %	sales \$m
Crestor	6,253	(6)	(4)	3,164	3	1,156	(6)	2	1,269	(24)	(23)	664	_	4	6,622
Atacand	1,009	(30)	(27)	150	(18)	422	(42)	(39)	142	(33)	(33)	295	(9)	(3)	1,450
Seloken/Toprol-XL	918	(7)	(4)	320	(21)	70	(18)	(12)	30	(21)	(21)	498	8	13	986
Onglyza	323	53	53	237	52	47	38	38	13	86	86	26	86	86	211
Plendil	252	(2)	(2)	4	(50)	18	(22)	(17)	12	(14)	(14)	218	3	2	256
Tenormin	229	(15)	(13)	10	(9)	50	(15)	(8)	106	(15)	(15)	63	(16)	(12)	270
Brilinta/Brilique	89	324	348	19	73	55	n/m	n/m	3	n/m	n/m	12	n/m	n/m	21
Byetta	74	n/m	n/m	74	n/m	-	-	-	-	-	-	-	-	-	_
Bydureon	37	n/m	n/m	37	n/m	_		_					_	_	
Others*	347	(12)	(8)	25	150	157	(17)	(12)	32	(15)	(15)	133	(15)	(12)	396
Total	9,531	(7)	(4)	4,040	5	1,975	(16)	(10)	1,607	(23)	(23)	1,909	-	4	10,212
2011															
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/Toprol-XL	986	(19)	(20)	404	(41)	85	(7)	(12)	38	(3)	(13)	459	17	15	1,210
Onglyza	211	206	206	156	189	34	240	240	7	250	250	14	367	367	69
Plendil	256	_	(4)	8	(47)	23	(15)	(19)	14	_	(7)	211	6	2	255
Tenormin	270	(2)	(8)	11	(15)	59	(3)	(8)	125	(2)	(10)	75	_	(1)	276
Brilinta/Brilique	21	n/m	n/m	11	n/m	9	n/m	n/m	_	_	_	1	n/m	n/m	_
Zestril	144	(8)	(11)	10	_	71	(12)	(16)	14	(18)	(24)	49	_	(2)	157
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

<sup>\*</sup> Includes Zestril

For a detailed narrative explanation of the financial performance of our products please see the Geographical Review from page 70.

AstraZeneca is one of the world leaders in cardiovascular (CV) medicines, working to improve the treatment of diseases that cause 17 million deaths each year.

We aim to build on our strong position, with a particular focus on thrombosis (blood clotting), atherosclerosis (hardening of the arteries), metabolic diseases, and diabetes and its complications. Despite improvements in the quality of diagnosis and treatment, the unmet medical need remains 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.

We are developing potential new therapies using a variety of approaches, including small molecules, antibodies, peptides and proteins, to address unmet medical need 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 ischaemic heart disease. There remains a significant need to improve outcomes and reduce the costs of treating ACS.

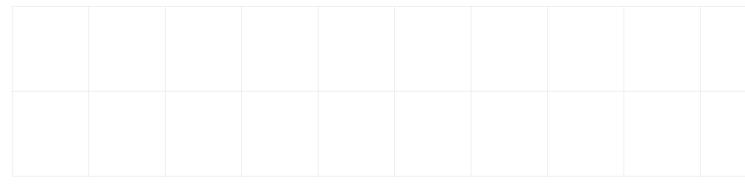
# Our 2012 focus

Globally, *Crestor* has continued to gain market share (by value) since its launch in 2003, 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, and from May several generic atorvastatin products have become available in the market.

Fewer than half the people thought to have high levels of low-density lipoprotein cholesterol (LDL-C) (so-called '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) (so-called 'good cholesterol') across the dose range and has again been shown to reduce atherosclerotic plague in the SATURN study published in 2011.

# Performance | Therapy Area Review



Crestor continues to face increasing challenges from generic products. Patents protecting Crestor have been subject to a number of challenges in different jurisdictions. Details of these matters are included in Note 25 to the Financial Statements from page 184.

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 antihypertensives 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 99 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 high-risk CV patients identified as being at gastrointestinal (GI) risk discontinue or take deliberate breaks from their low-dose ASA and one of the main reasons is GI problems, placing them at risk of a CV event after discontinuation. Following the first national approval in the EU in August 2011, Axanum is now approved in 27 countries and has been launched in 11 countries.

Brilinta/Brilique 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/Brilique remains under regulatory review in 23

countries. It has been approved in 88 countries, including 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 2013.

### **Clinical studies**

GALAXY, is our long-term global clinical research programme for *Crestor* investigating links between optimal lipid control, atherosclerosis and CV morbidity and mortality. The programme has completed over 29 studies involving approximately 64,000 patients in over 57 countries. The ongoing studies in GALAXY and our investigator sponsored studies programme aim to complete our understanding of the product profile for *Crestor*.

PEGASUS-TIMI 54, a 21,000 patient study, is ongoing in over 30 countries. The study examines the ability of *Brilinta/Brilique* plus aspirin to prevent adverse CV events safely compared with aspirin alone in higher-risk patients one to three years after a heart attack.

In July, AstraZeneca announced plans to conduct the EUCLID study, a global clinical trial involving 11,500 patients with peripheral artery disease (PAD), a condition affecting approximately 27 million people in Europe and North America. EUCLID, which began enrolling patients in early 2013, is a randomised, double-blind, parallel group, multi-centre study evaluating the efficacy of *Brilinta/Brilique* (monotherapy) compared to clopidogrel (monotherapy) in reducing the primary endpoint – a composite of CV death, myocardial infarction or ischaemic stroke – in patients with PAD.

Both PEGASUS-TIMI 54 and EUCLID are part of the PARTHENON programme, an AstraZeneca-funded comprehensive, long-term and evolving global research initiative designed to address unanswered questions in atherothrombotic disease and to investigate the impact of *Brilinta/Brilique* on reducing CV events and death. The PARTHENON programme is part of AstraZeneca's commitment to understand and advance treatments for CV diseases in an effort to improve

patient health. The benefit of *Brilinta/Brilique* on CV thrombotic events, including CV mortality, observed in patients who have had an ACS event supports continued study in other areas of CV disease. The current PARTHENON programme is designed to include more than 51,000 patients worldwide.

# **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 and GLP-1 agonists 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 co-transporter 2 (SGLT2). CV safety of these new classes has been given particular emphasis in recent regulatory reviews and guidance documents provided by the FDA and other regulatory authorities.

# Our 2012 focus

AstraZeneca continues its worldwide diabetes alliance with BMS to co-develop and co-commercialise two compounds discovered by BMS: *Onglyza* and *Forxiga* for the treatment of Type 2 diabetes.

Onglyza is a DPP-IV inhibitor used for the treatment of Type 2 diabetes and has been submitted for regulatory review in 94 countries and approved in 81, including the US, Canada, Mexico, the EU, India, Brazil and China.

Forxiga is a first-in-class SGLT2 inhibitor developed with BMS as a once daily oral therapy for the treatment of adult patients with Type 2 diabetes. In November, Forxiga was approved in the EU to improve glycaemic control in adult patients with Type 2 diabetes. Forxiga is intended to be used as an adjunct to diet and exercise in combination with other glucose-lowering medicinal products, including insulin, or

Overview

as a monotherapy in metformin-intolerant patients. With the European approval, *Forxiga* is now approved in 31 countries with six additional countries under regulatory review. Additional submissions are planned for 2013.

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 Forxiga. AstraZeneca and BMS have since had discussions with the FDA, which have resulted in a path forward for NDA resubmission. Additional data from ongoing clinical studies will be submitted to further support the benefit/risk profile of Forxiga with resubmission targeted for mid-2013.

Komboglyze, 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, has been submitted for regulatory review in 34 countries and is approved in the EU plus Norway, Iceland, Liechtenstein, Switzerland and Canada.

Kombiglyze XR, 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, has been submitted for regulatory review in 38 countries and is approved in 17 countries, including the US, Brazil, Mexico and India.

In August, AstraZeneca and BMS confirmed that, following the completion of BMS's acquisition of Amylin, AstraZeneca and BMS had expanded their worldwide diabetes alliance to include the codevelopment and co-commercialisation of Amylin's portfolio of products related to diabetes (and other metabolic diseases) with a primary focus on a franchise of GLP-1 agonists for the treatment of Type 2 diabetes. The products include *Byetta*, *Bydureon* and *Symlin*.

Byetta, a twice daily injectable medicine indicated to improve blood sugar (glucose) control along with diet and exercise in adults with Type 2 diabetes mellitus, has been submitted for regulatory review in 92 countries and approved in 88, including the US, the EU and Japan.

Bydureon, which is a weekly injectable medicine indicated to improve blood sugar (glucose), along with diet and exercise, in adults with Type 2 diabetes mellitus, has been submitted for regulatory review in 51 countries and approved in 39, including the US, the EU and Japan.

Symlin, an injected amylin analogue for the treatment of Type 1 and Type 2 diabetes in patients with inadequate glycaemic control on meal-time insulin, is approved in the US.

During the year, our research activities on anti-arrhythmics to treat atrial fibrillation were terminated.

# In the pipeline

We expanded our CV research to include End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD), with the licensing of an NHE3 inhibitor from Ardelyx. The NHE3 inhibitor is a novel approach to treating sodium and fluid retention in patients with renal impairment.

Metreleptin is a leptin analogue under development for the treatment of rare forms of inherited or acquired lipodystrophy, an orphan disease characterised by the deterioration or loss of the body's adipose tissue. This compound is part of the Amylin portfolio that AstraZeneca and BMS are co-developing. Completion of the Biologics Licence Application submission to the FDA is anticipated in the first half of 2013.

### **Clinical studies**

The SAVOR-TIMI 53 (saxagliptin assessment of vascular outcomes recorded in patients with diabetes mellitus) trial, which has completed recruitment, is designed to determine whether treatment with *Onglyza* when added to a patient's current standard of care will result in a reduction in a composite CV endpoint (CV death, non-fatal myocardial infarction, non-fatal ischaemic stroke) compared to placebo. This trial, involving 16,500 adult patients with Type 2 diabetes with a history of established CV disease or multiple risk factors, is also designed to fulfil a post-marketing requirement for the FDA.

In June, AstraZeneca and BMS announced results from a Phase III clinical study that showed that Forxiga 10mg demonstrated significant reductions in blood sugar levels (glycosylated haemoglobin levels, or HbA1c) compared with placebo at 24 weeks when either agent was added to existing sitagliptin therapy (with or without metformin) in adult patients with Type 2 diabetes. The results were maintained over a 24 week extension and similar results were observed when the data was analysed by subjects' background therapy. The study also demonstrated significant reductions in total body weight and fasting plasma glucose levels in patients taking Forxiga added to sitagliptin (with or without metformin), with results maintained throughout the duration of the study extension.

EXSCEL (EXenatide Study of Cardiovascular Event Lowering) is designed to determine if there are favourable CV effects of exenatide treatment, using *Bydureon* (exenatide extended release injectable suspension). The EXSCEL study started in 2010 and is planned to run until 2017. The study has enrolled patients during 2012 and is designed for 9,500 patients.



By 2030, almost 25 million people will die from CV disease, mainly from heart disease and stroke. CV diseases are projected to remain the single leading cause of death.

347 million people worldwide have diabetes. WHO projects that diabetes deaths will increase by 60% between 2008 and 2030.

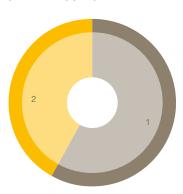
Source: WHO Fact Sheet September 2012

# Gastrointestinal

# \$38bn

Worldwide market value

# Therapy area world market (MAT/Q3/12) (\$bn)



1 PPI (proton pump inhibitors) 22.12 Other 15.94

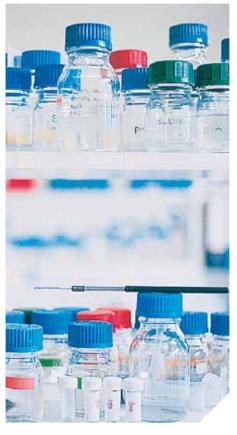
For a detailed narrative explanation of the financial performance of our products please see the Geographical Review from page 70.

# Our marketed products

- >Nexium (esomeprazole magnesium) 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		Wester	n Europe		Establisl	ned ROW		Emerging l	Markets	Prior year
2012	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	3,944	(11)	(10)	2,272	(5)	417	(45)	(41)	476	(12)	(11)	779	7	11	4,429
Losec/Prilosec	710	(25)	(24)	30	(21)	188	(22)	(17)	316	(29)	(29)	176	(20)	(20)	946
Others	198	24	25	145	44	38	(17)	(11)	6	_	_	9	29	29	161
Total	4,852	(12)	(11)	2,447	(4)	643	(39)	(34)	798	(20)	(19)	964	1	4	5,536

2011															
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

Overview Overview

We aim to develop our position in gastrointestinal (GI) treatments by continuing to focus on our existing proton pump inhibitors (PPIs) and the development of new therapies for irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).

# Our 2012 focus

Nexium is marketed in more than 125 countries and is available in oral (tablet, capsule and sachet for oral suspension) and intravenous (i.v.) dosage forms, for the treatment of acid-related diseases. Nexium is also approved for use in children from the age of one month in the US and from the age of one year in Europe and other markets. Nexium capsules were launched in Japan in September 2011 after a Japan-specific development programme.

Nexium is an effective short-term and long-term therapy for patients with gastroesophageal reflux disease (GERD). Nexium is also approved for the healing and prevention of ulcers associated with NSAID therapy and for the treatment of patients with the rare gastric disorder, Zollinger-Ellison syndrome. Nexium, in combination with antibiotics, is also approved for use for the treatment of duodenal ulcers caused by Helicobacter pylori infection in the US, Europe and other markets. Nexium is also approved for this use in children from the age of four years (approvals vary between countries).

Nexium i.v. is used as an alternative dosage form when oral administration is not suitable. Nexium i.v. is approved for this use in children from the age of one month in the US and from the age of one year in Europe and other markets. In addition, it is approved in Europe and other markets for the prevention of peptic-ulcer bleeding.

In August, AstraZeneca announced that it had entered into an agreement with Pfizer for the OTC rights for *Nexium*. Under the terms of the agreement, Pfizer will acquire the exclusive global rights to market *Nexium* for OTC indications worldwide.

Nexium continues to face increasing challenges from generic products. Patents protecting Nexium have been subject to a number of challenges in different jurisdictions. Details of these matters are included in Note 25 to the Financial Statements from page 184.

Losec/Prilosec, used for the short-term and long-term treatment of acid-related diseases, was first launched in 1988 and is approved for the treatment of GERD and other indications. 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 October, AstraZeneca and Ironwood announced an agreement to co-develop and co-commercialise in China Ironwood's product linaclotide, a guanylate cyclase-C (GC-C) agonist used for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in China. Ironwood markets the product under the name *Linzess* in the US. Clinical trial applications for linaclotide have been filed with the SFDA.

# In the pipeline

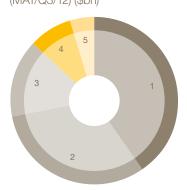
Our activities in the field of inflammatory bowel disease include clinical stage testing of two antibodies in collaboration with Amgen that target IL-13 and a4b7. In addition, we have expanded our GI research to include IBS and IBD with the NHE3 inhibitor programme, including the lead compound RDX5791 which we licensed from Ardelyx in October.



# Infection

# \$91.1bn Worldwide market value

# Therapy area world market (MAT/Q3/12) (\$bn)



- 1 Anti-bacterials 36.91
- 2 Anti-virals 28.67
- 3 Vaccines 13.75
- 4 Others 7.57
- 5 Anti-fungals 4.23

# **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

- >**Zinforo**1 (ceftaroline fosamil) is a novel injectable cephalosporin used in communityacquired pneumonia (CAP) and complicated skin and soft tissue infections (CSSTI).
- >**Cubicin**<sup>2</sup> (daptomycin) is a cyclic lipopeptide anti-bacterial used for the treatment of serious infections in hospitalised patients.
- >Merrem/Meronem<sup>3</sup> (meropenem) is a carbapenem anti-bacterial used for the treatment of serious infections in hospitalised patients.

### Influenza virus

- >FluMist/Fluenz (influenza vaccine live, intra-nasal) is an intra-nasal live, attenuated, trivalent influenza vaccine.
- Licensed from Forest.
- Licensed from Cubist Pharmaceuticals, Inc. Licensed from Dainippon Sumitomo.



# **Our financial performance**

			World		US		Wester	n Europe		Establis	hed ROW		Emerging	Markets	Prior year
2012	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
Synagis	1,038	6	6	611	7	427	5	5	-	-	-	-	-	-	975
Merrem/Meronem	396	(32)	(29)	38	(7)	64	(64)	(62)	18	(66)	(66)	276	(11)	(6)	583
FluMist	181	12	12	174	9	3	n/m	n/m	3	n/m	n/m	1	-	_	161
Others	100	(31)	(28)	58	(25)	6	(33)	(11)	16	(20)	(20)	20	(35)	(32)	137
Total	1,715	(8)	(7)	881	4	500	(16)	(15)	37	(49)	(49)	297	(13)	(8)	1,856

2011															
Synagis	975	(6)	(6)	570	(12)	404	3	3	-	-	-	1	-	_	1,038
Merrem/Meronem	583	(29)	(30)	41	(68)	179	(45)	(48)	53	(7)	(14)	310	2	_	817
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

For a detailed narrative explanation of the financial performance of our products please see the Geographical Review from page 70.

Overview

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*, the registration and launch of *Zinforo* in the EU, and through our other ongoing development programmes.

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 need. Complementing our biologics capabilities, we are building a small molecule anti-viral platform based on in-house capabilities and external collaborations, focused on respiratory viruses, such as respiratory syncytial virus (RSV) and human rhinovirus.

# 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. It is the leading cause of hospitalisations and admissions to paediatric intensive care units in the first year of life. 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 serious RSV disease than full-term healthy babies.

### Our 2012 focus

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 83 countries worldwide, Synagis remains the only

immunoprophylaxis in the marketplace indicated for the prevention of RSV in paediatric patients at high risk of serious RSV disease. *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. The lead vaccine candidate in clinical development is in Phase I.

# 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 immuno-suppressed patients and ageing populations. Many bacterial infections currently have few satisfactory treatment options, prompting demand for new and better therapies. Our discovery and early development platforms focus on the identification of pathogen-directed approaches, with a particular emphasis on multi-drug resistant gram-negatives and methicillin resistant staphylococcus aureus (MRSA).

# Our 2012 focus

Zinforo is a novel injectable cephalosporin, developed in collaboration with Forest, which is approved for use in the EU. Zinforo provides broad coverage against common causative pathogens, such as staphylococcus aureus, including MRSA, a cause of serious and difficult to treat complicated skin infections, streptococci in complicated skin infections, and streptococcus pneumoniae and methicillin-sensitive staphylococcus aureus (MSSA) in community acquired pneumonia. Forest markets ceftaroline in the US under the brand name Teflaro. In August, the European Commission granted marketing authorisation for Zinforo. This makes Zinforo the only approved cephalosporin monotherapy in the EU with demonstrated clinical efficacy against MRSA in difficult to treat complicated skin infections.

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.

Merrem/Meronem remains the leading carbapenem anti-bacterial which is approved in most countries outside Japan.

AZD9773 (formerly known as CytoFab), was a potential treatment for severe sepsis licensed from Protherics Inc. (now part of the BTG plc group). In August, further development of AZD9773 was halted after negative Phase Ilb study results.

# In the pipeline

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), CXL (a combination of ceftaroline and avibactam) and ATM AVI (a combination of aztreonam and avibactam). The CAZ AVI Phase III programme was initiated in 2011 and includes seven trials to confirm the efficacy and tolerability of CAZ AVI in adult patients with complicated intra-abdominal infections, complicated urinary tract infections or nosocomial pneumonia. 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 MRSA and streptococci as well as common gram-negative resistant strains is required.

Our early research and development efforts aim to address multi-resistant bacterial strains expressing metallo-betalactamases, for which very few, if any, treatment options exist. We are collaborating with regulatory authorities to design the clinical trials for these programmes.

# Performance | Therapy Area Review



# Influenza virus

Influenza is the most common vaccinepreventable disease in the developed world. According to WHO estimates, seasonal influenza results in three to five million cases of severe illness and up to half a million deaths globally each year, primarily among the elderly. Rates of infection are highest among children.

### Our 2012 focus

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 approved for eligible individuals in seven countries including the US, Canada and Brazil.

In February 2012, AstraZeneca received approval from the FDA for FluMist Quadrivalent (influenza vaccine live, intra-nasal), formerly known as MEDI3250, in the prevention of influenza. This marks the first four-strain influenza vaccine, and the only intra-nasal four-strain vaccine, approved by the FDA. Most other approved seasonal influenza vaccines currently available in the US are trivalent, containing three strains (two strains of type A influenza (A/H1N1 and A/H3N2) and one B lineage strain). FluMist Quadrivalent contains four strains (two type A strains and two type B lineages) to help provide broad protection against circulating influenza A and B.

# In the pipeline

The MAA for the quadrivalent live attenuated influenza vaccine (formerly known as MEDI3250) was submitted in September in the EU.

# Neglected tropical diseases

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 neglected tropical diseases. Our strategy is collaborative and seeks to leverage internal investment and expertise in tuberculosis (TB) and malaria. For other neglected tropical diseases, we participate in open innovation and knowledge-sharing platforms, enabling the use of AstraZeneca assets and infrastructure by external partners.

TB remains a complex research area in which collaborations play an 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), progressed to Phase IIa trials in South Africa, with support from The National Institute of Allergy and Infectious Diseases.

Malaria is another disease for which there remains a tremendous medical need. Our collaboration with Medicines for Malaria Ventures has progressed during 2012 according to plan, and is currently focused on the discovery of a new class of malaria medicines. We anticipate that this collaboration will continue to progress through discovery stages in 2013.

In 2012, we extended our range of external collaborations with new screening agreements with the Liverpool School of Tropical Medicine and the Drugs for Neglected Diseases Initiative. In these collaborations, AstraZeneca shares compounds with external partners with a view to identifying new leads against a variety of diseases of the developing world, including leishmaniasis, sleeping sickness, river blindness and Chagas disease. We also actively participated in the WIPO Re:Search initiative, promoting open innovation for the discovery of novel treatments.



According to a 2008 study, every year at least 25,000 patients in the EU alone die from an infection caused by multidrugresistant bacteria, and estimated additional healthcare costs and productivity losses are at least €1.5 billion.

Worldwide, annual epidemics of influenza result in about three to five million cases of severe illness and up to 500,000 deaths.

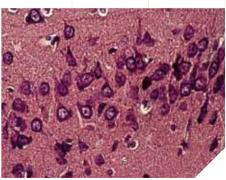
Source: (left) WHO Bulletin, Volume 89, 2011 Source: (above) WHO Fact Sheet April 2009

# Neuroscience

# \$145.3bn

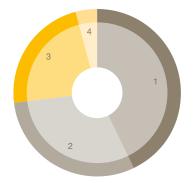
Wordwide market value





# Therapy area world market

(MAT/Q3/12) (\$bn)



- 1 Psychiatry 62.18 ■ 2 Neurology 44.27
- 3 Analgesia 32.95
- 4 Anaesthesia 5.94

# 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, major depressive disorder (MDD) and, in some countries, for generalised anxiety disorder

# 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**¹ (naproxen/esomeprazole magnesium) 375/20-500/20mg delayedrelease tablet 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.
- >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.
- Licensed from Pozen.

# **Our financial performance**

			World		US		Wester	n Europe		Establis	hed ROW	1	Emerging	Markets	Prior year
2012	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	World Sales \$m
Seroquel XR	1,509	1	4	811	4	446	(9)	(2)	97	9	10	155	17	27	1,490
Seroquel IR	1,294	(70)	(70)	697	(79)	226	(59)	(56)	202	(11)	(12)	169	(23)	(20)	4,338
Local Anaesthetics	540	(10)	(7)	_	(100)	201	(17)	(11)	206	_	_	133	(8)	(4)	602
Diprivan	291	(1)	2	-	(100)	32	(24)	(19)	78	(6)	(6)	181	15	19	294
Zomig	182	(56)	(54)	12	(92)	103	(41)	(37)	55	(19)	(19)	12	(8)	8	413
Vimovo	65	91	97	25	19	19	217	233	14	133	133	7	n/m	n/m	34
Others	42	30	36	16	n/m	11	(35)	(29)	1	(33)	(33)	14	17	25	33
Total	3.923	(46)	(44)	1.561	(64)	1.038	(32)	(27)	653	(4)	(4)	671	(1)	4	7.204

2011															
Seroquel XR	1,490	29	27	779	22	490	36	30	89	46	34	132	40	41	1,154
Seroquel IR	4,338	5	3	3,344	8	546	(3)	(8)	228	2	(8)	220	(15)	(17)	4,148
Local Anaesthetics	602	-	(6)	10	(66)	242	(9)	(13)	205	10	-	145	16	13	605
Diprivan	294	(9)	(13)	12	(73)	42	(16)	(20)	83	9	1	157	4	(1)	322
Zomig	413	(4)	(7)	158	(10)	174	1	(4)	68	(1)	(9)	13	18	9	428
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

For a detailed narrative explanation of the financial performance of our products please see the Geographical Review from page 70.

# Performance | Therapy Area Review

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 our experience with Seroquel XR and to discover and develop new drug candidates with meaningful therapeutic advantages, primarily in Alzheimer's disease, neuropathic pain control and depression. Many of these debilitating illnesses have no effective treatments and, for others, current therapies are poorly effective, leaving major unmet medical need.

Rapid progress is being made in understanding diseases of the brain, driven by technological advances in fields including genetics, cell biology, imaging and informatics. However, despite these advances there have been very few novel treatments delivered during the last 10 to 15 years and it is clear that a new way of working is required which captures advances in neuroscience and harnesses them through the drug development life-cycle.

AstraZeneca responded in 2012 by creating a new neuroscience Innovative Medicines Unit (Virtual iMed) made up of a team of approximately 40 scientists conducting discovery and development externally, through a network of partners in academia and industry. The team is based in Cambridge, Massachusetts, US and Cambridge, UK. The locations are strongly associated with neuroscience research and the team works closely with partners such as the Karolinska Institute in Sweden. The Virtual iMed is designed to be flexible, independent and lean in its structure. Scientists are empowered to make decisions quickly.

The team is focused on target identification to Proof of Concept studies, with high level focus on personalised medicine and innovative approaches to early clinical development. The Virtual iMed is designed to bring together scientific advances of the biotechnology and academic world and to develop their potential through the scientific, commercial and geographical reach of AstraZeneca.

We will consider any treatments for psychiatric, neurological or analgesic disorders affecting the central or peripheral nervous system which have a solid scientific basis, a high probability to deliver meaningful new medicines to patients, and will provide an acceptable return on investment. We will be looking at indications that affect smaller numbers of patients. We will focus on selected populations of patients whose disease biology makes them ideally suited for a particular treatment and we will test our therapeutic candidates in those populations first. Where treatments show promise in such selected patient groups, we will include a broader range of patients with the same disease or other disease states that might benefit from the approach. For example, a treatment that works on a fundamental disease process in neurons that eventually causes neurodegeneration might be best examined initially in patients with Huntington's disease. That same therapy could be as well suited for Parkinson's disease, amyotrophic lateral sclerosis (ALS) or other disorders.

# Neurology

Alzheimer's disease remains one of the largest areas of unmet medical need. Product development in this therapy area is particularly difficult 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. Most, if not all, marketed treatments will face patent expiry by 2015. Disease modification, delivered through biologics and/or small molecule treatments, is clearly the hope for Alzheimer's disease patients and for patients with other neurodegenerative disorders such as Parkinson's disease. Combined with better diagnostics, disease modifiers in both areas are expected to allow for earlier intervention and better clinical outcomes. Unfortunately, the first wave of disease modifiers is still several years away.

# In the pipeline

Alzheimer's disease is defined and characterised by the presence of the protein amyloid beta (Abeta) deposits in the brain. Present understanding of the pathophysiology of Alzheimer's disease suggests that alterations in Abeta production, distribution or aggregation lead to Abeta deposition which in turn impacts neuronal viability and function. A second protein altered in Alzheimer's disease is tau.

Our portfolio comprises small molecule and biologic projects addressing both tau and amyloid, as well as exploring new mechanisms based on the developments in disease understanding.

Our research pipeline is also exploiting opportunities presented by emerging biologic therapies and contains projects directed at modulating protein accumulation and signalling for a number of neurodegenerative diseases. In addition, the continued progress of technology platforms directed at facilitating the transport of macromolecules into the central nervous system compartment may provide benefits to patient health.

Overview

Through our collaborations 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 Alzheimer's disease early and to assess drug effects in Alzheimer's disease. 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.

A new alliance involving several academic centres, named A5, is a novel, openarchitecture alliance with four leading academicians that was launched in July to investigate potential new Alzheimer's disease treatments. The initiative is focused on the role of apoliprotein E (ApoE) in Alzheimer's disease. ApoE is considered second only to age as a risk factor for the development of Alzheimer's disease. Drug discovery efforts involving ApoE have been hampered by challenging biology and a lack of suitable in vivo models. In addition to ApoE, the A5 alliance will focus on identification, validation and risk reduction of other drug targets for treatment of Alzheimer's disease.

# **Psychiatry**

Globally, more than 350 million people of all ages suffer from depression (WHO 2012). Despite this, psychiatric illness remains under-detected, under-diagnosed and under-treated, and current treatments leave substantial unmet medical need. Three National Institute of Mental Health sponsored effectiveness studies in the US have reported treatment response rates in depression, bipolar disorder and schizophrenia to be less than 50%, with low (around 30%) rates of remission and poor compliance. Clear opportunities exist for novel approaches targeting defined patient sub-groups not adequately treated with current generic broad spectrum agents.

### Our 2012 focus

Seroquel XR has been approved in 85 countries for schizophrenia, 81 countries for bipolar mania, 72 countries for bipolar depression, 61 countries for bipolar maintenance, 65 countries for major depressive disorder (MDD) and nine countries for generalised anxiety disorder.

Patents protecting *Seroquel XR* have been subject to a number of challenges in different jurisdictions. In some cases, the patents have been found to be invalid. Details of these matters are included in Note 25 to the Financial Statements from page 184.

In March 2012, top-line results from the remaining Phase III studies investigating efficacy, tolerability and safety of TC-5214, as an adjunct therapy to an anti-depressant in patients with MDD who did not respond adequately to initial anti-depressant treatment, were released. RENAISSANCE 4 and RENAISSANCE 5, both of which are efficacy and tolerability studies, did not meet the primary endpoint of change on the Montgomery-Asberg Depression Rating Scale total score after eight weeks of adjunct treatment with TC-5214 as compared to placebo. These studies conclude the RENAISSANCE programme for TC-5214. Based on the totality of the results, AstraZeneca and Targacept decided not to pursue a regulatory filing for TC-5214 as an adjunct treatment for patients with MDD. We terminated the TC-5214 collaboration with Targacept, with all rights and licences granted under the licence agreement reverting to Targacept.

# In the pipeline

AZD6765, a low-trapping NMDA (N-methyl-D-aspartate) channel blocker to address the needs of patients with severe treatment-refractory depression, has progressed into Phase Ilb development. Phase Ila results presented in December demonstrated anti-depressant efficacy following single and repeated intravenous infusions in patients who have shown inadequate response to multiple oral therapies. An ongoing Phase Ilb study is designed to establish a chronic treatment regimen in this difficult to treat patient population. Additional early-stage research programmes are also focusing on this area.

# Analgesia and anaesthesia

The small number of currently approved products in the neuropathic pain market will come off patent 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. The chronic nociceptive pain market, including osteoarthritis 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.

# Performance | Therapy Area Review



Biologics are an emerging treatment option for pain control and this is an area in which we have an active interest.

It is believed that advances in the understanding of the mechanisms which lead to neuropathic pain will allow for improved patient segmentation and potential increases in the success rate of drug development. We are exploring smaller treatments in focused pain areas where patients can be selected on the basis of symptomatic characteristics within the overall development and regulatory approach.

# Our 2012 focus

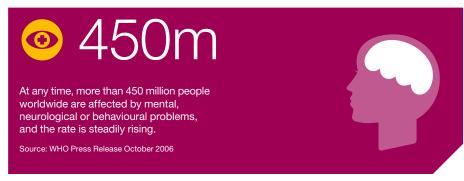
Vimovo, 375/20-500/20mg delayed-release tablets, co-developed by AstraZeneca and Pozen, is a fixed-dose combination of enteric-coated naproxen (an NSAID), and immediate-release esomeprazole, a stomach acid-reducing proton pump inhibitor (PPI). Vimovo is generally approved for symptomatic relief in the treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis in patients at risk of developing NSAID-associated gastric and/or duodenal ulcers. Vimovo is also indicated for treatment in patients where lower doses of naproxen or of other NSAIDs are not considered sufficient.

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 pipeline

Naloxegol (formerly NKTR-118), licensed from Nektar Therapeutics, is a once daily, oral, peripherally acting opioid receptor antagonist under investigation for treatment of opioid-induced constipation (OIC) as a side effect of prescription opioid pain medication. Positive top-line results from two Phase III trials and one safety extension trial in patients with non-cancer related pain and OIC, a common side effect of prescription opioids, were announced in November. Additional analyses and regulatory consultations are ongoing.

Our research pipeline is exploring biologic therapies and contains projects directed at modulating afferent signalling, inflammation associated with pain, and the interplay between the immune and nervous systems. Projects are directed at targeting well-defined patient segments, with subset selection based on, for example, an increase in particular inflammatory markers in osteoarthritis and pancreatitis. We continue to focus on areas of high unmet medical need, and thus, in addition to osteoarthritis, we are also active in researching novel therapies for neuropathic pain. Efforts to access targets in the central nervous system compartment, such as the spinal cord and the brain, continue to be facilitated by solid progression of technology platforms designed to transport biologics from the periphery to the central nervous system compartment.



# Oncology

# \$61.5bn

Wordwide market value



# Therapy area world market (MAT/Q3/12) (\$bn)



- 1 Chemotherapy 23.34
- 2 Monoclonal antibodies 18.85
- 3 Small molecule TKIs 11.02
- 4 Hormonal therapies 8.31



# Our marketed products

- >Arimidex (anastrozole) is an aromatase inhibitor used for the treatment of breast
- >Zoladex (goserelin acetate implant), in one and three month depots1, is a luteinising hormone-releasing hormone (LHRH) 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 epidermal growth factor receptor-tyrosine kinase (EGFR-TK) inhibitor that acts to block signals for cancer cell growth and survival in advanced 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 postmenopausal 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 medullary thyroid cancer (MTC) in patients with unresectable (non-operable) locally advanced or metastatic disease.

### Our financial performance

		World			US		Wester	n Europe	Established ROW			1	Prior year		
2012	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
Zoladex	1,093	(7)	(5)	24	(38)	221	(16)	(12)	448	(9)	(9)	400	4	9	1,179
Faslodex	654	20	24	310	17	186	(4)	4	62	n/m	n/m	96	16	27	546
Iressa	611	10	12	_	(100)	142	12	20	222	9	9	247	12	12	554
Arimidex	543	(28)	(26)	21	(50)	124	(52)	(49)	279	(9)	(9)	119	(18)	(16)	756
Casodex	454	(17)	(16)	(3)	n/m	51	(36)	(31)	301	(17)	(17)	105	(6)	(4)	550
Others	134	13	15	25	108	17	31	46	63	-	-	29	(6)	(3)	120
Total	3,489	(6)	(3)	377	7	741	(21)	(15)	1,375	(4)	(4)	996	2	6	3,705

2011															
Zoladex	1,179	6	3	39	(15)	262	(5)	(9)	494	10	-	384	12	18	1,115
Faslodex	546	58	55	264	71	193	56	48	6	n/m	n/m	83	30	28	345
Iressa	554	41	32	2	(50)	127	159	147	204	12	2	221	40	34	393
Arimidex	756	(50)	(53)	42	(91)	260	(55)	(56)	308	7	(2)	146	(3)	(6)	1,512
Casodex	550	(5)	(12)	(6)	(138)	80	(29)	(33)	364	5	(5)	112	9	7	579
Others	120	19	12	12	71	13	18	18	64	10	_	31	24	20	101
Total	3,705	(8)	(12)	353	(51)	935	(19)	(22)	1,440	8	(1)	977	16	16	4,045

For a detailed narrative explanation of the financial performance of our products please see the Geographical Review from page 70.

Depots are subcutaneous or intra-muscular injections.

# Performance | Therapy Area Review



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 2012 focus

Arimidex, first launched in 1995, remains a leading global hormonal therapy for patients with early breast cancer. 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.

Zoladex, a luteinising hormone-releasing hormone (LHRH) agonist, is approved in 120 countries for the treatment of prostate cancer, breast cancer and certain benign gynaecological disorders. In non-metastatic prostate cancer, Zoladex has been shown to improve overall survival, both when used in addition to radical prostatectomy and when used in addition to radiotherapy. In breast cancer, *Zoladex* is widely approved for use in advanced breast cancer in pre-menopausal women. In a number of countries, Zoladex is also approved for the adjuvant treatment of early stage pre-menopausal breast cancer as an alternative to and/or in addition to chemotherapy. Zoladex offers proven survival benefits for breast cancer patients with a favourable tolerability profile.

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.

Iressa is approved in 89 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 epidermal growth factor receptor (EGFR). In the EU, *Iressa* is the first personalised medicine for the treatment of adults with locally advanced or metastatic NSCLC with activating mutations.

Faslodex 500mg is now approved in 65 countries including the member states of 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. We are now exploring the efficacy and safety of Faslodex 500mg compared to *Arimidex* in the 1st line advanced breast cancer setting (hormonenaïve patients) in the Phase III FALCON trial.

Caprelsa fights cancer through two proven mechanisms: blocking the development of tumour blood supply by inhibition of the vascular endothelial growth factor pathway and by inhibiting the growth and survival of the tumour through EGFR and rearranged during transfection (RET) pathways. Caprelsa was approved by the FDA and granted Orphan Drug status in April 2011, and was approved in the EU in February 2012 for the treatment of medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. Caprelsa is also approved in Canada and remains under review by other regulatory agencies around the world.

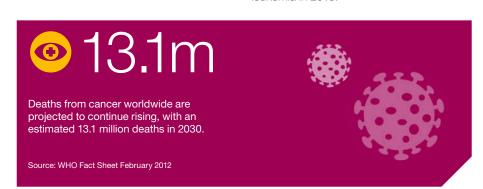
# In the pipeline

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. Despite set-backs in earlier Phase II trials, olaparib, a poly ADP-ribose polymerase (PARP) inhibitor, continues in Phase II trials in relapsed ovarian cancer, gastric cancer and germline BRCA mutation positive cancers. Olaparib has been approved to begin Phase III in 2013 pending the results of ongoing trials.

Selumetinib, a potent mitogen-activated protein kinase (MEK) inhibitor licensed from Array BioPharma, Inc., continues in Phase II development.

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 disrupting cancer cells' ability to grow or communicate (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 therapy).

We currently have five investigational biologics in Phase I clinical trials and four in Phase II clinical trials. Additional drug candidates are expected to progress into clinical trials in 2013. Moxetumomab is a monoclonal antibody approved to begin Phase III testing in hairy cell leukemia in 2013.

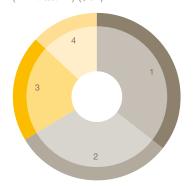


# Respiratory & Inflammation

# \$64bn

Wordwide market value

# Therapy area world market (MAT/Q3/12) (\$bn)



- 1 Asthma 22.78 ■ 2 Other 19.84 3 COPD 13.18
- 4 Rhinitis 8.19



# Our marketed products

- >**Symbicort** pMDI (budesonide/formoterol in a pressurised metered-dose inhaler) is a combination of an inhaled corticosteroid and a fast onset, long-acting beta2-agonist used for maintenance 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 beta2-agonist used for maintenance treatment of asthma and COPD. In asthma, it is also approved for Maintenance And Reliever Therapy (SMART). Symbicort Turbuhaler is used in most parts of the world outside the US.
- >**Pulmicort Turbuhaler** (budesonide in a dry powder inhaler) is an inhaled corticosteroid used for maintenance treatment of asthma.
- >**Pulmicort Respules** (budesonide inhalation suspension) is a corticosteroid administered via a nebuliser for the treatment of asthma in both children and adults.
- >Rhinocort (budesonide) is a nasal steroid used as a treatment for allergic rhinitis (hay fever), perennial rhinitis and nasal polyps.
- >Oxis Turbuhaler (formoterol in a dry powder inhaler) is a fast onset, long-acting beta<sub>2</sub>-agonist used for the treatment of bronchial-obstructive symptoms in asthma
- >Accolate (zafirlukast) is an oral leukotriene receptor antagonist used for the treatment of asthma.

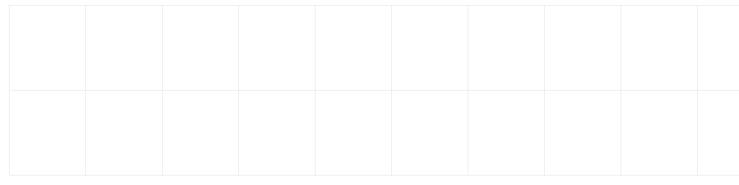
# **Our financial performance**

		World			US Western Europe				Established ROW			Emerging Markets			Prior year
2012	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	3,194	1	5	1,003	19	1,313	(8)	(3)	443	6	7	435	(3)	3	3,148
Pulmicort	866	(3)	(1)	233	(16)	156	(17)	(12)	127	1	1	350	17	19	892
Rhinocort	177	(17)	(14)	55	(26)	28	(24)	(19)	17	(15)	(15)	77	(5)	(1)	212
Others	178	(17)	(14)	10	25	92	(16)	(11)	23	4	4	53	(30)	(28)	216
Total	4,415	(1)	2	1,301	8	1,589	(10)	(5)	610	4	5	915	1	5	4,468

2011															
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

For a detailed narrative explanation of the financial performance of our products please see the Geographical Review from page 70.

# Performance | Therapy Area Review



We aim to build on our strong position in the respiratory and inflammation area 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. With our acquisition of Ardea we have expanded our inflammation focus to include gout.

# 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 the potential for 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, unmet medical need for patients whose asthma is inadequately controlled by current treatments remains an important issue and disease normalisation is currently not optimally achieved by any approved treatment.

The typical treatment for both COPD and asthma is a fixed-dose combination of an inhaled corticosteroid (ICS) with a long-acting beta<sub>2</sub>-agonist (LABA) (for example *Symbicort*) or for COPD specifically, an inhaled long-acting muscarinic antagonist as either monotherapy or adjunctive to ICS/LABA treatment. 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, as well as a MAb targeting allergic asthma for moderate to severe asthma patients. Over recent years, studies employing patientcentric tools, such as the asthma control questionnaire, have revealed surprisingly low asthma control at all severities, highlighting an underestimated medical need.

### Our 2012 focus

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 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 originally launched in markets outside the US in 2000 and in Japan in 2010 for the treatment of adult asthma and is co-promoted in Japan with Astellas Pharma, Inc. The COPD indication and the SMART treatment regimen were approved in Japan in 2012.

Symbicort SMART (Symbicort Maintenance And Reliever Therapy) provides improved asthma control including less risk for exacerbations relative to comparators 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, the Symbicort SMART approach reduces the usage of both inhaled and oral corticosteroids 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. Pulmicort continues to face increasing challenge from generic products. Patents protecting Pulmicort have been subject to a number of challenges in different jurisdictions. Details of these matters are included in Note 25 to the Financial Statements from page 184.

### **Clinical studies**

In April 2012, the FDA provided AstraZeneca with a Post-marketing Requirement for a *Symbicort* LABA safety study, designed to be pooled with similar studies with other

LABA products. AstraZeneca is required to conduct a trial comparing *Symbicort* Inhalation Aerosol with *Pulmicort* to evaluate the risk of serious asthma outcomes (hospitalisations, intubation, death) in 11,700 adult and adolescent patients. Recruitment in the trial is ongoing.

### In the pipeline

Building on our capabilities in combinations and inhaler device development demonstrated through our experience with Symbicort, we are aiming to further improve the mainstay of treatment for COPD patients by combining bronchodilators, being developed in collaboration with Pulmagen Therapeutics (Synergy) Limited, with inhaled anti-inflammatory compounds such as inhaled selective glucocorticoid receptor agonists (AZD5423, which continues in Phase II), being developed in collaboration with Bayer Schering Pharma AG. Additionally, we are targeting inflammation in COPD using oral routes of administration with AZD5069, a CXCR2 antagonist that targets neutrophils which is in Phase II. MEDI8968, an anti-interleukin-IL-1 receptor MAb, and benralizumab, an anti-interleukin-5 receptor MAb, are both in Phase II development for severe to very severe COPD.

We are targeting uncontrolled asthma focusing on reducing the rate of annual 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). Biological treatments in Phase Ilb include benralizumab and tralokinumab, a MAb that targets interleukin-13. Also, in Phase II, brodalumab is an anti-interleukin-17 receptor MAb (being developed in collaboration with Amgen) for asthma.

In April 2012, AstraZeneca and Amgen agreed to jointly develop and commercialise five MAbs from Amgen's clinical inflammation portfolio including brodalumab. The collaboration will provide Amgen with additional resources to optimally progress its portfolio, and Amgen will benefit from the strong respiratory, inflammation and asthma development expertise of AstraZeneca's biologics capabilities. The collaboration will also capitalise on AstraZeneca's global commercial reach in respiratory and gastrointestinal diseases.

						Overview
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# Rheumatology and gout

Rheumatoid arthritis is currently treated with generic disease-modifying anti-rheumatic agents and, where the relevant criteria are met, biologic disease-modifiers. There remains a need for novel effective treatments since only about a third of patients treated with biologics achieve their treatment goals. We anticipate that the rheumatoid arthritis market will experience modest annual growth over the next decade. Sales of the biologic tumour necrosis factor (TNF) alpha blockers accounted for 72% of major market rheumatoid arthritis sales in 2012. Use of other biologic approaches 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 may provide anti-TNF-like levels of efficacy and potentially more convenient dosing, especially in patients who currently are not taking or are ineligible to take injectable biologic agents.

Current treatment of systemic lupus erythematosus (SLE) focuses on suppressing symptoms and controlling disease flares, and in the case of lupus nephritis preventing renal failure. Although a biologic has recently been launched for SLE, significant unmet medical need remains. Most emerging biologic agents are likely to be used initially after failure of standard therapies (including corticosteroids and immunosuppressants) or in combination in order to provide incremental benefit, prevent flares and allow reduction of high-dose chronic steroid use.

Gout is a chronic, painful, debilitating arthritis caused by elevated serum uric acid due to overproduction and/or under excretion of uric acid. Gout is the second most common arthritis after osteoarthritis and is the most common form of arthritis in men over 40.

# In the pipeline

Fostamatinib was in-licensed from Rigel Pharmaceuticals, Inc. in 2010. Fostamatinib is a potential first-in-class oral spleen tyrosine kinase (SYK) inhibitor being evaluated for a rheumatoid arthritis indication. It is thought to block reversible signalling in multiple cell types involved in inflammation and tissue degradation

in rheumatoid arthritis. The ongoing Phase III programme, called OSKIRA, commenced in September 2010. In the Phase IIb dose finding study OSKIRA-4, fostamatinib as a monotherapy met the first primary objective showing a statistically significant superior DAS28 score change from baseline compared to placebo at six weeks at the 100mg twice daily dose and the 100mg twice daily for a month followed by 150mg once daily dose, but not at the 100mg twice daily for a month followed by 100mg once daily dose. The OSKIRA-4 study did not meet its second primary objective as all fostamatinib monotherapy doses were inferior to adalimumab monotherapy at week 24 based on DAS28. The safety and tolerability findings for fostamatinib as reported in the OSKIRA-4 study were generally consistent with those previously observed in the TASKi Phase II programme. Results from the ongoing Phase III OSKIRA programme are anticipated in the first half of 2013 and would form the basis of regulatory submissions.

In June, AstraZeneca acquired Ardea, a San Diego, California-based biotechnology company focused on the development of small molecule therapeutics. Ardea's clinically most advanced product candidate, lesinurad (formerly known as RDEA594), is currently in Phase III development. Lesinurad is a selective inhibitor of URAT1, a transporter in the proximal tubule cells of the kidney that regulates uric acid excretion from the body. The Phase III programme is exploring lesinurad as an oral, once daily treatment for the chronic management of hyperuricaemia in patients with gout. Regulatory filings are planned in the US and Europe for the first half of 2014. We also plan to develop and commercialise lesinurad in China and Japan.

In 2012, we continued to invest in several novel multi-functional MAbs in inflammatory and autoimmune conditions. Sifalimumab, which targets interferon-alpha, continued clinical development with an ongoing Phase IIb study in patients with SLE. MEDI-546, which targets the Type I IFN receptor, continued in a Phase IIb study in patients with SLE. Mavrilimumab, which targets the alpha sub-unit of the granulocytemacrophage colony stimulating factor receptor, continues in Phase IIb for patients with rheumatoid arthritis.

# Dermatology

Psoriasis is a chronic disease in which the immune system causes the skin cells to grow at an accelerated rate. Instead of being shed, the skin cells pile up, causing painful and itchy, red, scaly patches that can bleed. Up to 12 million patients are diagnosed with psoriasis across the US and Europe each year. Despite various treatment options for moderate to severe plaque psoriasis, many patients do not meet their therapeutic goals including resolution of underlying inflammation, clearing of symptoms and improving quality of life. Biologics are currently used in moderate to severe patients who are candidates for, or are unresponsive to, phototherapy or systemic therapy.

# In the pipeline

As mentioned previously, in 2012 AstraZeneca and Amgen entered into an agreement to jointly develop brodalumab, which has commenced Phase III development in patients with moderate to severe plaque psoriasis. In addition, brodalumab is being considered in a Phase IIb development programme in psoriatic arthritis.



Some 235 million people currently suffer from asthma. It is the most common chronic disease among children.

Source: WHO Fact Sheet May 2011



Total deaths from COPD are projected to increase by more than 30% in the next 10 years without interventions to cut risks.

Source: WHO Fact Sheet November 2012

# 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.

### 2012 in brief

- > In the US, sales were down 21% to \$10,655 million (2011: \$13,426 million; 2010: \$13,727 million). Loss of exclusivity on Seroquel IR in March 2012 as well as the impact of increased generic competition experienced by our other mature brands was partially offset by strong performance from our key brands, Brilinta, Crestor, Onglyza, Symbicort and Faslodex.
- > AstraZeneca is the fourth largest pharmaceutical company in the US, with a 5% market share of US pharmaceuticals by sales value.
- > AstraZeneca is the eighth largest prescription-based pharmaceutical company in Western Europe, with a 3.4% market share of sales by value.
- > Sales in Western Europe were down 19% to \$6,486 million (2011: \$8,501 million; 2010: \$9,168 million). Key drivers of the decline were the volume erosion on *Atacand, Seroquel IR, Nexium, Arimidex* and *Meronem*, following entry of generic competition and the negative price and volume impact primarily related to government interventions, particularly in Greece, Italy, Portugal and Spain. This development was partially offset by revenue growth from *Brilique*, *Onglyza*, *Vimovo* and *Iressa*.
- > Established ROW sales were down 14%. The entry of generic competition of *Crestor* in Canada, and *Seroquel IR* and *Arimidex* in Australia was partially offset by the successful first full year of launch of *Nexium* and *Faslodex* in Japan.

> Emerging Markets sales increased by 4% to \$5,752 million (2011: \$5,763 million; 2010: \$5,198 million) with sales growth in China of 17% and also in Russia of 17%.

### 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 Meronem. 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 of Symbicort, Crestor, Nexium and the Seroquel franchise. 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*.

For more information regarding our products, see the Therapy Area Review from page 50. Details of material legal proceedings can be found in Note 25 to the Financial Statements from page 184

and details of relevant risks are set out in the Principal risks and uncertainties section from page 75. See the Market definitions table on page 209 for information about AstraZeneca's market definitions. Sales figures in this Geographical Review are with reference to the customers' location.

### US

AstraZeneca is the fourth largest pharmaceutical company in the US, with a 5% market share of US pharmaceuticals by sales value.

Sales in the US decreased by 21% to \$10,655 million (2011: \$13,426 million; 2010: \$13,727 million), as strong performance from our key brands, Brilinta, Crestor, Onglyza, Symbicort and Faslodex, was offset by loss of exclusivity on Seroquel IR in March 2012 as well as the impact of increased generic competition experienced by our other mature brands. Combined sales of our key brands, Brilinta, Crestor, Onglyza, Symbicort and Faslodex, were up by 9% to \$4,733 million (2011: \$4,351 million; 2010: \$3,569 million). Other drivers of the sales decline include the reduction of sales for Zomia following the licensing of Zomig to Impax Pharmaceuticals Inc. in February 2012 down to \$12 million (2011: \$158 million; 2010: \$176 million), additional generic competition affecting sales of Toprol-XL down to \$320 million (2011: \$404 million; 2010: \$689 million), and loss of exclusivity of Atacand down to \$150 million (2011: \$182 million; 2010: \$216 million).

Brilinta achieved sales of \$19 million. Commercial preferred unrestricted managed markets access was 54%

# Our financial performance

		2012				2010	
	Sales \$m	Reported growth %	CER growth %	Sales \$m	Reported growth %	CER growth %	Sales \$m
US	10,655	(21)	(21)	13,426	(2)	(2)	13,727
Western Europe	6,486	(24)	(19)	8,501	(7)	(11)	9,168
Canada	1,090	(32)	(31)	1,604	6	1	1,510
Japan	2,904	(5)	(5)	3,064	17	6	2,617
Other Established ROW	1,086	(12)	(12)	1,233	18	4	1,049
Established ROW	5,080	(14)	(14)	5,901	14	4	5,176
Emerging Europe	1,165	(6)	2	1,244	7	7	1,165
China	1,512	20	17	1,261	20	15	1,047
Emerging Asia Pacific	923	(5)	(3)	968	9	5	890
Other Emerging ROW	2,152	(6)	_	2,290	9	12	2,096
Emerging Markets	5,752	_	4	5,763	11	10	5,198
Total	27,973	(17)	(15)	33,591	1	(2)	33,269

Overview Overview

and trial among target interventional cardiologist initiators was 39% at the end of 2012. Crestor demonstrated resilience in the face of the November 2011 market entry of a generic version and, from May, multiple generic versions of atorvastatin, all competitors of Crestor. Crestor's performance volume showed resilience in two of the largest and most profitable segments of the market, Commercial and Medicare. Crestor's existing patient base remained solid, and continuing patients represented 94% of Crestor's volume. Crestor achieved sales of \$3,164 million (2011: \$3,074 million; 2010: \$2,640 million) and a total prescription share of 11.8% within the statin market. In 2012. Crestor became the most prescribed branded pharmaceutical in the US.

Symbicort pMDI continued to deliver steady growth in the US with sales up 19% to \$1,003 million (2011: \$846 million; 2010: \$721 million) and prescription growth of 12.5%. It achieved a 21.3% total prescription share and a 22.5% new prescription share of the inhaled corticosteroid/long-acting beta<sub>2</sub>-agonist market.

Following the completion of BMS's acquisition of Amylin, AstraZeneca and BMS have been developing and commercialising Amylin's portfolio of products related to diabetes (and other metabolic diseases). Sales of GLP-1 agonists for the treatment of diabetes were \$74 million for *Byetta*, \$37 million for *Bydureon* and \$17 million for *Symlin*.

Onglyza/Kombiglyze XR captured more than one in five new DPP-IV patient treatment decisions and achieved a 2.8% total prescription market share gain in 2012, ending the year with a total prescription market share of 17.1% of the rapidly growing DPP-IV inhibitor market. Onglyza revenues in the US were \$237 million (2011: \$156 million; 2010: \$54 million).

The loss of exclusivity for Seroquel IR in March 2012 resulted in a decrease in sales of 79% to \$697 million (2011: \$3,344 million; 2010: \$3,107 million). In 2012, generics accounted for 58.5% of quetiapine prescriptions in the US. The presence of generic competition impacted the prescription volume of Seroquel XR in 2012. However, sales of Seroquel XR were up 4% to \$811 million (2011: \$779 million; 2010: \$640 million) because of higher prices.

Nexium was the third most prescribed branded pharmaceutical in the US. In the face of continuing generic, OTC and pricing pressures, Nexium sales declined 5% to \$2,272 million (2011: \$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.

In 2012, sales of *Synagis* were up 7% to \$611 million (2011: \$570 million; 2010: \$646 million). Sales in the 2011 to 2012 RSV season experienced payer pressure, which was offset by heightened awareness efforts surrounding the RSV burden of disease, appropriate patient identification and enhanced efforts to ensure continuity of care for patients from the hospital to the paediatrician's office.

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. In 2012, the overall reduction in our profit before tax for the vear 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 \$858 million. This amount reflects 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 on the 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 75.

Currently, there is no direct governmental 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 2012, 84% 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.

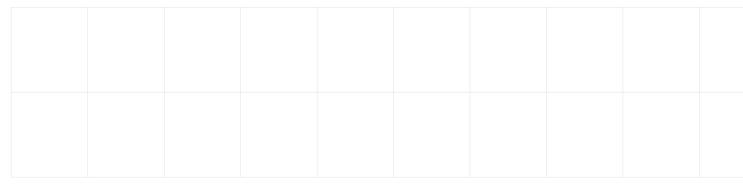
# **Rest of World**

Sales performance outside the US in 2012 was down by 11% to \$17,318 million (2011: \$20,165 million; 2010: \$19,542 million), due to loss of exclusivity, competition from generic products and the continuing challenging economic environment. Combined sales of key products (*Arimidex*, *Crestor*, *Nexium*, *Seroquel IR* and *Seroquel XR*, and *Symbicort*) were down 11% with sales of \$8,769 million (2011: \$10,301 million; 2010: \$9,923 million). Emerging Markets delivered strong sales, up 4% with sales of \$5,752 million (2011: \$5,763 million; 2010: \$5,198 million).

# Western Europe

AstraZeneca is the eighth largest pharmaceutical company in Western Europe, with a 3.4% market share of prescription sales by value.

# Performance | Geographical Review



The macro-economic situation has deteriorated, particularly in Greece, Italy, Portugal and Spain which have seen the implementation of new austerity measures, leading to increased pressure on healthcare budgets. 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. A number of 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.

Total sales in Western Europe were down 19% to \$6,486 million (2011: \$8,501 million; 2010: \$9,168 million) due largely to volume erosion on Seroquel IR, Nexium, Arimidex and *Meronem* following generic entrants and the negative price and volume impact primarily related to government interventions, particularly in Greece, Italy, Portugal and Spain. The loss of exclusivity for Atacand in April 2012 resulted in a decrease in sales of 39% to \$422 million (2011: \$731 million; 2010: \$736 million). Generics now account for 9.7% of candesartan prescriptions in Western Europe. This development was partially offset by revenue growth attributable to Brilique, Onglyza, Vimovo and Iressa.

Crestor outperformed the statin class with strong 2% sales growth. Generic versions of Seroquel IR are now available in Western Europe, with overall sales down 56% to \$226 million (2011: \$546 million; 2010: \$560 million).

Brilique has been launched in all markets in Western Europe and sales reached \$55 million in 2012 (2011: \$9 million).

In Germany, sales fell by 30% to \$775 million (2011: \$1,189 million; 2010: \$1,235 million), mainly driven by market entries of generic versions of *Atacand* (sales declined to \$141 million; 2011: \$255 million; 2010: \$252 million), *Seroquel IR* (sales declined to \$31 million; 2011: \$127 million; 2010: \$113 million) and *Seroquel XR* (sales declined to \$93 million; 2011: \$151 million; 2010: \$100 million).

In the UK, a 22% decrease in sales to \$668 million (2011: \$866 million; 2010: \$1,022 million) reflected strong volume erosion on Seroquel IR and Seroquel XR (sales declined to \$58 million; 2011: \$120 million; 2010: \$124 million), following generic entrants. Sales of Nexium decreased by 59% to \$17 million (2011: \$41 million; 2010: \$89 million) and sales of Arimidex decreased by 85% to \$4 million (2011: \$28 million; 2010: \$114 million), both following the impact of a full year of generic penetration. The decrease in UK sales was partially offset by the solid performance of Symbicort, up 6% to \$328 million (2011: \$312 million; 2010: \$272 million).

Sales in France decreased by 18% to \$1,314 million (2011: \$1,740 million; 2010: \$1,889 million), driven largely by volume erosion on Nexium, Atacand, Zomig and Arimidex, following generic entrants, and the impact from the disposal of Astra Tech, which was not entirely offset by the strong growth of Crestor and the successful launch of Seroquel XR, which had sales of \$37 million. Sales in Spain and Italy were down by 22% to \$510 million (2011: \$708 million; 2010: \$788 million) and by 15% to \$876 million (2011: \$1,113 million; 2010: \$1,198 million), respectively, mainly driven by generic entrants and the implementation of price and prescription controls associated with existing and new austerity measures.

# **Established ROW**

Sales in Established ROW decreased by 14%. The key products with sales growth in 2012 were *Symbicort*, *Seroquel XR*, *Onglyza*, *Faslodex* and *Iressa*.

# Canada

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.

Due to the loss of exclusivity for *Crestor* in Canada in April 2012, and the continued impact of the 'at risk' launch of a generic version of *Nexium* by a competitor in 2011, total Canadian sales decreased by 31% to \$1,090 million (2011: \$1,604 million; 2010: \$1,510 million). Combined sales of *Crestor*,

Nexium, Symbicort, Seroquel IR and Seroquel XR were \$742 million (2011: \$1,171 million; 2010: \$1,055 million).

### Japan

Sales in Japan decreased by 5% to \$2,904 million (2011: \$3,064 million; 2010: \$2,617 million). Strong performance from *Crestor*, *Symbicort*, *Faslodex* and *Iressa* was largely offset by biennial price cuts imposed in April 2012.

*Crestor* sales grew by 4%, becoming the number one brand in the statin market in Japan. *Symbicort* sales grew 12%, backed by additional therapeutic indications for SMART and COPD.

Nexium achieved sales of \$78 million in its first full year after launch, with sales accelerating following the lifting in October of the two week prescription limit imposed by the Japanese Ministry of Health, Labour and Welfare on new medicines during the first year from launch.

Our oncology business remains one of the leaders in Japan based on the performance of established brands including *Iressa*, *Arimidex*, *Zoladex* and *Casodex*. *Faslodex*, launched in November 2011, achieved sales of \$58 million in its first full year in the market.

# Other Established ROW

Our sales in Other Established ROW showed a decline of 12% to \$1.086 million (2011: \$1,233 million; 2010: \$1,049 million). Australian sales were impacted by price cuts triggered by loss of exclusivity of Seroquel IR and Arimidex in April 2012, as well as by price reductions due to the Australian government's therapeutic group policy, which impacted Crestor and Atacand. Price reductions were partially offset by performance of Crestor, Nexium and Symbicort, which all gained market share. Crestor achieved a 28.1% volume share in the statin class and became the number one drug in the statin market in Australia following loss of exclusivity of atorvastatin. Brilinta was successfully launched in Australia with reimbursement through the Australian pharmaceutical benefits scheme becoming available from August. Brilinta achieved formulary listing in the vast majority of hospitals in Australia in 2012. Marketing authorisation was obtained for Symbicort pMDI in Australia.

Overview

Crestor continues to face challenges from generic competitors. The patent protecting Crestor in Australia has been challenged. Details of this matter are included in Note 25 to the Financial Statements from page 184.

# **Emerging Markets**

In Emerging Markets, our sales increased by 4% to \$5,752 million (2011: \$5,763 million; 2010: \$5,198 million), which was principally driven by growth in China and Russia.

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 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. Some strong growth markets such as Vietnam are also implementing price and volume controls in an attempt to control government spending.

# **Emerging Europe**

Sales in Emerging Europe grew by 2% to \$1,165 million (2011: \$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 17% to \$314 million (2011: \$284 million; 2010: \$232 million) mainly due to increased sales of *Symbicort* by 24%, *Nexium* by 93%, *Crestor* by 14% and *Seroquel XR* by 154%, driven by growth in the retail segment. We have also consolidated our position among the growth leaders in the hospital and regional reimbursement segments.

In Romania, we delivered a strong performance with sales up 19% to \$161 million (2011: \$154 million; 2010: \$119 million), largely as a result of sales of *Atacand* increasing by 34%, *Seroquel XR* increasing by 41%, *Crestor* increasing by 10% and *Symbicort* increasing by 4%. In Turkey, a decrease in sales to \$252 million (2011: \$297 million; 2010: \$304 million) reflected the additional price and prescription controls imposed by the Turkish government in late 2011.

# China

Our sales in China (excluding Hong Kong) increased by 17% to \$1,512 million (2011: \$1,261 million; 2010: \$1,047 million). Sales of products in our Cardiovascular and Respiratory & Inflammation Therapy Areas continue to grow ahead of the market, driven by strong performances of Crestor, Betaloc Zok and Pulmicort Respules. Sales of Nexium and Symbicort grew strongly by 27% and 50% respectively, while our mature gastrointestinal and oncology brands experienced challenges from government pricing reductions. In 2012, we saw Zoladex 10.8mg successfully launched in China, the expansion of our co-promotion with BMS to achieve listing of Onglyza into key hospitals, and a new collaboration formed between AstraZeneca and Ironwood to co-develop and co-commercialise linaclotide in China. We continue to be one of the leading multinational pharmaceutical companies in China.

# **Emerging Asia Pacific**

Sales in Emerging Asia Pacific decreased by 3% to \$923 million (2011: \$968 million; 2010: \$890 million). This decline was driven by India, where sales decreased by 29% to \$67 million (2011: \$110 million; 2010: \$92 million), due primarily to supply issues; continued government interventions on pricing in countries such as Thailand, where sales decreased by 7% to \$97 million (2011: \$106 million; 2010: \$114 million); and by Vietnam, where sales decreased by 4% to \$45 million (2011: \$47 million; 2010: \$37 million). This was partially offset by sales growth in Indonesia, up 7% to \$39 million (2011: \$39 million; 2010: \$34 million); South Korea, up 4% to \$239 million (2011: \$235 million; 2010: \$213 million); and Malaysia, up 6% to \$73 million (2011: \$70 million; 2010: \$66 million).

# Other Emerging ROW

Sales in Other Emerging ROW were flat at \$2,152 million (2011: \$2,290 million; 2010: \$2,096 million), with increased sales in Latin America, Egypt, Maghreb, Saudi Arabia and the Gulf States balanced by reduced sales in South Africa and Israel.

The Latin American pharmaceutical market continues to grow, underpinned by a reasonably stable political and economic climate. However, in many of the countries, the majority of the growth in the market is being captured by generics, branded generics and private label product offerings, often from local, non-multinational, companies.

In Latin America, our sales were down 1% to \$1,331 million (2011: \$1,455 million; 2010: \$1,392 million). This was driven by declines in Mexico, down 22%, and Brazil. down 5%. Brazil continued to feel the effects of the loss of exclusivity on Seroquel IR and Crestor with year-on-year declines of 54% and 39% respectively. Growth of Seloken, Faslodex and older products such as *Diprivan* and *Meronem* helped to compensate for this development. In Mexico, challenging market conditions and the impact of an 'at risk' generic version of Crestor, resulted in weak performance with sales in Mexico declining by 22%. This was partially offset by sales growth in Venezuela (up 41%) and Argentina (up 24%). All key brands achieved double digit growth in Argentina (Nexium, Crestor, Atacand, Symbicort and Seroquel XR) and growth of more than 40% in Venezuela (Crestor, Symbicort, Seroquel XR, Atacand, Zoladex and Arimidex).

Successful product launches in the year included *Brilinta* and *Kombiglyze XR* in Mexico, Colombia and Argentina, and *Vimovo* in Brazil, Colombia and Argentina. *Faslodex* 500mg was launched in the fourth quarter of 2012 in Argentina, and is expected to launch in the first half of 2013 in Brazil and Venezuela.

In the Middle East and Africa, despite political challenges arising from the 'Arab Spring' revolutions, we further accelerated our growth with sales up 3%. Our largest markets were South Africa, Saudi Arabia and the Gulf States.

# Performance | Risk

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 30, 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 75.

# **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 to ensure that it conforms to its risk appetite. Line managers 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. Supporting tools are in place to assist the managers in this process and we continue to work on developing our risk management standards and guidelines.

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.

# **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 functions 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.

					Overview

# Oversight and monitoring

The SET is responsible for overseeing and monitoring the effectiveness of the risk management processes implemented by management. The Compliance and Finance functions, together with the GIA, 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 of Conduct can be found in the Compliance section on page 47.

# Management reporting and assurance

We provide 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 comprises five Non-Executive Directors. It 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 outcomes of internal audits and other compliance matters. 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, reports on performance against the Global Compliance scorecard, and summaries of compliance incidents and investigations including contact made by employees with AZethics via our helplines
- > Financial Control and Compliance Group: reports on Sarbanes-Oxley Act compliance and the financial control framework
- > Management: the Group-level risk summary from the annual business planning process and QBRs and reports on the performance management and monitoring processes.

For further information on the Audit Committee, see the Audit Committee section from page 115.

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. In the remainder of this section 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.

# Performance | Risk

# 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, 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.

# 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 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 NDAs 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.

# 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.

# **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 pre-clinical or clinical studies, regulatory demands, price negotiation, competitor activity and technology transfer.

# **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 business or results of operations.

# **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, increase the unpredictability of the process.

# **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 on page 35. 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 risk on page 78.

# **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 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 rights to, 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 we 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, the impact of price control measures imposed by governments and healthcare authorities, 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 relatively small clinical study patient samples.

The commercialisation of biologics is often more complex than for small molecule 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 business or 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, non-governmental organisations and governmental authorities to be increasing. We suffer a commensurate financial exposure to illegal trade and there is also a risk to public health. Regulators and the public expect us to secure the integrity of our supply chain and to co-operate actively in the reduction of illegal trade in AstraZeneca products, through surveillance, investigation and legal action against others engaged in illegal trade.

# **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.

# **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, business or results of operations.

# Performance | Risk

# 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 on page 35 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. Further, there may be increased pricing pressure on our still-patented products as a result of the lower prices of generic entrants.

# 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. The majority of our patented products, including Nexium, Crestor and Seroquel XR, 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 (for example, generic forms of Lipitor and Plavix and generic forms of Seroquel IR).

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, Crestor and Pulmicort, four of our key 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.

# 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 external parties. Such IP rights may also be the subject of validity challenges in patent offices. 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.

Where we assert our IP rights and allege infringement, we bear the risk that courts may decide that third parties do not infringe our IP rights. This may result in AstraZeneca losing exclusivity and/or erosion of revenues. Non-infringement defences are typically filed by third parties in response to patent infringement lawsuits including in so-called 505(b)(2) cases in the US. Details of 505(b)(2) actions can be found in Note 25 to the Financial Statements from page 184.

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 184.

# **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 *Plavix* in May, may adversely affect the growth of our still-patented products in the same product class (eg *Brilinta/Brilique*) in that market.

# **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 2012, US sales for *Seroquel XR*, *Nexium* and *Crestor* were \$811 million, \$2,272 million and \$3,164 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.

# **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 relation to biologics and vaccines, where patent infringement claims may relate to discovery or research tools, and manufacturing methods and/or 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 can 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 restrictive reimbursement policies and 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 alternative exists. These mechanisms can be used by payers to limit the use of branded products and put pressure on manufacturers to reduce net prices. Many of these mechanisms shift a greater proportion of the cost of medicines to the patient 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.

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 Pricing pressure section from page 18 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 business or results of operations.

We expect that these pressures on pricing will continue, and may increase.

# 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 health insurance exchanges and establishes new national entities focused on health system reforms. 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 fee. Implementation of several health system delivery reforms included in the law has commenced and will continue over the next two years. For example, a new comparative effectiveness research organisation, the Patient-Centered Outcomes Research Institute, has been established and an Independent Payment Advisory Board, with broad authority to propose to cut Medicare expenditures, is scheduled to commence in 2014.

The Affordable Care Act expands the patient population eligible for Medicaid and will provide new insurance coverage for individuals through state-operated and federal-operated health insurance exchanges from 2014. 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.

We anticipate further government intervention in the US in connection with the recent initiative to contain federal spending. For more information see the Regulatory requirements and Pricing pressure sections from page 17 and 18, respectively.

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.

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 cost-effectiveness of products in a particular health system. This comes as payers and policymakers attempt to drive increased efficiencies in the use and choice of pharmaceutical products.

Further information regarding these pressures is contained in the Regulatory requirements and Pricing pressure sections from page 17 and page 18, respectively.

# **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-related 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 industry-wide excise fee was \$858 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, by way of the implementation of existing or new reference pricing mechanisms, increases the pricing pressure affecting the industry. The importation of pharmaceutical products from countries where prices are low due to government price controls, or other market dynamics, to countries where prices for those products are higher, is already prevalent and may increase. In particular, as discussed in the Pricing pressure section on page 18, Greece, Portugal and Spain have all introduced measures to lower healthcare spending, including mandatory discounts, clawbacks and price referencing rules, which could have a material adverse effect on our business or results of operations.

# Performance | Risk

# **Biosimilars**

While no application for a biosimilar has been made in relation to an AstraZeneca biologic, various regulatory authorities are implementing or considering abbreviated approval processes for biosimilars 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 issued draft guidance in February 2012 on implementing an abbreviated biosimilar approval pathway. However, significant questions remain, including standards for designation of interchangeability. In 2012, the FDA also implemented user fee programmes to support biosimilar product review and policy development. In Europe, the EMA published final guidelines on similar biological medicinal products containing MAbs and in May, the first MAb biosimilar application was made. Notably, a number of jurisdictions have adopted either the EMA guidelines or those recently set forth by the WHO to enable biosimilars to enter the market after discrete periods of data exclusivity.

# Increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation

There is an increasing global focus on the implementation and enforcement of anti-bribery and anti-corruption legislation.

For example, the UK Bribery Act 2010 came into force in July 2011. 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. Details of these matters are included in Note 25 to the Financial Statements from page 184.

# 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 often based on current conditions and cannot always take into account any future changes to the pharmaceutical industry or our operations, including new business developments, wage or price increases.

# **Impact**

The extent to which biosimilars would be differentiated from patented biologics on price is unclear. However, due to their complex nature, it is uncertain whether biosimilars would have the same impact on patented biologics that generic products have had on patented small molecule products.

In addition, it is uncertain when any such abbreviated approval processes may be fully realised, particularly for more complex protein molecules such as MAbs. Any such processes may materially adversely affect the future commercial prospects for patented biologics, such as the ones that we produce.

# **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 reputation, business or results of operations.

# **Impact**

If inappropriately managed, the expected value of these initiatives could be lost through low employee engagement and hence productivity, increased absence and attrition levels, and industrial action.

Our failure to successfully implement these planned cost reduction measures, either through the successful conclusion of employee relations processes (including consultation, 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 business or results of operations.

# Changes in senior management, failure to attract and retain key personnel and failure to successfully engage with our employees

The success of our business is guided by our SET and their direct reports. The departure of senior leaders can introduce uncertainty in the business.

We rely heavily on recruiting and retaining talented employees with a diverse range of skills and capabilities to meet our strategic objectives. For example, the success of our R&D activities is particularly dependent on our ability to attract and retain sufficient numbers of high-quality researchers and development specialists. We face intense competition for qualified individuals, as the supply of people with specific skills and significant leadership potential or in specific geographic regions may be limited.

Our ability to achieve high levels of employee engagement in the workforce, and hence benefit from strong commitment and motivation, is key to the successful delivery of our business objectives.

### **Impact**

In 2012, we appointed a new CEO and in January 2013, we changed the composition of our SET. Senior management transitions can introduce uncertainty and could materially adversely impact our business or results of operations.

The inability to attract and/or retain highly skilled personnel, in particular those in key scientific and leadership positions, may weaken our succession plans for critical positions in the medium term, may materially adversely affect the implementation of our strategic objectives and could ultimately impact our business or results of operations.

Failure to engage effectively with our employees could lead to business disruption in our day-to-day operations, reduce levels of productivity and/or increase levels of voluntary turnover, all of which could ultimately adversely impact our business or results of operations.

While we are committed to working on improving drivers of engagement, such as increasing our employees' understanding of our new management, strategy and our ongoing efforts to reduce organisational complexity, our efforts may be unsuccessful.

# Failure of information technology

We are dependent on effective IT systems. These systems support key business functions such as our R&D, manufacturing, supply chain and sales capabilities, and are an important means of safeguarding and communicating data.

# Impact

Any significant disruption to these IT systems, including breaches of data centre security or cybersecurity, or failure to integrate new and existing IT systems, could harm our reputation and materially adversely affect our financial condition or results of operations.

While we have invested heavily in the protection of our data and IT, we may be unable to prevent breakdowns or breaches in our systems that could adversely affect our business.

For example, in 2012, the failure of the implementation of an IT interface in an enterprise resource planning IT system in our facility in Sweden (Södertälje) caused a disruption to our supply chain resulting in an estimated negative revenue impact of 1%.

As previously disclosed, we terminated our previous outsourcing relationship for the provision of IT infrastructure services. We continue to migrate applications and servers to equipment and facilities managed by AstraZeneca and our current providers of IT infrastructure services. This migration activity may not be completed on time and within budget, which could adversely impact our business or 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, IT systems, HR, and finance and accounting services.

# **Impact**

A failure to successfully manage and implement the integration of IT infrastructure services provided by our outsourcing providers could create disruption, which could materially adversely affect our business or results of operations.

Failure of outsource providers to deliver timely services, and to the required level of quality, and failure of outsource providers to co-operate with each other, could materially adversely affect our financial condition or results of operations. In addition, such failures could adversely impact our ability to meet business targets, maintain a good reputation within the industry and with stakeholders, and result in non-compliance with applicable laws and regulations.

# Performance | Risk

# 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.

# Difficulties and delays in the manufacturing, distribution and sale of our products

We may experience difficulties and delays in manufacturing our products, such as (i) supply chain continuity, including as a result of disruptions such as a natural or man-made disaster at one of our facilities or at a critical supplier or vendor; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for our products; (iii) seizure or recalls of products or shutdown of manufacturing plants; and (iv) other manufacturing or distribution problems including changes in manufacturing production sites, limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, or physical limitations or other business interruptions that could impact continuous supply.

# Reliance on third parties for goods

We increasingly rely on third parties for the timely supply of goods, such as raw materials (for example, the API 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 experience 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.

# 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 184 describes the material legal proceedings in which we are currently involved.

# 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**

Slight deviations in any part of the manufacturing process may result in lot failure, product recalls or spoilage, for example due to contamination.

### **Impact**

Manufacturing distribution and sale difficulties may result in product shortages and significant delays, which may lead to lost sales.

In 2012, supply from our site in India was disrupted for a period of time, following a voluntary recall of products that we determined did not meet our global quality standards.

In 2012, the failure of the implementation of an IT interface in an enterprise resource planning IT system in our facility in Sweden (Södertälje) caused a disruption to our supply chain resulting in an estimated negative revenue impact of 1%.

### **Impact**

Third party supply failure could materially adversely affect our financial condition or 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 key goods and biological materials may interrupt or prevent our research activities as planned and/or increase our costs. Further information is contained in the Managing risk section on page 74.

# **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 business or results of operations.

# **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 or results of operations, particularly where such circumstances are not covered by insurance. Furthermore, in the past we incurred substantial costs relating to product liability litigation involving *Seroquel IR*. For more information, see the Limited third party insurance coverage risk on page 84.

# 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 contractors or external partners.

# **Impact**

Failure to comply with applicable laws, including ongoing control and regulation, could materially adversely affect our business or results of operations. For example, once a product has been approved for marketing by the 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 changes 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 changes may be imposed on us by regulatory authorities as a result of continuing inspections to which we are subject or may be made at our own discretion. For example, if regulatory issues concerning compliance with current Good Manufacturing Practice or safety monitoring regulations for pharmaceutical products (often referred to as pharmacovigilance) arise, this could lead to loss of product approvals, product recalls and seizures, and interruption of production, which could create product shortages and delays in new product approvals.

# Failure to adhere to laws, rules and regulations relating to anti-competitive behaviour

Any failure to comply with laws, rules and regulations relating to anti-competitive behaviour may expose us to regulatory sanctions or lawsuits from private, non-governmental entities.

Certain of our commercial arrangements with generics companies, which have sought to settle patent challenges on terms acceptable to both innovator and generics manufacturer, may be subject to challenge by competition authorities. An example of such a challenge is the Federal Trade Commission inquiry. See Note 25 to the Financial Statements from page 184 for more details.

# Impact

Where a government authority investigates our adherence to competition laws, or we become subject to private party lawsuits, this may result in inspections of our sites or requests for documents and other information. Competition investigations or legal proceedings could be costly, divert management attention, or damage our reputation.

Unfavourable resolution of such challenges, investigations or legal proceedings against us could require us to make changes to our commercial practice and could subject us to fines and penalties and other sanctions. These could materially adversely affect our business or results of operations.

# Environmental and 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 183.

# 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 business or 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.

# Misuse of social media platforms and new technology

We increasingly use the internet, social media, mobile applications and other forms of new technology to communicate internally and externally. The accessibility and instantaneous nature of interactions with such media may facilitate or exacerbate the risk of data leakages from within AstraZeneca or false or misleading statements being made about AstraZeneca, which may be damaging to our reputation. As social media platforms expand, it becomes increasingly challenging to identify new points of entry and to put structures in place to secure and protect information.

# **Impact**

Inappropriate use of certain media vehicles could lead to misuse including public disclosure of sensitive information (such as personally identifiable information on employees, healthcare professionals or patients, for example, those enrolled in our clinical trials), which may damage our reputation and expose us to legal risks as well as additional legal obligations. Similarly, the involuntary public disclosure of commercially sensitive information such as trade secrets through external media channels, or an information loss, could materially adversely affect our business or results of operations. In addition, negative posts or comments on social media websites about us or, for example, the safety of any of our products, could harm our reputation.

# Performance | Risk

# 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 face 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.

More than 95% of our cash investments are managed centrally and are invested in AAA credit rated institutional money market funds backed by institutions in the US and the EU, which, in turn, invest in other funds, including sovereign funds. This means our credit exposure is a mix of US sovereign default risk and financial institution default risk

### Political and socio-economic conditions

We operate in over 100 countries across the world, some of which may be subject to political and social instability. There may be disruption to our business if there is instability in a particular geographic region, including as a result of war, terrorism, riot, unstable governments, civil insurrection or social unrest.

# 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 38% of our global 2012 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 25.9% of our employees are based.

# Limited third party insurance coverage

In recent years, the costs associated with product liability litigation have 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 any material 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. For example, product liability litigation cases relating to *Crestor* and *Nexium* in the US are not covered by third party product liability insurance. See Note 25 to the Financial Statements from page 183 for details.

### **Impact**

While we have adopted cash management and treasury policies to manage this risk (see Financial risk management policies section on page 99), we cannot be certain that these will be as effective as they are intended to be, in particular in the event of a global liquidity crisis. In addition, open positions where we are owed money and investments we have made in financial institution money market funds 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 our financial condition in general. Further information on debt funding arrangements is contained in the Financial risk management policies section on page 99.

# **Impact**

Deterioration of, or failure to improve, socio-economic conditions, and situations and/or events resulting therefrom, depending on their severity, could adversely affect our supply and/or distribution chain in the affected countries and the ability of customers or ultimate payers to purchase our medicines. This could materially adversely affect our business or results of operations.

# **Impact**

Movements in the exchange rates used to translate foreign currencies into US dollars may materially adversely affect our financial condition or 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 financial results of such subsidiaries could be affected by currency fluctuations arising between the transaction dates and the settlement dates for these transactions. In addition, there are foreign exchange differences arising on the translation of equity investments in subsidiaries. See Note 23 to the Financial Statements from page 175.

# Impact

If we are found to have a financial liability as a result of product liability or other litigation, in respect of which we do not have appropriate insurance, or if an insurer's denial of coverage is ultimately upheld, this could materially adversely affect our business or results of operations. For details about litigation with a number of insurers with respect to the Seroquel IR liability claim, see Note 25 to the Financial Statements from page 184.

For more information, see the Substantial product liability claims risk on page 82.

# **Taxation**

The integrated nature of our worldwide operations can produce conflicting claims from revenue authorities as to the profits to be taxed in individual countries. The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the incidence of double taxation on our revenues and capital gains.

# **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 business or 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 99 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 increase 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 167 for further details of the Group's pension obligations.

# Financial Review



# **Contents**

- 86 Introduction
- 86 2012 Business background and results overview
- 88 Measuring performance

### 2012

- 89 Results of operations– summary analysis of yearto 31 December
- 91 Cash flow and liquidity
- 92 Financial position
- 94 Capitalisation and shareholder return
- 94 Future prospects

# 2011

- 95 Results of operations– summary analysis of yearto 31 December
- 96 Cash flow and liquidity
- 97 Financial position
- 97 Revised Core financial measures
- 99 Financial risk management
- 99 Critical accounting policies and estimates
- 103 Sarbanes-Oxley Act Section 404

The financial performance for the full year 2012 was defined by the significant revenue decline associated with the loss of exclusivity for several products, with revenue down 15% in constant currency terms.

Spending discipline and restructuring benefits only partially mitigated the impact of the revenue decline on Core profits and margins, particularly as we remain committed to investment to drive future growth and value. Core earnings per share, which benefited from the favourable impact of two tax related matters and the sale of *Nexium* OTC rights, were down 9%.

Productivity and efficiency programmes continue to deliver their target levels of savings, providing the headroom to invest behind key growth platforms and in progressing the pipeline. Our cash generation remains strong, funding these investments for future growth and value whilst providing \$5.9 billion in net cash distributions to shareholders through net share repurchases of \$2.2 billion and \$3.7 billion from payment of the second interim dividend from 2011 and the first interim dividend from 2012. The Company's commitment to its progressive dividend policy was confirmed with the full year 2012 results announcement.

# Simon Lowth Chief Financial Officer

The purpose of this Financial Review is to provide a balanced and comprehensive analysis of the financial performance of the business during 2012, 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.

# 2012 Business background and results overview

The business background is covered in the Our industry section from page 16, the Therapy Area Review from page 50 and the Geographical Review from page 70, and describes in detail the developments in both our products and geographical regions.

As described earlier in this 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 risk of generic competition following loss of patent protection or patent expiry of one of our products or an 'at risk' launch by a competitor or the launch of a generic competitor in the same class as one of our products, with the potential adverse effects on sales volumes and prices. For example, in 2012, our performance was affected by generic competition in the US for Seroquel IR and, again in the US, there has been

# "The financial performance for the full year 2012 was defined by the loss of exclusivity for several products."

some volume decline of *Crestor* following the introduction of a large number of generic atorvastatin products. Further details of patent expiries for our key marketed products are included in the Patent expiries section on page 35.

- > The adverse impact on pharmaceutical prices as a result of the macroeconomic and regulatory environment. For instance, although there is no direct governmental control on prices in the US, action from federal and individual state programmes and health insurance bodies is leading to downward pressures on realised prices. In other parts of the world, there are a variety of price and volume control mechanisms and retrospective rebates based on sales levels that are imposed by governments.
- > 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 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 are expected to 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 2012 are:

- > Revenue was down 15% to \$27,973 million (Reported: 17%).
- > Loss of exclusivity on several brands, most notably Seroquel IR, and the disposals of Astra Tech and Aptium were the key drivers of the revenue decline.
- > Symbicort, Faslodex, Onglyza, Iressa, Brilinta/Brilique and Seroquel XR delivered aggregate CER revenue growth of \$600 million for the full year.
- > Emerging Markets revenue increased by 4% (Reported: unchanged).
- > Core operating profit was down 18% (Reported: 21%) to \$10,430 million, driven by lower revenues and lower Core gross margin, partially offset by reduced Core R&D and SG&A expenses.
- > Reported operating profit was down 34% (Reported: 36%) to \$8,148 million.
- > Core operating margin of 37.3% of revenue was down 1.6 percentage points at CER. Reported operating margin was 29.1% of revenue.

- > Core EPS decreased by 9% (Reported: 12%) to \$6.41. Basic EPS was down 29% (Reported: 32%) to \$4.99. Basic and Core EPS benefited by \$0.37 from two separate tax-related matters during the year. Proceeds from the sale of *Nexium* OTC rights contributed \$0.16 to Basic and Core EPS. The larger decline in Basic EPS reflects the \$1.08 per share benefit in 2011 from the sale of Astra Tech and higher restructuring costs in 2012, neither of which are included in Core earnings.
- > Dividends paid decreased to \$3,665 million (2011: \$3,764 million). Net share repurchases totalled \$2,206 million (2011: \$5,606 million). On 1 October, the Group announced the suspension of its share repurchase programme.
- > Total restructuring costs associated with the global programme to reshape the cost base of the business were \$1,558 million in 2012. Total costs to date for this third phase of restructuring, comprised of initiatives across the supply chain, SG&A and R&D, amount to \$1,819 million. This brings the total restructuring costs charged to 31 December, since the start of our restructuring programme in 2007, to \$6,427 million. Most of the remaining costs of approximately \$300 million for the third phase of our restructuring will be taken in 2013.

# Measuring performance

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

- > 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 exit arrangements with Merck in the US and other specified items. In determining the adjustments to arrive at the Core result, we use a set of established principles relating to the nature and materiality of individual items or groups of items, excluding, for example, events which (i) are outside of the normal course of business, (ii) are incurred in a pattern that is unrelated to the trends in the underlying financial performance of our ongoing business, or (iii) are related to major acquisitions, to ensure that investors' ability to evaluate and analyse the underlying financial performance of our ongoing business is enhanced. See the 2012 Reconciliation of Reported results to Core results table on the page opposite 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 2012 Reported operating profit table on the page opposite.
- > 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 the page opposite and page 95.
- > 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 2012 Reconciliation of Reported results to Core results table on the page opposite, 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 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 Core R&D costs recorded in the year. This measure reflects Core operating performance before reinvestment in internal R&D.

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 2012 Reported operating profit table on the page opposite, our reconciliation of Core financial measures to Reported financial information in the Reconciliation of Reported results to Core results table on the page opposite, and to the Results of operations – summary analysis of year to 31 December 2011 section from page 95 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.

With effect from the first quarter results of 2013, we will update our definition of Core financial measures to exclude all intangible asset amortisation charges and impairments, except those for IS-related intangibles. Further details of this change are included in the Revised Core financial measures section of this Financial Review from page 97. With the exception of the numbers detailed on page 98, all other references to Core in this Annual Report are calculated using our current definition of Core.

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 2012 2012 Reported operating profit

	2012				Percenta	ige of sales	2012 compared with 2011	
	Reported \$m	due to CER exchange Reported growth effects \$m \$m \$m	Growth due to exchange effects \$m	Reported \$m	Reported 2012 %	Reported 2011 %	CER growth %	Reported growth %
Revenue	27,973	(4,965)	(653)	33,591			(15)	(17)
Cost of sales	(5,393)	528	105	(6,026)	(19.3)	(17.9)	(9)	(11)
Gross profit	22,580	(4,437)	(548)	27,565	80.7	82.1	(16)	(18)
Distribution costs	(320)	16	10	(346)	(1.1)	(1.0)	(5)	(8)
Research and development	(5,243)	208	72	(5,523)	(18.8)	(16.5)	(4)	(5)
Selling, general and administrative costs	(9,839)	1,134	188	(11,161)	(35.2)	(33.2)	(10)	(12)
Profit on disposal of Astra Tech	-	(1,483)	-	1,483	_	4.4	n/a	n/a
Other operating income and expense	970	211	(18)	777	3.5	2.3	27	25
Operating profit	8,148	(4,351)	(296)	12,795	29.1	38.1	(34)	(36)
Net finance expense	(430)			(428)				
Profit before tax	7,718			12,367				
Taxation	(1,391)			(2,351)				
Profit for the period	6,327			10,016				
Basic earnings per share (\$)	4.99			7.33				

# 2012 Core operating results

		2012			2012 compare	d with 2011
	Core \$m	CER growth \$m	Growth due to exchange effects \$m	Core \$m	CER growth %	Total Core growth %
Gross profit	22,716	(4,355)	(548)	27,619	(16)	(18)
Gross margin %	81.2%			82.2%		
Distribution costs	(320)	16	10	(346)	(5)	(8)
Research and development	(4,452)	533	48	(5,033)	(11)	(12)
Selling, general and administrative costs	(8,541)	1,207	170	(9,918)	(12)	(14)
Other operating income and expense	1,027	200	(18)	845	24	22
Operating profit	10,430	(2,399)	(338)	13,167	(18)	(21)
Operating margin %	37.3%			39.2%		
Net finance expense	(430)			(428)		
Profit before tax	10,000			12,739		
Taxation	(1,885)			(2,797)		
Profit for the period	8,115			9,942		
Basic earnings per share (\$)	6.41			7.28		

# 2012 Reconciliation of Reported results to Core results

			Merck 8	k Medlmmune	Legal	
	2012 R Reported \$m	estructuring costs \$m	Amortisation \$m	Intangible impairments \$m	provisions and other \$m	2012 Core \$m
Gross profit	22,580	136	_	_	-	22,716
Distribution costs	(320)	_	_	_	_	(320)
Research and development	(5,243)	791	_	_	_	(4,452)
Selling, general and administrative costs	(9,839)	631	534	_	133	(8,541)
Other operating income and expense	970	-	57	_	_	1,027
Operating profit	8,148	1,558	591	_	133	10,430
Add back: Research and development	5,243	(791)	_	-	_	4,452
Pre-R&D operating profit	13,391	767	591	-	133	14,882
Pre-R&D operating margin %	47.9%					53.2%
Net finance expense	(430)	-	_	_	_	(430)
Profit before tax	7,718	1,558	591	_	133	10,000
Taxation	(1,391)	(375)	(87)	_	(32)	(1,885)
Profit for the period	6,327	1,183	504	-	101	8,115
Basic earnings per share (\$)	4.99	0.94	0.40	_	0.08	6.41

Revenue decreased by 15% on a CER basis and 17% on a Reported basis. More than 13 percentage points of the decline at CER (approximately \$4.5 billion) was related to loss of exclusivity on several brands in the portfolio. Seroquel IR revenues declined by \$3 billion and regional losses of exclusivity for Atacand, Nexium and Crestor combined for a further negative impact of more than \$1 billion. The disposals of Astra Tech and Aptium accounted for a further decrease of \$562 million, or approximately 1.7 percentage points of the year-on-year revenue change at CER. Disruptions to our supply chain, from the implementation of an enterprise resource planning IT system in our plant in Sweden early in the year, negatively impacted revenues by approximately 1%.

Revenue in the US was down 21% (Reported: 21%) with revenue in the Rest of World down 11% (Reported: 14%). Emerging Markets sales increased by 4% (Reported: flat). Further details of our sales performance are contained in the Therapy Area Review from page 50 and the Geographical Review from page 70.

Core gross margin of 81.2% decreased 0.9 percentage points (Reported: 1.0 percentage points). In 2012, benefits from the absence of the lower margin businesses of Astra Tech and Aptium, and from lower net expense related to our accounting for the amendments to the Merck exit arrangements (as detailed in Note 9 to the Financial Statements from page 159), were more than offset by an unfavourable impact from product mix. Core gross margin in 2011 benefited from a \$131 million settlement of a royalty dispute with PDL Biopharma Inc.

Core R&D expenditure was \$4,452 million, 11% lower than last year (Reported: 12%). Higher costs from new spending on in-licensed, acquired or partnered projects, including \$151 million relating to Amylin, Ardea and Amgen, were more than offset by lower intangible impairments in 2012 of \$186 million compared with 2011 impairments of \$527 million, a reduction of \$341 million, and reduced spend on projects.

Core SG&A costs of \$8,541 million were 12% lower than in 2011 (Reported: 14%), as a result of spending discipline, partially offset by amortisation expense related to the expansion of our diabetes alliance with BMS and increased promotional costs in Emerging Markets. The excise fee imposed by the enactment of US healthcare reform measures amounted to 2.8% (2011: 2.1%) of Core SG&A expense for the year.

Core other income of \$1,027 million was \$182 million higher (Reported growth) than the previous year principally as a result of \$250 million income from an agreement with Pfizer for OTC rights for *Nexium*.

Core pre-R&D operating margin was 53.2%, down 0.9 percentage points (Reported: 1.0 percentage points), as the benefit from higher Core other income was more than offset by higher Core cost of sales and Core SG&A costs as a percentage of revenue.

Core operating profit was \$10,430 million, a decrease of 18% (Reported: 21%). Core operating margin declined by 1.6 percentage points (Reported: 1.9 percentage points) to 37.3% as a result of an unfavourable impact from lower Core gross margin combined with higher Core R&D and SG&A costs as a percentage of revenue, being only partially mitigated by the increased Core other income for the year.

Core EPS was \$6.41, down 9% (Reported: 12%), lower than the decline in Core operating profit as a result of the benefits from net share repurchases and a lower tax rate.

Pre-tax adjustments to arrive at Core amounted to \$2,282 million in 2012 (2011: \$372 million). Excluded from Core results were:

- > Restructuring costs totalling \$1,558 million (2011: \$1,161 million), incurred as the Group commenced the third phase of restructuring announced in February 2012.
- > Amortisation totalling \$591 million (2011: \$537 million) relating to assets capitalised as part of the MedImmune acquisition and the Merck exit arrangements, the increase driven by the additional amortisation arising from the amendment to the Merck exit arrangements during 2012, as detailed in Note 9 to the Financial Statements from page 159.
- > \$72 million (2011: \$135 million) of legal provision charges in respect of ongoing Seroquel franchise legal matters, Average Wholesale Price litigation in the US, the Toprol-XL anti-trust litigation and Nexium commercial 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.
- > \$61 million (2011: \$nil) of acquisition- and transaction-related expenses in relation to our Ardea and new BMS collaboration arrangements. Further details of these transactions are included in Note 9 and Note 22 to the Financial Statements.
- > In 2011, the profit on sale of our subsidiary Astra Tech of \$1,483 million was also excluded from Core results. Further details of this disposal are included in Note 22 to the Financial Statements on page 173.

Reported operating profit was down 34% (Reported: 36%) at \$8,148 million. Reported EPS was \$4.99, down 29% (Reported:

32%). The larger declines compared with the respective Core financial measures are the result of the \$1,483 million benefit to Reported other income in 2011 from the sale of Astra Tech, together with higher restructuring and amortisation costs in 2012 compared with the prior year.

Net finance expense was \$430 million, in line with the \$428 million expense recorded in 2011. Net fair value losses on long-term debt and derivatives were \$10 million for the year, versus \$4 million gains in 2011. This was partially offset by reduced net finance cost on the Group's pension schemes.

The Reported taxation charge of \$1,391 million (2011: \$2,351 million) consists of a current tax charge of \$1,682 million (2011: \$2,578 million) and a credit arising from movements on deferred tax of \$291 million (2011: \$227 million). The current year tax charge includes a prior period current tax credit of \$79 million (2011: \$102 million).

The Reported tax rate for the year was 18.0% (2011: 19.0%). The Reported tax rate for the year benefited from a \$230 million adjustment to deferred tax balances following substantive enactment in 2012 of a reduction in the Swedish corporation tax rate from 26.3% to 22%, which is effective 1 January 2013, and a \$240 million adjustment in respect of prior periods following the favourable settlement of a transfer pricing matter. Excluding these items, the Reported tax rate for the year would have been 24.1%; this tax rate is applied to the taxable Core adjustments to operating profit, resulting in a Core tax rate for the year of 18.9%. The Reported tax rate for last year benefited from a non-taxable gain on the disposal of Astra Tech and a favourable adjustment to tax provisions of \$520 million 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 for the period from 2002 to the end of 2014 and a related valuation matter. Excluding these benefits, the Reported tax rate for 2011 was 26.4%.

Total comprehensive income for the year decreased by \$3,065 million from 2011 to \$6,405 million. This was driven by the decrease in profit for the year of \$3,689 million, partially offset by an increase of \$624 million in other comprehensive income, which was principally due to the non-recurrence in 2012 of \$741 million of actuarial losses recorded in 2011 on our defined benefit schemes, arising from lower discount rates applied to our long-term pension obligations reflecting external market conditions.

# Cash flow and liquidity - 2012

All data in this section is on a Reported basis.

# Summary cash flows

	2012 \$m	2011 \$m	2010 \$m
Net funds brought forward at 1 January	2,849	3,653	535
Earnings before interest, tax, depreciation, amortisation and impairment (EBITDA)	10,666	15,345	14,235
Profit on disposal of Astra Tech	_	(1,483)	_
EBITDA before profit on disposal of Astra Tech	10,666	13,862	14,235
Movement in working capital and short-term provisions	(706)	(897)	82
Tax paid	(2,043)	(3,999)	(2,533)
Interest paid	(545)	(548)	(641)
Non-cash and other movements	(424)	(597)	(463)
Net cash available from operating activities	6,948	7,821	10,680
Purchase of intangibles (net)	(3,947)	(458)	(1,180)
Other capital expenditure (net)	(473)	(737)	(708)
Acquisitions of business operations	(1,187)	_	(348)
Net cash received on disposal of Astra Tech	<del>-</del>	1,772	_
Investments	(5,607)	577	(2,236)
Dividends	(3,665)	(3,764)	(3,361)
Net share repurchases	(2,206)	(5,606)	(2,110)
Distributions	(5,871)	(9,370)	(5,471)
Other movements	312	168	145
Net (debt)/funds carried forward at 31 December	(1,369)	2,849	3,653

# Net debt/funds reconciliation

	2012 \$m	2011 \$m	2010 \$m
Cash and cash equivalents	7,701	7,571	11,068
Short-term investments	823	4,248	1,482
Net derivative financial instruments	417	358	325
Cash, short-term investments and derivatives	8,941	12,177	12,875
Overdraft and short-term borrowings	(879)	(221)	(125)
Finance leases	(84)	_	_
Current instalments of loan	_	(1,769)	_
Loans due after one year	(9,347)	(7,338)	(9,097)
Loans and borrowings	(10,310)	(9,328)	(9,222)
Net (debt)/funds	(1,369)	2,849	3,653

Cash generated from operating activities was \$6,948 million in the year to 31 December 2012, compared with \$7,821 million in 2011. The decrease of \$873 million is primarily driven by lower operating profits, offset by lower tax payments.

Investment cash outflows of \$5,607 million include the purchases of Ardea (\$1,187 million) and intangible assets associated with our collaboration with BMS on Amylin (\$3,358 million). The 2011 investment cash inflow of \$577 million benefited from the sale of Astra Tech (\$1,772 million). Further details of the Ardea acquisition and Astra Tech disposal are included in Note 22 to the Financial Statements from page 173. Our Amylin transaction is detailed in Note 9 to the Financial Statements on page 161.

Net cash distributions to shareholders decreased from \$9,370 million in 2011 to \$5,871 million in 2012, the reduction being driven by the suspension of our share repurchase programme in October. Included in net cash distributions to shareholders are dividend payments of \$3,665 million (2011: \$3,764 million).

At 31 December 2012, outstanding gross debt (interest-bearing loans and borrowings) was \$10,310 million (2011: \$9,328 million). Of this gross debt, \$901 million is due within one year, including \$774 million of commercial paper borrowings (2011: \$nil) with various short-term maturities all within 90 days. In 2011, amounts due within one year included \$1,769 million relating to current instalments of loans.

During September, the Company issued \$2 billion of new long-term debt in two

tranches; \$1 billion maturing in 2019 with a coupon of 1.95% and \$1 billion maturing in 2042 with a coupon of 4.00%. Net proceeds of \$1,980 million from the issue were used to repay a \$1.75 billion bond with a coupon of 5.40% maturing in September 2012 and for general corporate purposes.

Net debt was \$1,369 million at the end of the year, a decrease from net funds of \$2,849 million at the end of 2011, a movement of \$4,218 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	2012 Total \$m	2011 Total \$m
Bank loans and other borrowings <sup>1</sup>	1,365	2,649	2,536	10,766	17,316	15,515
Finance leases	23	46	32	_	101	_
Operating leases	102	140	83	109	434	392
Contracted capital expenditure	245	_	_	_	245	190
Total	1,735	2,835	2,651	10,875	18,096	16,097

<sup>1</sup> Bank loans and other borrowings include interest charges payable in the period, as detailed in Note 23 to the Financial Statements on page 175.

# Financial position - 2012

All data in this section is on a Reported basis.

# Summary statement of financial position

	2012 \$m	Movement \$m	2011 \$m	Movement \$m	2010 \$m
Property, plant and equipment	6,089	(336)	6,425	(532)	6,957
Goodwill and intangible assets	26,346	5,504	20,842	(1,187)	22,029
Inventories	2,061	209	1,852	170	1,682
Trade and other receivables	7,981	(773)	8,754	907	7,847
Trade and other payables	(10,222)	(862)	(9,360)	(326)	(9,034)
Provisions	(1,344)	518	(1,862)	76	(1,938)
Net income tax payable	(2,059)	275	(2,334)	1,521	(3,855)
Net deferred tax liabilities	(1,465)	(244)	(1,221)	449	(1,670)
Retirement benefit obligations	(2,265)	409	(2,674)	(202)	(2,472)
Non-current other investments	199	(2)	201	(10)	211
Net (debt)/funds	(1,369)	(4,218)	2,849	(804)	3,653
Net assets	23,952	480	23,472	62	23,410

In 2012, net assets increased by \$480 million to \$23,952 million. The increase in net assets is broadly as a result of the Group profit of \$6,327 million, offset by dividends of \$3,619 million and net share repurchases of \$2,206 million.

# Property, plant and equipment

Property, plant and equipment decreased by \$336 million to \$6,089 million. Additions of \$772 million (2011: \$807 million) were offset by depreciation of \$1,023 million (2011: \$1,086 million) and disposals of \$224 million (2011: \$233 million).

# Goodwill and intangible assets

The Group's goodwill of \$9,898 million (2011: \$9,862 million) principally arose on the acquisition of MedImmune in 2007 and the restructuring of our US joint venture with Merck in 1998. Goodwill of \$30 million arising on our acquisition of Ardea, as detailed in Note 22 to the Financial Statements on page 173, was capitalised in 2012.

Intangible assets amounted to \$16,448 million at 31 December 2012 (2011: \$10,980 million). Intangible asset additions were \$6,916 million in 2012 (2011: \$442 million), including \$1,464 million arising on the acquisition of Ardea, \$3,358 million arising from the expansion of our diabetes alliance with BMS and \$1,475 million in connection with our Merck arrangements. Amortisation in the year was \$1,296 million (2011: \$911 million) and impairments totalled \$199 million (2011: \$553 million). Further details of our additions to intangible assets, and impairments recorded, are included in Note 9 to the Financial Statements from page 159.

# Receivables, payables and provisions

Trade receivables decreased by \$934 million to \$5,696 million in line with lower revenues in 2012.

Included within trade receivables is approximately \$420 million of net receivables, representing 7% of our trade receivables, due from customers in the eurozone countries of Spain, Italy, Portugal and Greece (Spain: \$120 million; Italy: \$205 million; Portugal: \$30 million; and Greece: \$65 million). Within this balance is approximately \$130 million of overdue government trade receivables. In light of current market conditions, debts within these eurozone 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 the budget constraints of individual countries. In 2012, our revenue from these four countries was \$876 million (Italv). \$510 million (Spain), \$241 million (Greece) and \$168 million (Portugal).

Other receivables decreased by \$402 million to \$835 million as a result of monies being released from externally held settlement funds in relation to *Seroquel* franchise legal matters. Prepayments and accrued income increased by \$563 million driven, principally, by an increase in prepayments related to our Amylin transaction (see Note 9 to the Financial Statements on page 161).

Trade and other payables increased by \$862 million in 2012 to \$10,222 million, with increases in accruals of \$1,323 million due to our Merck exit commitments, as detailed in Note 9 to the Financial Statements from page 161, being offset by a decrease

in rebates and chargeback accruals of \$799 million. The decrease in rebates and chargebacks is principally driven by the reduction in US revenues recorded in 2012. Further details of the movements on rebates and chargebacks are included from page 99.

The reduction in provisions of \$518 million in 2012 includes \$1,096 million of additional charges recorded in the year, offset by \$1,476 million of cash payments. Included within the \$1,096 million of charges for the year is \$873 million for our global restructuring initiative and \$90 million in respect of legal charges. Cash payments of \$1,476 million include a reduction in our Seroquel franchise-related provisions of \$427 million, following release of monies from our settlement funds as detailed above, and \$853 million for our global restructuring programme. 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 \$275 million to \$2,059 million, principally due to the settlement of a transfer pricing matter as detailed in Note 4 to the Financial Statements from page 152. Our tax receivable balance of \$803 million 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) and cash tax timing differences. Net deferred tax liabilities increased by \$244 million in the year.

# Retirement benefit obligations

Net retirement benefit obligations decreased by \$409 million, driven by an additional lump sum payment made into the UK defined benefit scheme in 2012. 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. 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 £715 million (\$1,103 million). The first of these lump sum payments of £180 million (\$278 million) was paid into the pension scheme from the escrow account in December 2011. A further £300 million (\$463 million) was paid into the pension scheme during January 2012 and the balance will be paid in due course. In 2011, £132 million (\$213 million) was paid into the escrow account and a further £230 million (\$355 million) was paid in during January 2012. At 31 December 2012, £462 million (\$748 million) escrow fund assets are included within other investments (as detailed in Note 10 to the Financial Statements on page 163).

In 2012, approximately 97% 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 167.

# 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 99 and in Note 25 to the Financial Statements from page 189.

# Research and development collaboration payments

Details of future potential R&D collaboration payments are also included in Note 25 to the Financial Statements from page 183. As detailed in Note 25 to the Financial Statements, 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 R&D, as a crucial element of the development of our business.

The Group has completed over 130 major externalisation transactions over the past three years, two of which were accounted for as business acquisitions under IFRS 3 'Business Combinations', being the acquisition of Ardea in 2012 for \$1.3 billion and Novexel in 2010 for \$0.5 billion, and all others were strategic alliances and collaborations. Further details of our business acquisitions and disposals in the past three years are contained in Note 22 to the Financial Statements from page 173. 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 Onglyza, a DPP-IV and Forxiga, a selective sodium-glucose co-transporter 2 (SGLT2) inhibitor, both for the treatment of Type 2 diabetes. The agreement is global with the exception of Japan for Onglyza. 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 Onglyza and \$170 million for Forxiga, will make a further payment of \$80 million for Forxiga in early 2013, and may make future milestone payments of up to \$150 million on *Forxiga* 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.
- > In August, AstraZeneca expanded its diabetes alliance with BMS to incorporate the development and marketing of

Amylin's portfolio of diabetes products. Amvlin, a wholly owned subsidiary of BMS, is a biopharmaceutical company dedicated to the discovery, development and commercialisation of innovative medicines for patients with diabetes and other metabolic diseases. Amylin's primary focus is on the research, development and commercialisation of a franchise of GLP-1 agonists for the treatment of Type 2 diabetes. The portfolio of collaboration products includes Byetta (exenatide) injection and Bydureon (exenatide extended-release for injectable suspension/exenatide 2mg powder and solvent for prolonged release suspension for injection) that are approved for use in both the US and Europe, Symlin (pramlinitide acetate) injection that is approved for use in the US, and metreleptin, a leptin analogue currently under review at the FDA for the treatment of diabetes and/or hypertriglyceridaemia in patients with rare forms of inherited or acquired lipodystrophy. AstraZeneca has expanded the alliance for a total consideration of \$3.7 billion. This includes an amount of \$135 million relating to an option of AstraZeneca contained in the collaboration agreement to acquire certain additional governance rights in respect of the collaboration. The Group notified BMS of its decision to exercise the option in August and the balance of \$135 million will be payable once applicable anti-trust and competition approvals are received by AstraZeneca. The Group expects to make this payment in the first half of 2013. Profits and losses arising from the collaboration will be shared equally. Further details of this collaboration and our accounting treatment for this arrangement are included in Note 9 to the Financial Statements on page 161.

> In April 2012, AstraZeneca announced an agreement to jointly develop and commercialise five monoclonal antibodies from Amgen's clinical inflammation portfolio: AMG 139, AMG 157, AMG 181, AMG 557 and brodalumab (AMG 827). Under the terms of the agreement, AstraZeneca made a \$50 million upfront payment and the companies share both costs and profits. Approximately 65% of costs for the 2012 to 2014 period will be funded by AstraZeneca. Thereafter, the companies will split costs equally. In addition, AstraZeneca will make milestone payments to a maximum of \$30 million up to launch. On commercialisation, Amgen will retain a low single-digit royalty for brodalumab and a mid-single-digit royalty for the rest of the portfolio after which the companies will share profits equally.

# Capitalisation and shareholder return

# Dividend for 2012

	\$	Pence	SEK	Payment date
First interim dividend	0.90	58.1	6.26	10 September 2012
Second interim dividend	1.90	120.5	12.08	18 March 2013
Total	2.80	178.6	18.34	

# 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	3,653	9,668
2012	57.8	2,635	2.80	3,4931	6,128
Total	610.8	29,170	21.225	31,089	60,259

<sup>&</sup>lt;sup>1</sup> Total dividend cost estimated based upon number of shares in issue at 31 December 2012.

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 R&D 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, payments capitalised under the Group's externalisation arrangements, other than those detailed above, amounted to \$156 million in 2012, \$123 million in 2011 and \$337 million in 2010. The Group recognised other income in respect of other externalisation arrangements totalling \$255 million in 2012, including \$250 million of income from an agreement with Pfizer for OTC rights for *Nexium*, \$18 million in 2011 and \$82 million in 2010.

# Capitalisation

The total number of shares in issue at 31 December 2012 was 1,247 million. 12.2 million Ordinary Shares were issued in consideration of share option exercises for a total of \$429 million. Share repurchases amounted to 57.8 million Ordinary Shares at a cost of \$2,635 million. Shareholders' equity increased by \$491 million to \$23,737 million at the year end. Non-controlling interests decreased to \$215 million (2011: \$226 million).

# Dividend and share repurchases

The Board has recommended a second interim dividend of \$1.90 (120.5 pence, 12.08 SEK) to be paid on 18 March 2013. This brings the full year dividend to \$2.80 (178.6 pence, 18.34 SEK).

This dividend is consistent with the progressive dividend policy, by which the Board intends to maintain or grow the dividend each year. In adopting this policy, the Board recognised that some earnings fluctuations are to be expected as the Group's revenue base transitions through this period of exclusivity losses and new product launches. The Board's view is that the annual dividend will not just reflect the financial performance of a single year taken in isolation, but reflect its view of the earnings prospects for the Group over the entirety of the investment cycle.

The Company has revised the basis by which it assesses dividend cover. The previous basis was a dividend cover target of two times (ie a payout ratio of 50%) based on Reported earnings (before restructuring

costs). With the adoption of new definitions of Core financial measures, as detailed from page 97, the dividend cover target is now two times based on Core earnings under the new definition. In the context of the earnings fluctuations that are to be expected as the Group's revenue base transitions through this period of exclusivity losses and new product launches, the Board recognises that dividend cover in any year is likely to vary from the two times target level through the investment cycle.

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

We believe challenging market conditions will persist in 2013, including continued government interventions in price. The revenue impact from the loss of exclusivity will also continue to affect our performance. In the context of the ongoing update to our strategy, we have withdrawn the planning assumptions for revenue and margin evolution for the period 2010 to 2014 we outlined in January 2010. We plan to hold a Capital Markets Day in March 2013 to provide a more detailed exposition of our strategic priorities.

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

			2011		Percer	ntage of sales	2011 compared with 20	
	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 profit	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			2011 compared with 2010	
	Core \$m	CER growth \$m	Growth due to exchange effects \$m	Core \$m	CER growth %	Total Core growth %
Gross profit	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 & Medlmmune			Profit on		
	2011 Reported \$m	Restructuring costs	Amortisation \$m	Intangible impairments \$m	Legal settlements \$m	disposal of Astra Tech \$m	2011 Core \$m
Gross profit	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 profit	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

2011 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 the *Seroquel* franchise but was offset by lower revenues for *Nexium*, *Arimidex* and *Seloken/Toprol-XL*. Emerging Markets sales growth of 10% in 2011 (Reported: 11%) and Established ROW 4% (Reported: 14%) was offset by a decline in 2011 US sales of 2% (Reported: 2%) and Western Europe of 11% (Reported: 7%). Further details of our sales performance are contained in the Therapy Area Review from page 50 and the Geographical Review from page 70.

Core gross margin in 2011 of 82.2% increased 1.3 percentage points (Reported: 1.0 percentage points). The 2011 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 a royalty dispute with PDL Biopharma Inc. in 2011.

Core R&D expenditure in 2011 was \$5,033 million, 15% higher than 2010 (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.

2011 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 in 2011 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% in 2011, up 1.0 percentage points (Reported: 0.7 percentage points), as the higher 2011 gross margin was only slightly offset by lower Core other income and higher SG&A costs as a percentage of revenue.

2011 Core operating profit was \$13,167 million, a decrease of 4% from 2010 (Reported: 3%). Core operating margin declined by 1.2 percentage points (Reported: 1.6 percentage points) to 39.2% in 2011 as a result of the higher R&D spend and lower Core other operating income.

Core EPS was \$7.28 in 2011, up 7% (Reported: 9%), with the lower operating profit offset by a lower tax rate, lower net interest as well as the benefit of a lower average number of shares outstanding.

Within Core adjustments for 2011, restructuring costs and amortisation were broadly in line with 2010. 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 2011 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 IR* product liability litigation, Average Wholesale Price litigation in the US and the *Toprol-XL* anti-trust litigation.
- > Restructuring costs totalling \$1,161 million in 2011 (2010: \$1,202 million), incurred as the Group continued its previously announced efficiency programmes.
- > Amortisation totalling \$537 million (2010: \$518 million) relating to assets capitalised in 2011 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 2011, 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 173.

2011 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 was \$7.33 in 2011, 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 in 2011, 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 Reported taxation charge of \$2,351 million (2010: \$2,896 million) consisted 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 2011 current year tax charge included a prior period current tax credit of \$102 million (2010: charge of \$370 million). The Reported tax rate for 2011 was 19.0% (2010: 26.4%). The 2011 Reported tax rate 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 had 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. Excluding these benefits, the Reported tax rate for 2011 was 26.4%.

Total comprehensive income for 2011 increased by \$1,364 million to \$9,470 million. This was driven by the increase in profit in 2011 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 in 2011 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 was primarily driven by higher tax payments made in 2011, 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 in 2011 included the sale of Astra Tech (\$1,772 million). Cash outflows on the purchase of tangible fixed assets amounted to \$839 million in 2011, in line with the previous year.

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.

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 was due within one year (2010: \$125 million).

# Financial position - 2011

All data in this section is on a Reported basis.

In 2011, net assets increased by \$62 million to \$23,472 million. The increase in net assets as a result of the 2011 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 in 2011. Additions of \$807 million (2010: \$808 million) were offset by depreciation of \$1,068 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 at 31 December 2011 (2010: \$9,871 million) principally arose on the acquisition of MedImmune and the restructuring of our US joint venture with Merck in 1998. No goodwill was 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 intangible assets were disposed of on the sale of Astra Tech in 2011.

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.

# Receivables, payables and provisions

In 2011, 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 at 31 December 2011 driven by an increase in our *Seroquel IR*-related settlement funds.

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 from page 99.

The movement in provisions of \$76 million in 2011 included \$716 million of additional charges recorded in the year, offset by \$657 million of cash payments. Included within the \$716 million of charges in 2011 was \$135 million in respect of legal charges and \$450 million for our global restructuring initiative. 2011 cash payments of \$657 million included \$377 million against our ongoing global restructuring initiative and \$153 million related to legal matters.

# Tax payable and receivable

Net income tax payable in 2011 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. The tax receivable balance of \$1,056 million 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 \$449 million in 2011.

# Retirement benefit obligations

Net retirement benefit obligations increased by \$202 million in 2011, 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).

# **Revised Core financial measures**

As detailed in our announcement of 12 November 2012, with effect from our first quarter results in 2013, the Group will update its definition of Core financial measures to exclude all intangible asset amortisation charges and impairments, except those for IS-related intangibles. As intangible assets acquired as a result of externalisation become an increasing proportion of the Group's asset base,

the new definition has been extended to provide better clarity of the impact from amortisation and impairment charges included in Reported results and, in addition, while recognising that non-GAAP measures differ between companies, it will aid comparability of our results versus our peers.

The items excluded from Core results under the existing definition, as disclosed in detail on page 88, remain a constituent part of the new definition. The existing definition excludes from our Core numbers certain significant items, such as charges and provisions related to our global restructuring programmes, amortisation and impairment of the significant intangibles relating to our acquisition of MedImmune in 2007 and our exit arrangements with Merck in the US, and other specified items. In determining the adjustments to arrive at the Core result, we use a set of established principles relating to the nature and materiality of individual items or groups of items, excluding, for example, events which (i) are outside of the normal course of business, (ii) are incurred in a pattern that is unrelated to the trends in the underlying financial performance of our ongoing business, or (iii) are related to major acquisitions, to ensure that investors' ability to evaluate and analyse the underlying financial performance of our ongoing business is enhanced.

# Adjustments between Reported and revised Core performance measures

Under the revised definition of Core, our Reported performance will be adjusted for:

> Amortisation and impairments of intangible assets. The definition of this item will be updated to include all amortisation and impairment charges for intangible assets except for those arising on IS-related assets. Adjusting for these items removes the volatility when impairments are booked on such assets and is intended to provide a better measure of underlying business performance. It will be extended to cover all amortisation and impairments relating to product marketing and distribution rights and other intangibles, incorporating those already excluded under the current definition relating to our acquisition of MedImmune and our exit arrangements with Merck. The amortisation and impairment of IS-related intangibles

- are not included in the adjustment, and will remain in Core.
- > Restructuring costs. The definition for this item has not been changed. These charges arise from the major restructuring programmes announced by the Group.
- > Legal charges and other charges. The definition for this item has not been changed. Legal payments, charges and expenses related to settlements, judgments and fines in the context of product liability litigation, anti-trust litigation, patent litigation and government

investigations will be excluded from the Core measures and the adjustment will be stated net of related insurance recoveries. In the ordinary course of business, external legal professional fees, including those relating to IP protection costs, and the costs of AstraZeneca's in-house legal function will remain in Core. Professional fees directly attributable to AstraZeneca's significant acquisitions and other significant business combination activity will continue to be excluded from Core. Other specified items deemed not

- to be in the ordinary course of business will continue to be excluded from Core.
- > Tax on adjustments. The definition for this item has not been changed. The Group's Reported tax rate, adjusted for significant one-off items embedded within that rate, is applied to all taxable Core adjustments.

# Reconciliations of Existing Core to Revised Core

The adjustments that will be made to our existing Core definition to arrive at our revised Core definition for use from 2013 onwards are detailed in the tables below.

# 2012 Reconciliation of Existing Core results to Revised Core results

		Revised Core additional adjustments			2012 compa	Revised Core ared with 2011
	2012 Existing Core \$m (page 89)	Amortisation	Impairments	2012 Revised Core \$m	CER growth	Total growth
Revenue	27,973	-	-	27,973	(15)	(17)
Cost of sales	(5,257)	325	_	(4,932)		
Gross profit	22,716	325	_	23,041	(15)	(17)
Distribution costs	(320)	_	_	(320)	(5)	(8)
Research and development	(4,452)	25	186	(4,241)	(4)	(5)
Selling, general and administrative costs	(8,541)	152	_	(8,389)	(13)	(15)
Other operating income and expense	1,027	41	_	1,068	29	26
Operating profit	10,430	543	186	11,159	(17)	(20)
Net finance expense	(430)	_	_	(430)		
Profit before tax	10,000	543	186	10,729	(18)	(20)
Taxation	(1,885)	(107)	(45)	(2,037)		
Profit for the period	8,115	436	141	8,692	(15)	(17)
Basic earnings per share (\$)	6.41	0.35	0.11	6.87	(8)	(11)

# 2011 Reconciliation of Existing Core results to Revised Core results

		Revised Core additional adjustments			Revised Core 2011 compared with 2010		
	2011 Existing Core \$m (page 95)			2011 Revised Core \$m	CER growth %	Total growth %	
Revenue	33,591	_	-	33,591	(2)	1	
Cost of sales	(5,972)	129	_	(5,843)			
Gross profit	27,619	129	-	27,748	(1)	2	
Distribution costs	(346)	_	_	(346)	(1)	3	
Research and development	(5,033)	27	527	(4,479)	6	10	
Selling, general and administrative costs	(9,918)	78	4	(9,836)	(2)	1	
Other operating income and expense	845	_	_	845	(8)	(7)	
Operating profit	13,167	234	531	13,932	(2)	(1)	
Net finance expense	(428)	_	_	(428)			
Profit before tax	12,739	234	531	13,504	(1)	_	
Taxation	(2,797)	(28)	(140)	(2,965)			
Profit for the period	9,942	206	391	10,539	4	5	
Basic earnings per share (\$)	7.28	0.15	0.29	7.72	10	11	

# Financial risk management Financial risk management policies Insurance

Our risk management processes are described in the Managing risk section from page 74. 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. Insurance for product liability has not been available on commercially acceptable terms for several years and the Group has not held product liability insurance since February 2006.

# **Taxation**

Tax risk management forms an integrated part of the Group's 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 175 and in the Risk section from page 74

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 175.

# 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 overleaf.

Accrual assumptions are built up on a product-by-product and customer-bycustomer basis, taking into account specific contract provisions coupled with expected performance, and are then aggregated into a weighted average rebate accrual rate for each of our products. Accrual rates are reviewed and adjusted on a monthly basis. There may be further adjustments when actual rebates are invoiced based on utilisation information submitted to us (in the case of contractual rebates) and claims/invoices are received (in the case of regulatory rebates and chargebacks). We believe that we have 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 customers' contractual performance.

The large increase in managed-care and group purchasing organisation rebates in 2011 was principally driven by the impacts of the Affordable Care Act. See page 71 of the Geographical Review for more information. The 2012 adjustment in respect of prior years includes refinements of the provisions recorded for the Affordable Care Act.

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

# Gross to net sales - US Pharmaceuticals

	2012 \$m	2011 \$m	2010 \$m
Gross sales	20,747	23,613	22,909
Chargebacks	(2,261)	(1,958)	(2,075)
Regulatory – US government and state programmes	(1,426)	(2,293)	(1,949)
Contractual – Managed-care and group purchasing organisation rebates	(5,597)	(5,437)	(4,755)
Cash and other discounts	(401)	(452)	(437)
Customer returns	(182)	(72)	(21)
Other	(273)	(276)	(265)
Net sales	10,607	13,125	13,407

# Movement in provisions - US Pharmaceuticals

	Brought forward at 1 January 2012 \$m		Adjustment in respect of prior years \$m	Returns and payments \$m	Carried forward at 31 December 2012 \$m
Chargebacks	395	2,296	(35)	(2,343)	313
Regulatory – US government and state programmes	1,290	1,585	(159)	(1,891)	825
Contractual – Managed-care and group purchasing organisation rebates	1,600	5,578	19	(5,849)	1,348
Cash and other discounts	41	401	_	(409)	33
Customer returns	121	117	65	(92)	211
Other	80	273	_	(308)	45
Total	3,527	10,250	(110)	(10,892)	2,775

	Brought forward at 1 January 2011 \$m	Provision for current year \$m	Adjustment in respect of prior years \$m	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

	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

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 products are not exchanged for products 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 products are destroyed. At the point of sale in the US, we estimate the quantity and value of products 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 Seroquel IR 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 2012 net US pharmaceuticals revenue by 1.0% (2011: increased revenue by 1.1%; 2010: increased revenue by 1.1%). However, taking into account the adjustments affecting both the current and the prior year, 2011 revenue was reduced by 0.3%, and 2010 revenue was not impacted, by adjustments between years.

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 158. 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. Our weighted average cost of capital reflects factors such as our capital structure and our costs of debt and equity. 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.

The majority of our investments in intangible assets and goodwill arose from the restructuring of the joint venture with Merck in 1998, the acquisition of MedImmune in 2007 and the payments to partially retire Merck's interests in our products in the US in 2008 and 2010. Additions in 2012 have included intangible assets acquired through our new collaboration with BMS concerning Amylin's portfolio of products, our acquisition of Ardea and revised arrangements with Merck concerning the final step in our exit arrangements. The Group, including acquisitions, is considered a single cash-generating unit for impairment purposes. We are satisfied that the carrying values at 31 December 2012 are fully justified by estimated future cash flows. The accounting for our arrangements with Merck and our Amylin collaboration with BMS are fully explained in Note 9 to the Financial Statements from page 159. Further details of our acquisition of Ardea are included in Note 22 to the Financial Statements from page 173.

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

# 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 183.

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.

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 mortgage bonds as the market in high quality corporate 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.

As detailed in our Accounting Policies section of the Financial Statements on page 146, the Group will adopt the amended IAS 19 from 1 January 2013.

### **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

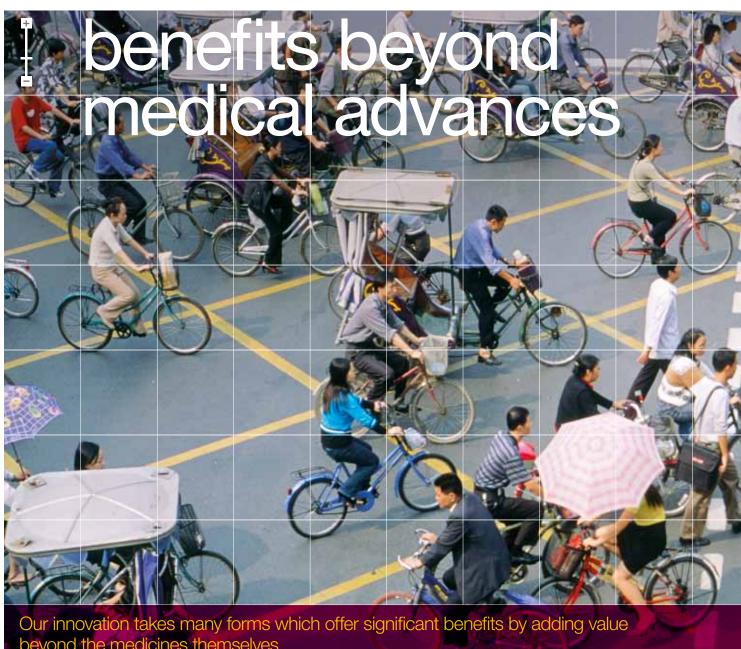
As a consequence of our NYSE listing, AstraZeneca is required to comply with those provisions of the Sarbanes-Oxley Act applicable to foreign issuers. Section 404 of the Sarbanes-Oxley Act requires companies annually to assess and make public statements about the quality and effectiveness of their internal 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 2012 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 2012 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.

# Innovation means



beyond the medicines themselves.

For example, we are exploring new ways of increasing access to healthcare which take account of the different barriers to healthcare around the world and which are tailored locally to different patient needs. Our broad market strategy in China means we are expanding the affordability of our medicines to reach an increasing number of physicians and hospitals in communities outside of the most affluent cities, which do not currently have regular access to healthcare and high quality medicines.

We are active in pioneering public/private sector collaborations to identify pragmatic ways of overcoming barriers to healthcare at a global level.



# Corporate Governance | Board of Directors

as at 31 January 2013



# 1 Leif Johansson (61) Non-Executive Chairman of the Board, Chairman of the Nomination and Governance Committee and member of the Remuneration Committee

Elected as a Director in April 2012 and became Non-Executive Chairman of the Board on 1 June. Leif Johansson is also the Chairman of global telecommunications company, LM Ericsson, a position he has held since April 2011. From 1997 until 2011, he was Chief Executive of AB Volvo, one of the world's leading manufacturers of trucks, buses, construction equipment, drive systems and aerospace components. He spent a significant part of his early career at AB Electrolux, latterly as Chief Executive from 1994 to 1997. He was a Non-Executive Director of BMS from 1998 to September 2011, serving on the board's audit committee and compensation and management development committee. He is Chairman of the European Round Table of Industrialists and the International Advisory Board of the Nobel Foundation. He holds board positions at Svenska Cellulosa Aktiebolaget SCA and Ecolean AB. He holds an MSc in engineering from Chalmers University of Technology, Gothenburg, and has been a member of the Royal Swedish Academy of Engineering Sciences since 1994. He became Chairman of the Academy in 2012.

# 2 Pascal Soriot (53) Executive Director and Chief Executive Officer

Pascal Soriot was appointed as a Director and as CEO in October. From 2010 to September 2012, he served as Chief Operating Officer of Roche AG's pharmaceuticals division. Prior to that, he was CEO of Genentech, a biologics business, and led its successful merger with Roche. He joined the pharmaceutical industry in 1986 and has worked in senior management roles throughout the world in a number of major companies since then. He brings to AstraZeneca a significant breadth of experience in both established and emerging markets, strength of strategic thinking, a successful track record of managing change and putting strategy into operation, as well as the ability to lead a diverse organisation having lived in Australia, Japan,

the US and Europe. He is a doctor of veterinary medicine (École Nationale Vétérinaire d'Alfort, Maisons-Alfort) and holds an MBA from L'Institut Supérieur des Affaires, Jouy-en-Josas.

# 3 Simon Lowth (51) Executive Director and Chief Financial Officer

Appointed as a Director and as CFO in November 2007, and served as Interim CEO from June to September 2012, 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 Geneviève Berger (58) Non-Executive Director and member of the Science Committee

Elected as a Director in April 2012. Geneviève Berger is Chief Science Officer at Unilever PLC and a member of the Unilever Leadership Executive. She holds three doctorates in physics, human biology and a medical doctorate. She was appointed Professor of Medicine at Université Pierre et Marie Curie, Paris in 2006. From 2003 to 2008 she was Professor and Hospital Practitioner at l'Hôpital de la Pitié-Salpêtrière, Paris. Previous positions she has held include Director of the Biotech and Agri-Food Department, then Head of the Technology Directorate at the French Ministry of Research and Technology (1998-2000); Director General, Centre National de la Recherche Scientifique (2000-2003); and Chairman of the Health Advisory Board of the EU Commission (2006-2008). She was a non-executive board member of Unilever from 2007 to 2008 before being appointed to her current position and was a Non-Executive Director of Smith & Nephew plc from 2010 to 2012.

# 5 Bruce Burlington (64) Non-Executive Director and member of the Audit Committee and the Science 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 the International Partnership for Microbicides, 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 Graham Chipchase (50) Non-Executive Director and member of the Audit Committee

Elected as a Director in April 2012. Graham Chipchase is the Chief Executive of global consumer packaging company, Rexam PLC. He was appointed to the position in 2010 after previous service at Rexam as Group Director, Plastic Packaging (2005-2009) and Group Finance Director (2003-2005). Prior to joining Rexam, he was Finance Director of Aerospace Services at global engineering group, GKN plc, from 2001 to 2003. After starting his career with Coopers & Lybrand Deloitte, he held a number of finance roles in the industrial gases company, The BOC Group plc (now part of The Linde Group) (1990-2001). He is a Fellow of the Institute of Chartered Accountants in England and Wales and holds an MA (Hons) in chemistry from Oriel College, Oxford.



## 7 Jean-Philippe Courtois (52) 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. He is President of Microsoft International and a board member of PlaNet Finance. 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.

#### 8 Rudy Markham (66)

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

Appointed as a Director in September 2008. Rudy Markham takes a particular interest on behalf of the Board in SHE assurance. He 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., 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. He served as a Non-Executive Director of the UK Financial Reporting Council from 2007 to 2012.

# 9 Nancy Rothwell (57) 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 oversees responsible business on behalf of the Board, as is described more fully in the Responsible Business section from page 48. She 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 Co-Chair 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.

## 10 Shriti Vadera (50) 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.

# 11 John Varley (56) Senior independent 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 Business Disability Forum, and Honorary President of the UK Drug Policy Commission.

## 12 Marcus Wallenberg (56) 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 prior to 1999. He is the Chairman of Skandinaviska Enskilda Banken AB, AB Electrolux, Saab AB and LKAB, and a Non-Executive Director of Investor AB, Stora Enso Oyj, Temasek Holdings Limited and the Knut and Alice Wallenberg Foundation.

Other officers of the Company at 31 January 2013 included members of the SET, as set out on pages 108 and 109, and Adrian Kemp, Company Secretary.

#### Corporate Governance | Senior Executive Team

as at 31 January 2013



#### 1 Pascal Soriot Chief Executive Officer

See page 106.

#### 2 Simon Lowth Chief Financial Officer

See page 106.

#### 3 Katarina Ageborg Chief Compliance Officer

Katarina Ageborg was appointed Chief Compliance Officer in July 2011 and has overall responsibility for the design, delivery 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 Ruud Dobber Executive Vice-President, Europe

Ruud Dobber was appointed as Executive Vice-President, Europe in January 2013 and leads AstraZeneca's commercial operations in Europe. In this capacity, Ruud is responsible for sales, marketing and commercial operations across AstraZeneca's businesses in the 27 EU member states. Ruud joined AstraZeneca in 1997 and has held a number of senior commercial roles including Regional Vice-President of AstraZeneca's European, Middle East and African division and Regional Vice-President for the Group's Asia Pacific region. Since 2012, Ruud has been an Executive Committee Member of EFPIA. In 2011, Ruud was the Chairman of the Asia division of Pharmaceutical Research and Manufacturers of America. Ruud commenced his career as a scientist, researching in the field of immunology and ageing. He holds a doctorate in immunology from the University of Leiden in the Netherlands.

#### **5 Paul Hudson** Executive Vice-President, North America

Paul Hudson was appointed Executive Vice-President, North America in January 2013 and leads AstraZeneca's commercial operations in North America. In this capacity, he is accountable for driving growth and maximising the contribution of North America to AstraZeneca's global business. Paul joined AstraZeneca in 2006 as Vice-President and Primary Care Director, UK. Paul's most recent role with AstraZeneca was President of AstraZeneca's Japanese business. He has served as a Standing Board Member of Japan Pharmaceuticals Manufacturers Association and EFPIA in Japan. Previously, Paul was President of AstraZeneca's business in Spain. Before AstraZeneca, Paul worked for Schering-Plough, where he held senior global marketing roles. Paul received a degree in economics from Manchester Metropolitan University and a DipM from the UK's Chartered Institute of Marketing.

#### 6 Bahija Jallal Executive Vice-President, MedImmune

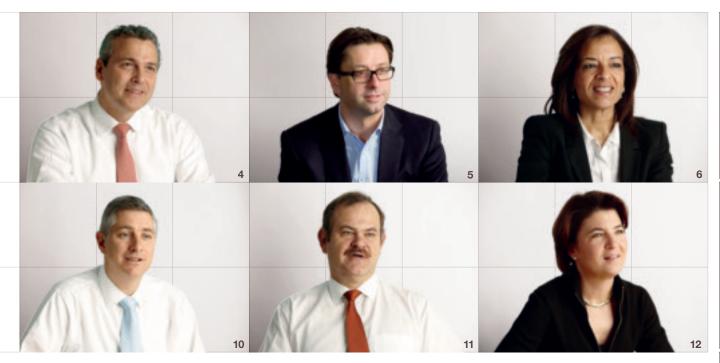
Dr Bahija Jallal was appointed Executive Vice-President, MedImmune in January 2013 and is responsible for biologics research, development and clinical activities. Bahija is tasked with advancing the biologic pipeline of drugs. Bahija joined MedImmune as Vice-President, Translational Sciences in 2006 and has held roles of increasing responsibility. Prior to joining AstraZeneca, Bahija worked with Chiron Corporation where she served as Vice-President, Drug Assessment and Development. Bahija received a master's degree in biology from the Université de Paris VII and her doctorate in physiology from the Université Pierre et Marie Curie, Paris. She conducted her postdoctoral research at the Max-Planck Institute of Biochemistry in Martinsried, Germany. She is a member of the American Association of Cancer Research, the American Association of Science, the Pharmacogenomics Working Group and is a member of the Board of Directors of the Association of Women in Science.

#### 7 Mark Mallon Executive Vice-President, International

Mark Mallon was appointed as Executive Vice-President, International in January 2013 and is responsible for the growth and performance of AstraZeneca's commercial businesses in regions including Asia Pacific, Russia, Latin America, the Middle East and Africa. Since joining AstraZeneca in 1994, Mark has held a number of senior sales and marketing roles including Regional Vice-President for Asia Pacific, President of AstraZeneca China and head of marketing, sales and commercial operations for AstraZeneca in Japan. Mark has a degree in chemical engineering from the University of Pennsylvania and an MBA in marketing and finance from the Wharton School of Business.

#### 8 Briggs Morrison Executive Vice-President, Global Medicines Development

Dr Briggs Morrison was appointed Executive Vice-President, Global Medicines Development in January 2013 and leads our global late-stage development organisation for both small molecules and biologics. He joined AstraZeneca in 2012 from Pfizer, where he was Head of Medical Excellence, overseeing development, medical affairs, safety and regulatory affairs for Pfizer's human health businesses. Briggs has a track record of successfully developing novel medicines in roles at both Pfizer and Merck. Briggs has a biology degree from Georgetown University and a medical doctorate from the University of Connecticut. Briggs has also undertaken an internship and residency in internal medicine at the Massachusetts General Hospital, a fellowship in medical oncology at the Dana-Farber Cancer Institute and a post-doctoral research fellowship in genetics at Harvard Medical School.



#### 9 Menelas Pangalos Executive Vice-President, Innovative Medicines

Menelas (Mene) Pangalos, was appointed Executive Vice-President, Innovative Medicines in January 2013 and leads AstraZeneca's small molecule discovery research and early development activities. Mene joined AstraZeneca from Pfizer, where he was Senior Vice-President and Chief Scientific Officer of Neuroscience Research. Previously, Mene held senior discovery and neuroscience roles at Wyeth and GSK. He completed his undergraduate degree in biochemistry at the Imperial College of Science and Technology, London and earned a doctorate in neurochemistry from the University of London. He is a Visiting Professor of Neuroscience at King's College, London. In the UK, Mene sits on the Medical Research Council and the Innovation Board for the Association of the British Pharmaceutical Industry.

#### 10 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 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.

## 11 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.

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

Lynn Tetrault was appointed Executive Vice-President, Human Resources & 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 in AstraZeneca's US business 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.

The SET position of Executive Vice-President, Global Portfolio & Product Strategy is currently vacant, pending the appointment of an individual for this role.

During 2012, Martin Mackay, President, Global R&D (below left) and Tony Zook, Executive Vice-President, Global Commercial Operations (below right) served as SET members. With effect from 15 January 2013, these two roles were eliminated and the newly-constituted SET shown above was appointed. Martin and Tony left the Company at the end of February 2013.





#### Corporate Governance | Corporate Governance Report

### Corporate Governance Report Leif Johansson

Chairman and Chairman of the Nomination and Governance Committee

Since joining the Board and becoming Chairman, I have focused on three main priorities. As Chairman of the Nomination and Governance Committee, my first priority was to lead a thorough search for a new CEO, which started in April 2012. The section on page 117 describing the work of the Nomination and Governance Committee gives more information about this and how the Committee and the Board approach succession planning generally. I am delighted that we were able to recruit Pascal Soriot and appoint him as AstraZeneca's new CEO with effect from 1 October. Pascal stood out from a strong field of candidates and has a number of attributes that made him the outstanding candidate. Succession planning remains the main focus of the Nomination and Governance Committee's work.

Alongside the CEO search, I also spent a significant amount of time following my appointment meeting shareholders in the UK, Sweden and the US and listening to their comments and views. I was supported in this by John Varley, who became senior independent Non-Executive Director in April 2012, and Simon Lowth, CFO who acted as Interim CEO for four months at a critical

time for the Company. My thanks go to John and Simon for their work in this regard and for their support during the transition to a new CEO. Since his appointment, Pascal has also met numerous investors. He, Simon and I, supported by John Varley, will work hard to maintain these contacts and a constructive and frank dialogue with

of AstraZeneca's strategy. Due to the timing of the CEO succession process, this has run over a longer period than usual to enable Pascal to form his conclusions about AstraZeneca's strengths, weaknesses and the best strategy for its future success. From a corporate governance perspective, my aim has been to ensure that the review has been thorough; that a good, open and robust discussion about all aspects of the strategy has taken place at the Board table with management being challenged appropriately about their proposals and recommendations; and that all Board members have felt able to and have, in fact, contributed fully to that discussion.

#### Leif Johansson Chairman

our shareholders. My third priority has been the annual review

controls and risk management.

This Corporte Governance Report

its Committees and the SET.

and responsibilities

describes how the Group is organised,

roles and responsibilities of the Board,

**Board composition, processes** 

The Board comprises two Executive

Directors (the CEO and the CFO) and

2013 and information about individual

Directors is contained in the Board of

membership of the Board at 31 January

Directors section on pages 106 and 107.

All Directors are collectively responsible

for exercising independent, objective

and for scrutinising and challenging

for the success of the Group. In addition,

judgement in respect of Board decisions

management. The Non-Executive Directors

also have various responsibilities concerning

the integrity of financial information, internal

the Non-Executive Directors are responsible

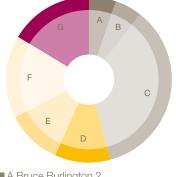
10 Non-Executive Directors. The

including the overall structure and principal

#### Corporate governance

We have prepared this Annual Report with reference to the UK Corporate Governance Code published by the UK Financial

#### Length of tenure of Non-Executive Directors (years)



■ A Bruce Burlington 2

■ B Shriti Vadera 2

C Marcus Wallenberg 13

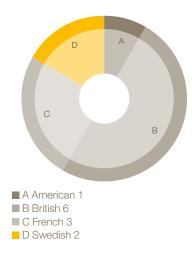
D Jean-Philippe Courtois 4

E Rudy Markham 4

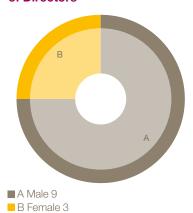
F John Varley 6 ■ G Nancy Rothwell 6

> Leif Johansson, Geneviève Berger and Graham Chipchase have served for less than one year

#### **Directors' nationalities**



#### **Gender split** of Directors



Overview

Reporting Council (FRC) in June 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. Leif Johansson, our Non-Executive Chairman, is responsible for leadership of the Board. Our CEO, Pascal Soriot, leads the SET and has executive responsibility for running our business. The Board comprises 10 Non-Executive Directors, including the Chairman, and two Executive Directors – the CEO, Pascal Soriot, 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.

John Varley, who joined the Board as a Non-Executive Director in 2006, was appointed as our senior independent Non-Executive Director in April 2012. 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 is responsible for establishing, 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 and the CEO are documented, as are the Board's delegated authorities and reserved powers.

#### 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 14 meetings in 2012, which included sessions to cover its usual annual strategy review. Eight of those meetings were telephone meetings, some convened at short notice, at which Board changes and business development transactions were discussed and approved. All of the meetings held in person took place in London, UK. The Board is currently scheduled to meet six times in 2013, 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.

#### Corporate Governance | Corporate Governance Report

The Board aims to maintain a balance in terms of the range of experience and skills of individual Board members, which includes relevant international business, pharmaceutical industry and financial experience, as well as appropriate scientific and regulatory knowledge. The biographies of Board members set out on pages 106 and 107 give more information about current Directors in this respect. The Board views gender, nationality and cultural diversity among Board members as important considerations when reviewing the composition of the Board. The Board recognises, in particular, the importance of gender diversity. Currently, 30% of the Company's Non-Executive Directors are women and they make up 25% of the full Board. Since the formation of AstraZeneca in 1999, the proportion of women Board members has been approximately 25%. Although it has not set any specific measurable objectives, 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 from page 43.

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

- > Louis Schweitzer and David Brennan, formerly Chairman and CEO respectively, retired from the Board on 1 June.
- > Leif Johansson was elected as a Non-Executive Director at the AGM on 26 April 2012 and appointed Chairman of the Board with effect from 1 June. He was appointed Chairman of the Nomination and Governance Committee and as a member of the Remuneration Committee with effect from 26 April 2012.
- > Pascal Soriot was appointed CEO with effect from 1 October.
- > Simon Lowth served as Interim CEO with effect from 1 June and remained in this role until Pascal Soriot's appointment, following which he reverted to his position as CFO.
- > Michele Hooper retired from the Board at the end of the AGM on 26 April 2012.
- > John Varley was appointed as senior independent Non-Executive Director with effect from 26 April 2012.
- > Rudy Markham was appointed as Chairman of the Audit Committee and as a member of the Nomination and Governance Committee with effect from 26 April 2012. He also remained in his role as a member of the Remuneration Committee.
- > Geneviève Berger was elected as a Non-Executive Director and appointed as a member of the Science Committee with effect from 26 April 2012.
- > Graham Chipchase was elected as a Non-Executive Director and appointed as a member of the Audit Committee with effect from 26 April 2012.

### Independence of the Non-Executive Directors

During 2012, 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. Leif Johansson 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. He is a Non-Executive Director of Investor AB, which has a 4.13% interest in the issued share capital of the Company as at 31 January 2013. 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, he was appointed as a member of the Science Committee, reflecting his interest in innovation and R&D, knowledge of the

#### **Board Committee membership**

			Nomination and		
Name					Independent1
Geneviève Berger				✓	✓
Bruce Burlington	✓			/	/
Graham Chipchase	✓				<b>√</b>
Jean-Philippe Courtois	✓			-	✓
Leif Johansson		1	Chair		<b>√</b> <sup>2</sup>
Simon Lowth					n/a
Rudy Markham	Chair	✓	✓	-	✓
Nancy Rothwell		✓	✓	Chair	<b>√</b>
Pascal Soriot					n/a
Shriti Vadera	✓				✓
John Varley		Chair	✓		<b>√</b>
Marcus Wallenberg				✓	Х

<sup>&</sup>lt;sup>1</sup> As determined by the Board for UK Corporate Governance Code purposes

<sup>&</sup>lt;sup>2</sup> Leif Johansson 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.

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.

#### 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 are 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 117 gives information about the appointment process for new Directors.

Newly appointed Directors are provided with comprehensive documentation containing information about the Group and their role as Non-Executive Directors. They also typically attend tailored induction programmes that take account of their individual skills and experience.

#### Time commitment

Our expectation is that Non-Executive Directors should be prepared to commit about 15 days per annum, as a minimum, to the Group's business. In practice, Board members' time commitment usually exceeds this minimum expectation when all the work that they undertake for the Group is considered, particularly in the case of the Chairman of the Board and the Chairmen of the Board Committees. As well as their work in relation to formal Board and Board Committee meetings, the Non-Executive Directors also commit time throughout the year to meetings and telephone calls with various levels of executive management, visits to AstraZeneca's sites throughout the world and, for new Non-Executive Directors, induction sessions and site visits.

On occasions when a Director is unavoidably absent from a Board or Board Committee meeting, for example 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 2012. 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.

#### Board and Board Committee meeting attendance in 2012

	Board	Board			Nomination and	
Name	(scheduled)	(unscheduled) <sup>1</sup>				Science
Geneviève Berger <sup>2</sup>	4 (4)	2 (5)	-	_	_	7 (7)
David Brennan <sup>3</sup>	2 (2)	3 (3)	2 (2)	_	_	_
Bruce Burlington	6 (6)	8 (8)	7 (7)	_	_	7 (7)
Graham Chipchase <sup>4</sup>	4 (4)	3 (5)	4 (4)	_	_	_
Jean-Philippe Courtois	5 (6)	5 (8)	5 (7)	_	_	_
Michele Hooper⁵	2 (2)	3 (3)	3 (3)	_	2 (2)	_
Leif Johansson <sup>6</sup>	4 (4)	5 (5)	-	9 (9)	4 (4)	_
Simon Lowth	6 (6)	6 (8) <sup>7</sup>	7 (7)	_	-	_
Rudy Markham	6 (6)	6 (8)	7 (7)	9 (12)	4 (4)	_
Nancy Rothwell	6 (6)	8 (8)	-	7 (12)	6 (6)	7 (7)
Louis Schweitzer <sup>8</sup>	2 (2)	3 (3)	_	5 (5)	2 (2)	_
Pascal Soriot <sup>9</sup>	2 (2)	_	2 (2)	_	_	_
Shriti Vadera	6 (6)	8 (8)	7 (7)	_	_	_
John Varley	6 (6)	8 (8)	_	12 (12)	6 (6)	_
Marcus Wallenberg	6 (6)	6 (8)	_	-	-	5 (7)

Note: number in brackets denotes number of meetings during the year that Board members were entitled to attend.

- 1 The Board held eight unscheduled meetings by telephone during the year, some convened at short notice, at which Board changes and business development transactions were discussed and approved.
- Geneviève Berger was elected to the Board on 26 April 2012.
- 3 David Brennan retired from the Board on 1 June.
- Graham Chipchase was elected to the Board on 26 April 2012.
- Michele Hooper retired from the Board on 26 April 2012.
- <sup>6</sup> Leif Johansson was elected to the Board on 26 April 2012.
- At the Chairman's request, Simon Lowth absented himself from two of the eight unscheduled meetings at which Board changes were discussed.
- Louis Schweitzer retired from the Board on 1 June.
- 9 Pascal Soriot was appointed to the Board on 1 October.

#### Corporate Governance | Corporate Governance Report

#### Performance evaluation

During the year, the Board conducted the annual evaluation of its own performance and that of its Committees and individual Directors.

The 2012 evaluation was conducted internally and involved a series of web-based questionnaires. A draft report based on responses from the questionnaires was prepared and reviewed by the Chairman and the Company Secretary. The final report was circulated to the full Board and discussed at the Board meeting held in January 2013. 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 the Board prioritises matters. Separate questionnaires covered the operation and effectiveness of the Board's Committees, and relevant Board members (those serving in the period January to April 2012) also responded to a questionnaire dealing specifically with shareholder engagement.

The composition and dynamics of the Board were generally thought to be balanced and appropriate. Information flows to the Board from the management team, and from Board Committees, were usually considered to be good and Board meetings were generally felt to be well-structured. The expanded role of the Science Committee reviewing the R&D aspects of a number of business development and acquisition proposals on behalf of the Board was seen as a positive development. However, a number of areas were identified for improvement. The importance of shareholder engagement and succession planning were highlighted by the performance evaluation. The Board's visibility of major shareholders' views will be improved. The engagement of the new Chairman and, more recently, the new CEO with the Company's largest investors is contributing to this but, in addition, more structured and regular discussion on this topic and greater analyst/broker insight at Board-level will be implemented. In recent years, the Board's overview of senior executive succession planning work has increased but needs to be further improved by the Board receiving more detailed information about the work of the Nomination and Governance Committee.

As part of the assessment process, each Director had an individual discussion with the Chairman to discuss their contribution to the work of the Board and personal development needs. Each Director continues to perform effectively and to demonstrate commitment to their role.

The Board's annual performance evaluation was last externally facilitated in 2011.

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 of the Directors will retire at the AGM in April 2013. 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 2012, 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 2012 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 74, 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 122.

#### **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.

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, John Varley, 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 Rudy Markham (Chairman of the Audit Committee), Bruce Burlington, Graham Chipchase, Jean-Philippe Courtois and Shriti Vadera (and, until her retirement at the 2012 AGM, Michele Hooper). They are (or in the case of Michele Hooper, 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 2012, 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 Rudy Markham and Graham Chipchase 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
- > our internal control over financial reporting
- > our Code of Conduct and whistleblower procedures
- > 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, any serious issues of non-compliance and how the Audit Committee has discharged its responsibilities. 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 and the UK Financial Reporting Council 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, auditrelated 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 together with one other Audit Committee member 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. Fees paid to the auditor for audit, audit-related and other services are analysed in Note 27 to the Financial Statements on page 190.

The Audit Committee held seven scheduled meetings in 2012. The individual attendance record of members of the Audit Committee is set out in the Board and Board Committee meeting attendance in 2012 table on page 113. 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 2012 and January 2013, the Audit Committee 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. These included the areas described in the Financial Review under the heading 'Critical Accounting Policies and Estimates' (with a focus on accounting issues relevant to litigation and taxation matters and goodwill impairment) from page 99 and discussion was supported by papers prepared by management and the external auditor.

#### Corporate Governance | Corporate Governance Report

- > 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 remained focused 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 103.
- Data about reports made by employees via the AZethics helpline, 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' compliance with the CIA (for more information about the obligations imposed on the Board by the CIA, see below).
- > Regular progress updates from IS/IT on the status of the transition from the existing outsource provider to the new providers.
- > 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.
- > Going concern assessment and adoption of the going concern basis in preparing this Annual Report and the Financial Statements.
- > 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 amount of audit and non-audit fees of the external auditor throughout 2012. 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 2012 is disclosed in Note 27 to the Financial Statements on page 190.
- > The rotation of the lead partner of the external auditor. In advance of the expiry of the permitted tenure of the lead audit partner, Jimmy Daboo, at the conclusion of the 2012 audit, the Audit Committee oversaw a process whereby a number of potential successors were considered and Tony Cates was endorsed as his successor. The Audit Committee also considered the external auditor's proposed arrangements to ensure an effective handover of responsibilities.
- > A review and assessment of the Audit Committee's performance which concluded that such performance was satisfactory.

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 Chief Compliance Officer, the General Counsel and the Company's external auditor. These meetings were held 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.

In addition to its usual business as described above, during 2012, 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. These included:

- > Considering the potential impact of the eurozone crisis on AstraZeneca's operations, in particular in Greece, Italy and Spain.
- > Hearing from the regional finance directors of the Americas, Asia Pacific and EMEA regions on the financial objectives, the local challenges and organisational structures in their respective regions and learning how the Group Finance organisation supports AstraZeneca's network of local marketing companies.

- > Learning about AstraZeneca's business processing outsourcing centre of excellence and the work it does to support the various outsourcing initiatives currently ongoing in the business as we seek to reduce our cost base.
- > Receiving regular updates from the IS/IT team in connection with the transition from the Company's previous IT infrastructure outsourcing provider to its new providers.
- > Considering a presentation on the lessons learnt from the implementation of an enterprise resource planning IT system at our plant in Sweden which led to disruptions in our supply chain during the year.
- > Meeting with the Global Compliance Leadership Team which comprises representatives from the second line assurance functions in R&D, Operations, and Sales and Marketing.
- > Considering the risks associated with the Group's pension and other benefit obligations and the steps taken to manage those risks.
- Monitoring the operation of controls and reporting arrangements, cognisant of the additional pressures on management during the tenure of the Interim CFO.

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 2012. 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 second 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 accordance with its normal practice, the Audit Committee considered the performance of our external auditor KPMG Audit Plc (KPMG). It also 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, 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 2013, be proposed to shareholders at the AGM in April 2013.

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. Neither these terms of engagement nor any other agreement 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. In December 2012, the Audit Committee reviewed the changes to the UK Corporate Governance Code with regard to putting the external audit contract out to tender at least every 10 years. It noted that KPMG was first appointed as sole external auditor to AstraZeneca in 2001 following a competitive tender. The Audit Committee concluded that, as the lead audit partner at KPMG is rotating in 2013, then in accordance with the transitional guidance issued by the FRC, the audit would be put out to tender by 2018.

At the January 2013 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 2012. 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 2013 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 worldwide to all full-time and part-time AstraZeneca Directors, officers, employees and temporary staff. Further information relating to the Code can be found in the Compliance section on page 47.

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 122.

### 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. It continually reviews the composition of the Board using a matrix that records the skills and experience of current Board members and comparing this with the desired skills and experience it believes are appropriate to the Company's overall business and strategic needs both now and in the future. 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 2012, the members of the Nomination and Governance Committee were Louis Schweitzer (Chairman of the Committee until 26 April 2012 and member until his retirement on 1 June), Leif Johansson (member and Chairman of the Committee from 26 April 2012), John Varley, Rudy Markham (from 26 April 2012) and Michele Hooper (until her retirement on 26 April 2012). Each of them is (and in the case of each of Louis Schweitzer and Michele Hooper, was) a Non-Executive Director and considered independent by the Board. Each of Louis Schweitzer and Leif Johansson 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 considers both planned and unplanned (unanticipated) succession scenarios. It was anticipated that Louis Schweitzer would retire from the Board in 2012 and, consequently, a thorough search for a new Chairman was started at the beginning of 2011. Although Mr Schweitzer retired a few months earlier than originally envisaged, succession plans were well-advanced and our new Chairman, Leif Johansson, joined the Board in April 2012 and became Chairman in June. In the fourth quarter of 2010, in anticipation of the likelihood of David Brennan retiring within the next two years, the Nomination and Governance Committee engaged the search firm Spencer Stuart to carry out a desktop exercise to identify potential external candidates for this position. This work, combined with a good overview of potential internal candidates as a result of the Board's normal work with and exposure to senior executives, put the Nomination and Governance Committee in a position to react quickly to Mr Brennan's decision in 2012 that he wished to retire. A strong slate of internal and external candidates was identified, who were thoroughly assessed over the summer of 2012, leading to the appointment of Pascal Soriot as CEO with effect from 1 October.

The Nomination and Governance Committee met six times in 2012. Much of its work during the year naturally focused on the recruitment of Mr Soriot. The Committee engaged Spencer Stuart to assist it with the assignment.

#### Corporate Governance | Corporate Governance Report

The ad hoc Board Committee formed for the purpose of appointing a new Chairman of the Board also completed its work during 2012 and the appointment of Leif Johansson was announced by the Company on 1 March 2012. He was elected as a Director at the AGM on 26 April 2012 and became Chairman with effect from 1 June. This work was led by Michele Hooper in her capacity as senior independent Non-Executive Director and the search firm, MWM Consulting, was engaged to assist with the assignment.

The Nomination and Governance Committee also recommended to the Board the appointments of Geneviève Berger and Graham Chipchase during the year as part of routine Board succession planning. Professor Berger and Mr Chipchase were elected to the Board on 26 April 2012 and became members of the Science Committee and the Audit Committee, respectively, from the same date. Professor Berger strengthens the Board's scientific and R&D knowledge and experience. Mr Chipchase adds to the Board's international business leadership. The Nomination and Governance Committee engaged MWM Consulting and The Zygos Partnership to assist it with the assignments to appoint Professor Berger and Mr Chipchase respectively.

Neither MWM Consulting nor The Zygos Partnership has any other connection to the Company. Spencer Stuart undertakes executive search assignments for the Company periodically.

The individual attendance record of the Nomination and Governance Committee's members is set out on page 113. During the year, the Nomination and Governance Committee also reviewed the composition of Board Committees in the light of the Board changes described above and recommended to the Board appropriate changes, which are described in this Annual Report.

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, career opportunities and talent development
- > benchmarking against industry and scientific best practice, where appropriate.

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. However, during 2012 the Science Committee did review on behalf of the Board the R&D aspects of a number of specific business development or acquisition proposals and advised the Board on its conclusions.

During 2012, 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 Geneviève Berger (from 26 April 2012). The President, Global R&D; the Executive Vice-President, Innovative Medicines; the Executive Vice-President, MedImmune: and the Executive Vice-President, Global Medicines Development attended meetings of the Science Committee in 2012. The Vice-President, Strategy, Portfolio & Performance, R&D also attended all meetings and acted as secretary to the Science Committee.

The Science Committee met twice in person in 2012, in Cambridge and London, UK and held five meetings by telephone to review specific business development or acquisition proposals.

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 the page opposite.

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.

#### **Business organisation** Senior Executive Team

The CEO is responsible for establishing, and chairs, the SET. The SET normally meets once a month to consider and decide major business issues, or as otherwise required by business needs. Typically, it also reviews, in advance of submission to the Board, those matters that are to be submitted to the Board for review and decision.

In addition to the CEO, the CFO, the General Counsel, and the Chief Compliance Officer, the SET comprises nine Executive Vice-Presidents representing: Innovative Medicines (small molecules); MedImmune (biologics); Global Medicines Development; North America; Europe; International; Global Portfolio & Product Strategy; Operations & Information Services; and Human Resources & Corporate Affairs. The Company Secretary acts as secretary to the SET.

#### Portfolio Investment Board (PIB)

The CEO is responsible for establishing, 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 groups and the Global Medicines Development demand forecast, by confirming the allocation of resources across early-stage 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 in 2012 were: the CFO; the President, Global R&D; the Executive Vice-President, Global Commercial Operations; the Executive Vice-President, Innovative Medicines; the Executive Vice-President, MedImmune; the Executive Vice-President, Global Medicines Development; and the Vice-President, Strategic Partnering & Business Development. The PIB has a permanent secretary and typically meets at around the time of the monthly SET meetings, or as otherwise required by business needs.

#### **Disclosure Committee**

Our disclosure policy provides a framework for the handling and disclosure of inside information and other information of interest to shareholders and the investment community. It also defines the role of the Disclosure Committee. The members of the Disclosure Committee in 2012 were: the CEO; the CFO, who chaired the Disclosure 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 acted as secretary to this Committee. The Disclosure Committee meets regularly to assist and inform the decisions of the CEO concerning inside information and its disclosure. Periodically, it reviews 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 2013, 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. Further information can be found in the Compliance section from page 47.

Global Compliance provides direct assurance to the Audit Committee on matters concerning compliance issues, including the results of monitoring and auditing conducted by Global Compliance and an analysis of compliance breaches. 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 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 (DTR)

The disclosures that fulfil the requirements of a corporate governance statement under the DTR 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 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.

#### Corporate Governance | Corporate Governance Report

### 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 (scientific office), Angola, Azerbaijan, Belarus, Bulgaria, Chile, Costa Rica, Croatia, Cuba, Georgia, Ghana (scientific office), Ireland, Jordan, Kazakhstan, Macedonia, Nigeria, Romania, Russia, Saudi Arabia (scientific office), Serbia and Montenegro, Slovenia, Syria and Ukraine.
- > AstraZeneca AB: Egypt (scientific office), Slovakia and the United Arab Emirates.
- > AstraZeneca Singapore Pte Limited: Vietnam.

### Distributions to shareholders and dividends for 2012

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 94 and Notes 20 and 21 to the Financial Statements on page 173.

The Company's dividends for 2012 of \$2.80 (178.6 pence, SEK 18.34) per Ordinary Share amount to, in aggregate, a total dividend payment to shareholders of \$3,665 million. Two of our employee share trusts, AstraZeneca Share Trust Limited and AstraZeneca Quest Limited, waived their right to a dividend on the Ordinary Shares that they hold and instead received a nominal dividend.

A shareholders' resolution was passed at the 2012 AGM authorising the Company to purchase its own shares. Pursuant to this resolution, the Company repurchased (and subsequently cancelled) 57.8 million Ordinary Shares with a nominal value of \$0.25 each, at an aggregate cost of \$2,635 million, representing 4.6% of the closing total issued share capital of the Company. The Company suspended its share repurchase programme on 1 October as a prudent step to maintain flexibility while the Board and the newly-appointed CEO completed the Company's annual strategy update.

During our share repurchase programmes that operated between 1999 and September 2012, a total of 615.2 million Ordinary Shares were repurchased, and subsequently cancelled, at an average price of 2777 pence per share for a consideration, including expenses, of \$29,352 million.

#### Going concern accounting basis

Information on the business environment AstraZeneca operates in, including the factors underpinning the industry's future growth prospects, is included in the Directors' Report. Details of the product portfolio of the Group (including patent expiry dates for key marketed products), 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 86. In addition, Note 23 to the Financial Statements from page 175 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 to the Financial Statements from page 164.

The Group has considerable financial resources available. As at 31 December 2012, the Group had \$9.8 billion in financial resources (cash balances of \$7.7 billion and undrawn committed bank facilities of \$3 billion which are available until April 2017, with only \$0.9 billion of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, recent government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, 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.

#### Changes in share capital

Changes in the Company's Ordinary Share capital during 2012, including details of the allotment of new shares under the Company's share plans, are given in Note 20 to the Financial Statements from page 172.

#### 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 because each Ordinary Share has a nominal value of \$0.25). Such holding must be obtained within two months of the date of the Director's appointment. At 31 December 2012, 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 from page 134. 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 122.

#### Political donations

Neither the Company nor its subsidiaries made any EU political donations or incurred any EU political expenditure in 2012 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 2013 AGM, similar to that passed at the 2012

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 2012, the Group's US legal entities made contributions amounting in aggregate to \$1,759,450 (2011: \$1,099,450) 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

The Notes to the Financial Statements, including Note 23 (from page 175), include further information on our use of financial instruments.

#### Creditor payment policy

Our policy is 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. 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. On 26 June 2012, AstraZeneca and Merck agreed to amend certain provisions of their ongoing Agreements with respect to the Second Option, as detailed in Note 9 to the Financial Statements from page 161. Our trade creditors' balance excluding payments to Merck and other items not directly related to trade purchases in the US is our most accurate calculation of balances owed by the Company's subsidiaries to trade creditors at the balance sheet date. This was equivalent to 56 days' average purchases (2011: 43 days; 2010: 57 days). Historically, we have also disclosed the total figure including any trade balances payable to Merck. By including these items, an average of 58 days is obtained (2011: 50 days; 2010: 62 days).

The Company has no external trade creditors.

#### **Annual General Meeting**

The Company's AGM will be held on 25 April 2013. 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 25 April 2013 for the re-appointment of KPMG as auditor of the Company. The external auditor has undertaken various non-audit work for us during 2012. 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 115, 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 2012.

#### Directors' Report

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

- > Strategy
- > Performance
- > Corporate Governance
- > Development Pipeline
- > Shareholder Information
- > Corporate Information

and has been signed on behalf of the Board.

#### A C N Kemp

Company Secretary 31 January 2013

Directo	ors' Rer	muneration			
Repor	t				
John Varley					
Non-Executive					
and Chairman	of the			Allowed to the	
Remuneration	Committee			AN	

The performance of AstraZeneca as set out in this Annual Report was mixed. Revenues and profit were down versus prior year. Although Core earnings per share and cash flow fell versus 2011, they both exceeded targets set at the beginning of the year. Shareholders also had mixed fortunes. Total shareholder return performance was weak. But cash distributions (including buybacks) reflected the strong cash flow generation, which also supported the strengthening of the product pipeline through the acquisition of Ardea, the collaboration with Amgen and the extension of our diabetes alliance with BMS. We know that our shareholders expect pay appropriately to reflect performance. The Remuneration Committee has taken these diverse factors and expectations into account in making its judgements in 2012.

The business environment for the Company will continue to be challenging in 2013, and beyond, in terms of the fiscal pressures on governments, which in most markets have a direct affect on the Company's business; the need to continue to address R&D productivity: and the need to maintain a level of investment that is right for the future of AstraZeneca but which is also balanced against shareholders' expectations for return on their investment in the Company. The Remuneration Committee has to take a judicious view of performance stretch and reward. So performance targets must be stretching; but not so stretching as to compromise or weaken incentivisation. For example, we have increased for 2013, many of the revenue targets in priority areas (Emerging Market sales and sales of Brilinta/ Brilique would be two cases in point). But the environmental factors referred to above were also recognised by the Remuneration Committee in setting the free cash flow

threshold under the AstraZeneca Performance Share Plan (PSP) in March 2012 (relating to performance over the period 2012 to 2014 inclusive), which is lower (principally but not solely because of patent expiry) than the equivalent cash flow targets applicable to previous awards (details are set out on pages 129 and 130).

Following Pascal Soriot's appointment as CEO in October, the Remuneration Committee has been reviewing the Company's remuneration framework. The Remuneration Committee wishes to ensure that remuneration structures continue to be closely aligned with the Company's strategy, and that they will support and drive achievement of our business objectives.

The Remuneration Committee is proposing a number of changes to both short-term and long-term incentive arrangements for Executive Directors and other senior executives.

> The composition of performance metrics for the annual bonus plan will be adjusted. From 2013, they will be based on an integrated Group scorecard that includes both financial and non-financial performance metrics, as well as reflecting individual performance. No changes are being made to the funding of the bonus pool, the overall quantum at the Group or individual level, or the payout curve. The new integrated Group scorecard will be based on four key priorities: 'Achieve scientific leadership', 'Restore growth', 'Achieve Group financial targets' and 'Ensure AstraZeneca is a great place to work', with all but the last scorecard priority forming part of the financial determination of the bonus outcome. Targets for each category have been set for 2013.

> Proposed changes to performance metrics (but not to the rules nor the quantum of compensation opportunity) of the PSP are under consideration. The Remuneration Committee will consult the Group's largest investors about the PSP proposals and will take those views into account before reaching its final decision. This consultation process will take place in the first quarter of 2013 and before any awards are made under the PSP. The Remuneration Committee's intention in considering these changes is to ensure that the PSP continues to provide incentives for management to perform successfully against a balance of both financial and non-financial metrics. Further information about the new PSP performance metrics will be made available at the AGM. Shareholders will of course have an opportunity to vote on the new PSP arrangements as part of the vote on remuneration policy to be introduced by the new UK Department for Business, Innovation & Skills' executive remuneration proposals, which we expect to be implemented with effect from 2014.

Given the Board changes during the year, the Remuneration Committee gave careful consideration to a number of related remuneration matters. In particular, the remuneration package for our new CEO; the arrangements for Simon Lowth's four months service as Interim CEO and his return to the role of CFO; and the arrangements relating to the retirement of our former CEO, David Brennan. We consulted with our major investors where appropriate on these matters, and related information was provided to the market by way of announcements at the relevant times. The arrangements are described in detail in this Remuneration Report.

Overview

There are a number of ways in which we seek to listen and respond to the views of shareholders on remuneration matters during the year, including at the AGM, and via consultation with the Company's largest investors about specific remuneration matters. In the latter part of each year, the Company usually hosts a meeting to which we invite our largest shareholders and seek their views on executive remuneration and corporate governance more broadly. In previous years, a number of Non-Executive Directors have been available to shareholders at that meeting, including the Chairman of the Board, myself as Chairman of the Remuneration Committee as well as other Board members. Although we cancelled the meeting proposed to be held in December in anticipation of our dialogue with shareholders on remuneration matters in the first guarter of 2013, we intend to continue to hold such meetings annually, with the aim of maintaining a constructive discussion with shareholders on these topics.

Anticipating the coming into effect of the new regulations proposed by the UK Department for Business, Innovation & Skills, we have taken the opportunity to structure this 2012 Directors' Remuneration Report to incorporate a number of the proposed features. As a result, this Remuneration Report has been prepared with separate sections that set out, first, our remuneration policy (Policy Report) and, second, how that policy has been implemented in 2012 (Implementation Report). We have not yet produced a Remuneration Report that is fully compliant with the proposed new regulations because they are still to be published in their final form. But our 2013 Remuneration Report will fully reflect the new regulations and we will place resolutions before shareholders accordingly at the 2014 AGM.

As last year, we have sought in this Remuneration Report to answer the question: what have we paid our Executive Directors and why? The answer to this question is largely contained in the Implementation Report, which commences on page 127. To simplify the narrative and structure of this year's Remuneration Report we have placed a lot of detailed disclosure (including pensions, the fees paid to the Chairman and Non-Executive Directors, and facts and figures relating to the longterm incentive plans) in the Appendix from page 131. We have taken into account Group and individual performance in 2012. We are guided in our judgements by our compensation schemes and their rules. But we know that we must exercise appropriate discretion to ensure that reward outcomes at AstraZeneca are appropriately consistent with the protection of your interests as our shareholders.

As ever, we would welcome your feedback.

#### John Varley

Chairman of the Remuneration Committee

#### Remuneration Committee membership

The Remuneration Committee members are John Varley (Chairman of the Remuneration Committee), Leif Johansson, Rudy Markham and Nancy Rothwell. Leif Johansson was considered by the Board to be independent upon his appointment as Chairman of the Board; in accordance with the UK Corporate Governance Code, the test of independence is not appropriate in relation to the Chairman after his appointment. All other members of the Remuneration Committee are independent Non-Executive Directors. The Deputy Company Secretary acts as the secretary to the Remuneration Committee.

#### Terms of reference

A copy of the Remuneration Committee's terms of reference is available on our website, astrazeneca.com. The Remuneration Committee conducted a review of its terms of reference during 2012. A small number of minor changes were recommended to the Board, principally to reflect updated guidance issued by the Association of British Insurers in September. The changes were approved by the Board in January 2013.

### Main work of the Remuneration Committee during 2012

The Remuneration Committee met 12 times in 2012. The individual attendance record of Remuneration Committee members is set out on page 113. At the invitation of the Remuneration 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 Remuneration Committee meetings in 2012 and provided advice and services that materially assisted the Remuneration Committee. In addition, all meetings of the Remuneration Committee were attended by Carol Arrowsmith, representing Deloitte LLP (Deloitte), the Remuneration Committee's independent adviser.

The work of the Remuneration Committee focused on the following principal matters during 2012:

- > Executive Directors' remuneration arrangements on appointment, change of role and retirement as described elsewhere in this Remuneration Report.
- > The terms of other senior executives' remuneration packages on appointment, promotion or termination.

- > The Non-Executive Chairman's remuneration arrangements on appointment.
- > The assessment of Group and individual performance against performance targets to determine the level of executive bonuses for performance during 2011 and to set executive bonus performance targets for 2012.
- > The assessment of performance against targets to determine the level of vesting in 2012 under the PSP, and the setting of PSP and AZIP performance thresholds for awards made in 2012.
- > The determination of individual awards made under the Group's main long-term incentive plans: the PSP, the AZIP and the AstraZeneca Global Restricted Stock Plan to SET members and other participants.
- > The determination of restricted share awards to a number of senior executives under the AstraZeneca Restricted Share Plan.
- > Proposed changes to certain elements of short-term and long-term incentive arrangements.
- > A review of Group reward data, including CEO pay relative to average pay, and average salary data analysed by gender, and bonus data for the direct reports of SET members.
- > A review of the sources and robustness of market remuneration data provided to the Remuneration Committee.
- A benchmarking review of the Remuneration Committee's activities and policies against institutional investor quidelines.
- > A review of the shareholding requirements for Executive Directors and the shareholding levels of other SET members.
- > 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.
- > Consideration of the UK government's June proposals concerning executive pay.
- > A review of the performance of Deloitte, the independent adviser to the Remuneration Committee.
- > The annual review of the performance of the Remuneration Committee.
- > The preparation, review and approval (in January 2013) of this Remuneration Report.

#### Adviser to the Remuneration Committee

The Remuneration Committee retains Deloitte, represented by Carol Arrowsmith, who provided independent advice on various matters considered by the Remuneration Committee in 2012. The cost of this service to the Company in 2012 was £229,260 (including VAT). During the year, Deloitte also provided taxation advice and other specific non-audit services to the Group. The Remuneration Committee reviewed the potential for conflicts of interest and judged that there were no conflicts. Deloitte is a member of the Remuneration Consultants' Group, which is responsible for the stewardship and development of the voluntary code of conduct in relation to executive remuneration consulting in the UK. The principles on which the code is based are transparency, integrity, objectivity, competence, due care and confidentiality. Deloitte adheres to the code.

#### Shareholder context

At the Company's AGM in April 2012, the resolution to approve the Directors' Remuneration Report for the year ended 31 December 2011 was passed with 91.37% of the votes cast for the resolution and 8.63% of the votes cast against the resolution.

### Basis of preparation of this Remuneration Report

This Remuneration 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 Remuneration Report will be proposed at the AGM on 25 April 2013.

#### **Policy Report**

#### Key elements of remuneration policy

Bassassiani.	Purpose and link to strategy	Operation	Performance measures
Base salary	Base salary is intended to be sufficient (but no more than necessary) to attract, retain and develop high-calibre talent.	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 periodically (but not annually) against external comparators.	
Benefits	Non-cash benefits are designed to be sufficient (but no more generous than necessary) to attract, retain and develop high-calibre talent.	Based on local median market practice.	
Annual bonus	The annual bonus rewards short-term performance against specific Group and individual objectives.	An annual cash incentive opportunity determined by reference to an integrated Group scorecard and individual performance, measured over a single financial year of the Company relative to targets set at the beginning of each year.  The Remuneration Committee requires that certain percentages of the annual bonus are converted into stock to be held for three years before vesting.	The Group performance measures ensure that all eligible employees receive an element of reward based on the Group's overall financial and non-financial performance.  Individual goals are based on annual objectives. More information about the performance measures for the 2012 annual bonus in respect of the Executive Directors is set out on page 129.
AstraZeneca Performance Share Plan (PSP)¹ As described in the introduction to this Remuneration Report from the Chairman of the Remuneration Committee, changes to performance metrics for the PSP are under consideration. It is planned that consultation with shareholders and implementation of the changes will take place in 2013. The information set out in this table refers to awards made under the PSP, up to and including 2012.	The PSP rewards the outperformance of industry peers in terms of shareholder value creation measured by relative TSR, and the generation of cash at levels to finance investment in the business, debt repayment and the Company's shareholder distribution policy.	The PSP was approved by shareholders at the 2005 AGM and provides for the grant of awards over Ordinary Shares or ADSs.  The three year performance periods commence on 1 January in the year of the award. The vesting date is the third anniversary of the date of the award.  In respect of any financial year of the Company, the maximum market value of shares that may in theory be put under an award under the PSP is 500% of a participant's base salary (which converts into an expected value of 250%). The actual individual limits that apply under the PSP, subject to this maximum, are set by the Remuneration Committee from time to time. In the event that employment ceases for anything other than a 'good leaver' reason, any unvested awards lapse unless the Remuneration Committee decides otherwise.	Fifty percent based on the relative TSR performance of the Company over the relevant three year performance period against a predetermined peer group of global pharmaceutical companies.  Fifty percent based on the achievement of a cumulative free cash flow target over the relevant three year performance period, based on a sliding scale between a threshold target and an upper target.  More information about the PSP's performance measures is set out on page 129.
AstraZeneca Investment Plan (AZIP)¹	The performance and holding periods of the AZIP are influenced by the Group's targeted product development cycle, reflecting the long-term investment horizons that are a feature of the industry. Dividend-based performance hurdles motivate the generation of returns for shareholders on a sustainable basis over an extended period of time.	The AZIP was approved by shareholders at the 2010 AGM and provides for the grant of awards over Ordinary Shares or ADSs.  The AZIP is operated over a four year performance period and a subsequent four year holding period. Performance periods commence on 1 January in the year of the award. Holding periods commence at the end of the performance period and end eight years from 1 January in the year of the award.  In respect of any financial year of the Company, the maximum market value of shares that may, in theory, be put under an award under the AZIP is 500% of a participant's base salary (which converts into an expected value of 500%). The actual individual limits that apply under the AZIP, subject to this maximum, are set by the Remuneration Committee from time to time.  Clawback – the Remuneration Committee may claw back some or all of the shares that are the subject of a participant's award at any time during the performance or the holding period if, in the opinion of the Remuneration Committee (acting fairly and reasonably), this is warranted by 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.	A combination of dividend and dividend cover hurdles, assessed over the relevant four year performance period.  More information about the AZIP's performance hurdles is set out on page 130.
Pension	Provision of retirement benefits.	Benchmarked against the relevant local	

<sup>&</sup>lt;sup>1</sup> In respect of long-term incentive awards, the current distribution between the PSP and the AZIP is in the ratio 75% to 25%.

#### Performance evaluation process

AstraZeneca conducts an annual performance evaluation process for all of its executives. In the case of members of the Senior Executive Team, this is conducted by the CEO. In the case of the CEO, this is conducted by the Chairman of the Board. Recommendations are then made to the Remuneration Committee. Those reviews take place relative to Group and individual objectives which are set at the beginning of each year.

#### Service contracts

The notice periods and unexpired terms of Executive Directors' service contracts at 31 December 2012 are shown in the table below.

Subject to the arrangements in respect of the first 12 months of Pascal Soriot's service, which are described below, either AstraZeneca or the Executive Director may terminate the service contract on 12 months' notice. It is the Remuneration 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.

Executive Director	Date of service contract	Unexpired term at 31 December 2012	Notice period
Pascal Soriot	27 August 2012	21 months <sup>1</sup>	Reducing to 12 months <sup>1</sup>
Simon Lowth	5 November 2007	12 months	12 months

<sup>1</sup> The notice period in Mr Soriot's service contract is 24 months initially, which is reducing by one month for each month of service and will stabilise at a 12 month notice period.

#### 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 that such 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 this position, he received fees of £130,000 for his services in 2012.

#### Considering the wider employee context

The Remuneration Committee sets overall remuneration policy and makes decisions about specific remuneration arrangements in the broader context of employee remuneration throughout the Group. The Remuneration Committee annually reviews Group remuneration data including ratios of average pay to senior executive pay; bonus data; gender and geographical data in relation to base salaries and variable compensation; and aggregate data about the shareholding levels of senior managers. In reviewing the base salaries of Executive Directors and SET members, the Remuneration Committee considers the overall level of any salary increases being awarded to employees across the Group in the relevant year.

#### Shareholder and broader context

In all aspects of its work, the Remuneration 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 Remuneration Committee and other Remuneration Committee and Board members. The Remuneration 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 annual bonus plan, in which all employees participate, contains goals relating to the demonstration of commitment to integrity, with the aim of enhancing the Company's reputation and avoiding reputational damage.

#### **Implementation Report**

#### Implementation of remuneration policy in 2012

#### **Pascal Soriot**

Mr Soriot joined AstraZeneca as CEO on 1 October. In establishing his remuneration arrangements, the Remuneration Committee sought to offer a package that was internationally competitive, but pay no more than was necessary. In doing so, to the extent possible, the Remuneration Committee put in place a framework that maintained broadly the same balance in terms of its constituent elements and overall quantum as for the previous CEO, which the Remuneration Committee considers to be right for AstraZeneca and its shareholders.

At the time of Mr Soriot's appointment as CEO, certain share awards and payments, which are described below, were negotiated and agreed. They were approved by the Remuneration Committee in order to compensate Mr Soriot for the forfeiture of unvested long-term incentive awards and forfeited 2012 bonus opportunity from his previous employer. The principle governing the decision of the Remuneration Committee was that the buyout should be implemented predominantly in shares of AstraZeneca in circumstances where the vesting and, in the case of the award under the AZIP, the holding period operate over several years. The unvested long-term incentive awards from Mr Soriot's previous employer were valued with the assistance of an independent third party, using its standard methodology for such work and, where relevant, taking into account the extent to which such awards might have been expected to vest.

General information about annual bonus outcomes for performance in 2012 can be found on page 129. In awarding Mr Soriot's bonus for 2012, the Remuneration Committee recognised the strong start he had made since becoming CEO and his positive impact on the organisation.

	2012	Notes
Base salary	£275,000	The annual rate of base salary for the CEO in 2012 was £1,100,000.
		Mr Soriot was appointed as CEO with effect from 1 October.
Benefits	£1,017,000	This sum is made up of:
		£991,000 being cash paid to compensate Mr Soriot in respect of his forfeited bonus opportunity for 2012 from his previous employer, paid at his previous employer's target bonus rate and pro-rated from 1 January 2012 to 30 September.  Mr Soriot is required to invest this sum, after payment of income tax, in AstraZeneca shares; and
		£26,000 being remaining cash following selection of benefits within the Company's UK flexible benefits programme.
Annual bonus	£335,000	Mr Soriot was awarded a bonus for performance during 2012 of 122% of base salary out of a maximum possible award of 180% of base salary (range 0% – 180% with a target annual bonus of 100%). This award was pro-rated from 1 October to 31 December to reflect the date of Mr Soriot's appointment as CEO.
		One-third of any pre-tax bonus must be deferred into Ordinary Shares or ADSs. These are held for three years before being released.
		The bonus is not pensionable.
Award of restricted shares <sup>1</sup>	£2,000,000	On 26 October, Mr Soriot was granted an award of 69,108 restricted Ordinary Shares at a price of 2894 pence per share by way of compensation for the loss of long-term incentives from his previous employer.
		No performance conditions apply.
		Vesting schedule for this award (subject to Mr Soriot's continued employment with the Company):
		> 40% on 1 October 2013
		> 30% on 1 October 2014 > 30% on 1 October 2015.
Pension	£66,000	Cash payment equivalent to 24% of base salary (time pro-rated to take account of Mr Soriot's joining date in 2012) taken by Mr Soriot as a cash alternative to participation in a defined contribution pension scheme.

<sup>&</sup>lt;sup>1</sup> In addition to the award of restricted shares, on 26 October, Mr Soriot was also granted an award of 69,108 Ordinary Shares at a price of 2894 pence per share under the AZIP (also by way of compensation for the loss of long-term incentives from his previous employer). This award is subject to a four year performance period (1 January 2012 to 31 December 2015) and a subsequent four year holding period (1 January 2016 to 31 December 2019). The performance hurdles that apply to this award are that the annual dividend per share paid to holders of Ordinary Shares must increase from \$2.80 over the four year performance period (\$2.80 being the full-year dividend for 2011), and that dividend cover over the same period (based on Reported earnings before restructuring costs) does not fall below 1.5 times.

#### Simon Lowth

During 2012, at a time of considerable change within the Group, Mr Lowth served as Interim CEO for the period 1 June to 30 September, reverting to his previous role as CFO on 1 October.

To reflect his additional responsibilities during his tenure as Interim CEO, he was awarded a temporary increase in base salary. General information about annual bonus outcomes for performance in 2012 can be found on the page opposite. The Remuneration Committee also recognised Mr Lowth's excellent performance as Interim CEO, and his strong support to Mr Soriot in his new position as CEO, in determining the quantum of his annual bonus award.

	2012	Notes
Base salary	£740,000	Base salary for the CFO in 2012 was £660,000.
		Temporary base salary increase effective from June to September inclusive (period as Interim CEO) was £20,000 gross per month creating an annualised base pay figure of £900,000. This compares with the annualised salary of the outgoing CEO of £997,223. This temporary base salary increase was not pensionable.
Benefits	£103,000	This sum is made up of:
		£47,000 being cash paid in respect of dividends accrued on Ordinary Shares which vested in 2012, having been deferred in 2009 in respect of Mr Lowth's annual bonus awarded for performance in 2008;
		$$50,\!000$$ being remaining cash following selection of benefits within the Company's UK flexible benefits programme; and $$6,\!000$$ for other benefits, including healthcare insurance.
Annual bonus	(a) £554,000	(a) Mr Lowth was awarded a bonus for performance during his period as CFO during 2012 of 126% of base salary out of a maximum possible award of 150% of base salary (range 0% – 150% with a target annual bonus of 90%).
	(b) £480,000 Total: £1.034.000	(b) The annual bonus target was increased from 90% to 100% of base salary effective from June to September inclusive (Mr Lowth's period as Interim CEO), in line with that applicable to the CEO. For this period, Mr Lowth was awarded a bonus of 160% (range 0% – 180% with a target annual bonus of 100%).
		One-third of any pre-tax bonus must be deferred into Ordinary Shares or ADSs. These are held for three years before being released.
		The bonus is not pensionable.
AstraZeneca	£897,000	This sum is made up of:
Performance Share Plan (PSP)		£771,000 being the estimated market value <sup>1</sup> of Ordinary Shares which will vest in March 2013 in respect of the 2010 PSP award (three year performance period 2010 to 2012); and
		£126,000 being cash to be paid on the vesting of this award in respect of dividends accrued.
Pension	£158,000	Cash payment equivalent to 24% of base salary (as CFO) taken by Mr Lowth as a cash alternative to participation in a defined contribution pension scheme.

<sup>&</sup>lt;sup>1</sup> Estimated market value of 3153 pence per Ordinary Share based on the London Stock Exchange closing price on 30 January 2013.

#### **David Brennan**

In April 2012, Mr Brennan informed the Board that he wished to retire. Mr Brennan relinquished his responsibilities as a Director and as CEO on 1 June.

	2012	Notes
Base salary	£499,000	Base salary for the CEO in 2012 was at the rate of £997,223.  Mr Brennan retired as CEO and as a Director on 1 June. His employment with the Company ended on 30 June.
Pay in lieu of notice	£914,000	On leaving the Company at a date determined by the Board, Mr Brennan received a lump sum payment in lieu of contractual notice, representing 11 months' base pay.
Benefits	£252,000	This sum is made up of: an allowance of up to £120,000 for relocation costs under Mr Brennan's contract; £86,000 being cash paid in respect of dividends accrued on Ordinary Shares which vested in 2012, having been deferred in 2009 in respect of Mr Brennan's annual bonus awarded for performance in 2008; £17,000 allowance for professional fees (legal and pensions advice in connection with Mr Brennan's retirement); £16,000 for other benefits including healthcare insurance; and £13,000 car allowance.
Annual bonus	None awarded	Mr Brennan informed the Remuneration Committee that he did not wish to be considered for a bonus in respect of that part of 2012 during which he was CEO. The Remuneration Committee determined that no such bonus would be awarded and also that there should be no bonus award relating to the contractual notice period.
AstraZeneca Performance Share Plan (PSP)	£1,577,000	This sum is made up of: £1,355,000 being the estimated market value¹ of Ordinary Shares which will vest in March 2013 in respect of the 2010 PSP award (three year performance period 2010 to 2012), and being pro-rated from 7 May 2010 to 30 June 2012 to reflect the period of Mr Brennan's employment since the award was granted; and £222,000 being cash to be paid on the vesting of this award in respect of dividends accrued.  The Remuneration Committee determined that the share awards made to Mr Brennan in 2011 and 2012 under the PSP and the AZIP should be forfeited.
Pension		Mr Brennan's pension entitlement was provided through a combination of the AstraZeneca US Defined Benefit Pension Plan and US defined contribution arrangements. He had an accrued pension at 30 June of \$1,584,000 (£1,000,000) per annum from his defined benefit arrangements. Full details can be found on page 131.

<sup>&</sup>lt;sup>1</sup> Estimated market value of 3153 pence per Ordinary Share based on the London Stock Exchange closing price on 30 January 2013.

### Variable elements of the CEO's and CFO's remuneration in 2012 – additional disclosures Annual bonus outcomes for performance in 2012

For Executive Directors, the principal drivers of annual bonus opportunity are EPS (27% weighting), cash flow (9% weighting), and scorecards (Group and SET area, 64% weighting). For the CEO, the average of all SET area scorecards is used to create an aggregate scorecard weighting. For the CFO, the average of Finance and Strategic Partnering and Business Development scorecards is used. Reward driven by EPS and cash flow performance depends on EPS and cash flow outcomes versus targets set at the beginning of each year. Reward driven by the scorecards depends on performance outcomes relative to goals in the areas of Values, Pipeline and People set at the beginning of each year. At constant exchange rates, there were declines in revenue, Core operating profit and EPS versus prior year. However, the Core EPS outcome and the cash flow outcome both exceeded the target set at the beginning of 2012. That element of the bonus payout which was driven by EPS and cash flow performance therefore exceeded target. In respect of the scorecards, a number of factors were taken into consideration. These include the supply problems described elsewhere in this Remuneration Report and the slower than expected uptake of *Brilinta/Brilique*. But they also include the strengthening of the pipeline through the acquisition of Ardea, the collaboration with Amgen, and the extension of our diabetes alliance with BMS through the inclusion of the Amylin product portfolio. Both *Forxiga* and *Zinforo* were launched in Europe, and we had a successful launch of *Nexium* in Japan. These factors collectively drove a score relative to scorecard performance of slightly below target.

The outturn is that the total variable short-term compensation of Executive Directors and other SET members in 2012 fell relative to the equivalent number in 2011.

The Remuneration Committee decided that Mr Soriot's annual bonus should amount to 122% of base salary, representing 68% of the potential maximum. The Remuneration Committee decided that Mr Lowth's annual bonus should be 140% of base salary, representing 86% of the potential maximum.

Mr Brennan informed the Remuneration Committee that he did not wish to be considered for a bonus in respect of that part of 2012 during which he was CEO and the Remuneration Committee determined that no such bonus would be awarded.

#### Annual bonus deferral

Part of the annual bonus of Executive Directors and other SET members is deferred into shares, helping to 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 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.

#### Performance measures under the PSP

The vesting of PSP awards is contingent on performance against specified performance measures over the relevant three year performance period and continued employment with the Group. Equal weighting is given to the two performance measures used: relative TSR and cumulative free cash flow.

Relative TSR – Fifty percent of the award is based on the Group's relative TSR performance against a predetermined peer group of global pharmaceutical companies. The peer group 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 peer 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 award. Payouts against performance in relation to TSR for PSP awards are expressed as a percentage of the maximum award currently payable, shown within a range of 0% to 100%, as set out in the table below.

TSR ranking of the Company	% of the maximum PSP award that vests
Below median	0%
Median	25%
Between median and upper quartile	Pro rata
Upper quartile	75%
Significantly above upper quartile	100%

Although 100% of the maximum award may vest at the Remuneration Committee's discretion if the Company's TSR performance is substantially better than that of the upper quartile of the comparator group, the Company would need to have sustained a level of performance significantly in excess of upper quartile over a period of years for the Remuneration Committee to be satisfied that the vesting of awards at this level was warranted.

In addition to the TSR performance target being met for each PSP award, the Remuneration Committee has to satisfy itself that achievement of the TSR performance target is an appropriate reflection of the Group's underlying financial performance. It has the discretion to prevent PSP awards from vesting or only allow them to vest partially where this, in the judgement of the Remuneration Committee, is warranted.

The TSR graphs on page 134 show, for each PSP 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 2012, and how the Company ranks against those other peer companies on this basis.

Cumulative free cash flow – Fifty percent of the award vests subject to the achievement of the free cash flow performance measure, which operates as a cumulative cash flow target over the same three year performance period as the TSR performance measure. The measure for the cash flow target is net cash flow (before distributions) (subject to any further adjustments the Remuneration Committee chooses to make at its discretion and thus referred to as 'adjusted cumulative cash flow') and the level of vesting is based on a sliding scale between a threshold cash flow target and an upper target. Vesting levels in relation to the threshold target and the upper target are shown in the table overleaf.

Adjusted cumulative cash flow – all PSP awards made before 2012	Adjusted cumulative cash flow – PSP awards made in 2012	% of the maximum PSP award that vests
Less than \$16 billion	Less than \$12 billion	0%
\$16 billion	\$12 billion	25%
Between \$16 billion and \$23 billion	Between \$12 billion and \$18 billion	Pro rata
\$23 billion and above	\$18 billion and above	100%

Cumulative 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 Remuneration 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.

#### Vesting of share awards made in 2010 under the PSP

In 2012, the TSR ranking of the Company was below median and therefore none of the award will vest in respect of that element of the performance measure. Fifty percent of the PSP award is based on free cash flow and in 2012 the Company achieved 95% of the free cash flow performance measure. The PSP share awards made in 2010 in respect of the 2010 to 2012 performance period will therefore vest at 47% for SET members, including Simon Lowth but excluding Pascal Soriot who does not hold any 2010 PSP awards. For the former CEO, David Brennan, vesting of his 2010 PSP awards will be pro-rated from 7 May 2010 to 30 June 2012 to reflect the period of his employment since the award was granted.

#### Performance hurdles under the AZIP

The performance hurdles for the AZIP awards are shown in the table below.

Year in which AZIP award made	Relevant four year performance period	Dividend hurdle	Dividend cover hurdle (based on Reported earnings before restructuring costs)
2010	1 January 2010 to 31 December 2013	That the annual dividend per share paid to holders of Ordinary Shares is increased from \$2.30 over the performance period (\$2.30 being the full year dividend for 2009)	That dividend cover does not fall below 1.5 times over the performance period
2011	1 January 2011 to 31 December 2014	That the annual dividend per share paid to holders of Ordinary Shares is increased from \$2.55 over the performance period (\$2.55 being the full year dividend for 2010)	That dividend cover does not fall below 1.5 times over the performance period
2012	1 January 2012 to 31 December 2015	That the annual dividend per share paid to holders of Ordinary Shares is increased from \$2.80 over the performance period (\$2.80 being the full year dividend for 2011)	That dividend cover does not fall below 1.5 times over the performance period

The AZIP awards made to date remain outstanding other than those made to David Brennan in 2011 and 2012, which the Remuneration Committee determined should be forfeited.

#### Statement of Executive Directors' shareholdings

In addition to the shareholding requirements imposed by the Board on Executive Directors and SET members and shown in the table below, under the Articles, all Directors must, within two months of their appointment, acquire a beneficial interest in at least 500 shares.

	Pascal Soriot	Simon Lowth
Shareholding requirement for the CEO and CFO¹	300% of base salary	200% of base salary
Total number of shares beneficially owned as at 31 January 2013	3,500	56,960
Estimated market value of total number of shares beneficially owned based on the London Stock Exchange closing price of 3153 pence per share on 30 January 2013	£110,000	£1,796,000
Estimated market value of total number of shares beneficially owned as a percentage of 2012 base salary	10%	272%
Total number of shares subject to deferral	69,108	29,042
Total number of shares subject to performance conditions	69,108	205,397

 $<sup>^{\</sup>mbox{\tiny 1}}$  The shareholding requirement for all other SET members is 125% of base salary.

Further information about Executive Directors' shareholdings can be found from page 134.

#### Appendix - Additional information

#### Audit

The Executive Directors' pension arrangements disclosed in the Pension arrangements section below, the Directors' emoluments disclosed in the Directors' emoluments in 2012 section from page 132 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 134 have been audited by KPMG Audit Plc.

#### Pension arrangements

#### Pascal Soriot and Simon Lowth

Pascal Soriot and Simon Lowth are 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, Mr Lowth has elected to take the cash allowance in lieu of a pension, which during 2012 amounted to £158,000 (\$251,000) (2011: £153,000 (\$245,000)). In respect of 2012, Mr Soriot made a similar election, which amounted to £66,000 (\$105,000).

In the event of a senior employee in the UK DCP (including one who has taken the 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, dependents are entitled to a lump sum secured from a multiple of 10 times salary, capped at £4.3 million.

#### **David Brennan**

David Brennan is a member of the AstraZeneca US Defined Benefit Pension Plan (US DBP). Benefits for members of the US DBP are delivered on a tax-qualified basis, with accrued benefits that exceed specific limits under the US DBP'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 his retirement in 2012, Mr Brennan was 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 combined age and service exceeding 85 years.

Mr Brennan's participation in the US DBP was subject to a service cap at 35 years' service, which was attained during his tenure as CEO and therefore service beyond 35 years is not shown in the table below. During his tenure as a Director, bonus payments were removed from the calculation of his pensionable pay under the US DBP.

Pension is payable to Mr 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 2012 set out on page 133. Transfer values are calculated to be consistent with the value of the lump sum distribution equivalent to his deferred accrued pension annually.

		David Brennar	
		£000	\$000
Defined benefit arrangements			
1. Accrued pension at 1 January 2012		988	1,565
2. Increase in accrued pension during year as a result of inflation		_	_
Adjustment to accrued pension as a result of salary increase relative to inflation		12	19
Increase in accrued pension as a result of additional service		_	_
5. Accrued pension at 30 June 2012 <sup>1</sup>		1,000	1,584
6. Employee contributions during 2012		_	_
7. Transfer value of accrued pension at 31 December 2011	1	4,200	22,488
8. Transfer value of accrued pension at 30 June 2012 <sup>1</sup>		14,776	23,400
9. Change in transfer value during the period less employee contributions		576	912
10. Age at 30 June 2012 <sup>1</sup>	58 <sup>10/12</sup>		
11. Pensionable service (years) at 30 June 2012 <sup>1</sup>	35		

 $<sup>^{\</sup>scriptscriptstyle 1}\,$  Mr Brennan's employment with AstraZeneca ended on 30 June 2012.

In addition to the US DBP, Mr Brennan (as a US citizen) was a contributing member of the US 401(k) savings plan. He also participated 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 2012, total employer matching contributions of \$47,000 (£30,000) (2011: \$96,000 (£60,000)) were made to his 401(k) plan and EDCP. Member contributions of £224,000 (\$355,000) were paid through salary sacrifice into the plans.

#### Summary of other share plans

#### AstraZeneca Global Restricted Stock Plan

The AstraZeneca Global Restricted Stock Plan (GRSP) was introduced in 2010 and provides for the grant of restricted stock awards over the Company's Ordinary Shares or ADSs. The GRSP is operated for below SET-level employees only. Typically, awards are made in March each year and, in relation, for example, to new appointments or promotions, in August. Awards under the GRSP do not involve the issue or allotment of new Ordinary Shares or ADSs but rely instead on the market purchase of Ordinary Shares or ADSs.

#### AstraZeneca Restricted Share Plan

The AstraZeneca Restricted Share Plan (RSP) was introduced in 2008 and provides for the granting of restricted share awards to key employees, excluding Executive Directors. Awards are made on an *ad hoc* basis with variable vesting dates. The RSP was used in 2012 to make awards (totalling an aggregate of 643,000 Ordinary Shares under the plan for the calendar year 2012) to a number of key senior executives in specific situations considered by the Remuneration Committee. The Remuneration Committee has responsibility for agreeing any awards under the RSP and for setting the policy for the way in which the RSP operates. Awards under the RSP do not involve the issue or allotment of new Ordinary Shares or ADSs but rely instead on the market purchase of Ordinary Shares or ADSs.

#### AstraZeneca Share Option Plan

The AstraZeneca Share Option Plan (SOP) expired in May 2010. Details of outstanding options granted to Executive Directors are shown in the table on page 137. The Remuneration Committee imposed performance conditions in respect of the exercise of such options by SET members (including the Executive Directors) which, in the view of the Remuneration Committee, were considered appropriately stretching. In order for options 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 Remuneration 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 options to vest and become exercisable, the Remuneration Committee can make a determination to reflect this. No such determination was made in 2012.

#### Other plans

In addition to the plans described above, the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca All-Employee Share Plan are operated in the UK, both of which are HM Revenue & Customs approved plans. Executive Directors and certain other SET members are eligible to participate in these plans.

#### 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 AstraZeneca's share plans has a dilutive effect because they do not involve the issue or allotment of new Ordinary Shares or ADSs but rely instead on the market purchase of Ordinary Shares or ADSs.

#### Chairman

The Remuneration Committee determines the terms of service, including remuneration, of the Chairman. The annual Board fees payable to the Chairman are set out in the table below. In addition to the Chairman's fee, a proportion of the office costs of the Chairman are reimbursed; the sum paid in this respect in 2012 is set out in the Directors' emoluments section below. The Chairman receives no additional fee or allowance for Remuneration Committee membership. The Chairman does not participate in the Group's incentive plans or pension or healthcare arrangements.

#### **Non-Executive Directors**

None of the Non-Executive Directors has a service contract but all have letters of appointment. In accordance with the 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 are set out below.

Under the Articles, all Directors must, within two months of their appointment, acquire a beneficial interest in at least 500 shares. In addition to this mandatory shareholding requirement, 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 Committee <sup>1</sup>	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 2012

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 2012 was £7,308,000 (\$11,572,000). The remuneration of individual Directors is set out in the Directors' remuneration tables opposite in pounds sterling and US dollars. All salaries, fees, bonus 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 2012 £000	Total 2011 £000	Total 2010 £000
Leif Johansson	318 <sup>2</sup>	-	-	-	_	318	_	_
Pascal Soriot	275	223	112	_	1,017³	1,627	-	_
Simon Lowth	740	689	345	6	300⁴	2,080	1,785	1,642
Geneviève Berger	58	_	-	_	_	58	_	_
Bruce Burlington	105	-	_	_	_	105	98	33
Graham Chipchase	65	-	_	_	_	65	_	_
Jean-Philippe Courtois	95	-	-	-	_	95	95	80
Rudy Markham	124	-	_	_	_	124	110	90
Nancy Rothwell	107	_	-	_	_	107	107	96
Shriti Vadera	95	-	_	_	_	95	95	_
John Varley	130	_	_	_	_	130	110	99
Marcus Wallenberg	85	-	_	_	_	85	85	71
Former Directors								
Louis Schweitzer	208⁵	-	_	_	_	208	500	456
David Brennan	499 <sup>6</sup>	-	_	11	1,653 <sup>7</sup>	2,163	3,370	3,044
Michele Hooper	488	-	-	-	_	48	145	120
Others	_	-	-	-	_	-	35	149
Total	2,952	912	457	17	2,970	7,308	6,535	5,880

#### Directors' remuneration - US dollars

Name	Salary and fees \$000	Bonus cash \$000	Bonus Shares¹ \$000	Taxable benefits \$000	Other payments and allowances \$000	Total 2012 \$000	Total 2011 \$000	Total 2010 \$000
Leif Johansson	504 <sup>2</sup>	-	_	-	_	504	-	_
Pascal Soriot	436	353	177	_	1,611³	2,577	_	_
Simon Lowth	1,172	1,091	546	10	475⁴	3,294	2,857	2,537
Geneviève Berger	92	_	_	_	_	92	-	-
Bruce Burlington	166	_	_	_	-	166	157	51
Graham Chipchase	103	_	-	_	-	103	_	_
Jean-Philippe Courtois	150	_	_	_	_	150	152	124
Rudy Markham	196	_	_	_	-	196	176	139
Nancy Rothwell	169	-	_	_	_	169	171	148
Shriti Vadera	150	_	_	-	-	150	152	_
John Varley	206	-	-	_	_	206	176	153
Marcus Wallenberg	135	_	_	-	-	135	136	110
Former Directors								
Louis Schweitzer	329⁵	_	_	_	_	329	800	705
David Brennan	790 <sup>6</sup>	_	_	17	2,618 <sup>7</sup>	3,425	5,393	4,705
Michele Hooper	76 <sup>8</sup>	_	-	_	_	76	232	185
Others	_	_	_	_	-	_	56	231
Total	4,674	1,444	723	27	4,704	11,572	10,458	9,088

- These figures represent that portion of the 2012 bonuses required to be deferred into shares to be held for a three year period under the Deferred Bonus Plan.
- $^2$  Includes office costs of £19,000 (\$30,000).
- Relates to remaining cash following selection of benefits within AstraZeneca's UK flexible benefits programme and cash of £991,000 (\$1,571,000) paid to compensate Mr Soriot in respect of forfeited bonus opportunity for 2012 from his previous employer.
- 4 Relates to remaining cash following selection of benefits within AstraZeneca's UK flexible benefits programme and cash of £203,000 (\$322,000) on the vesting of a PSP Share Award and £47,000 (\$74,000) on the release of shares under the Deferred Bonus Plan, in each case paid in respect of dividends accrued.
- Part year only as ceased to be a Director on 1 June.
- 6 This figure includes a sum of £224,000 (\$355,000) 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 section relating to David Brennan on page 131 for further details). Part year only as employment ceased on 30 June.

  Relates to £914,000 (\$1,447,000) payment in lieu of notice, other allowances for professional fees, a car allowance and cash of £498,000 (\$789,000) on the vesting of a PSP Share Award and £86,000 (\$136,000) on the release of shares under the Deferred Bonus Plan, in each case paid in respect of dividends accrued.
- 8 Part year only as ceased to be a Director on 26 April 2012.

In the tables on this page and on the previous page, salaries have been converted between pounds sterling and US dollars at the average exchange rate for the year in question. These rates were:

	GBP/USD
2012	0.631
2011	0.625
2010	0.647

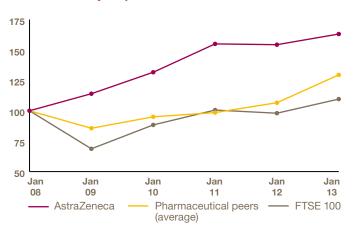
Details of share options exercised by Directors and the aggregate of gains realised on the exercise of options and of awards under long-term incentive plans in the year are given in the Directors' interests in shares section on page 134.

No Director has a family relationship with any other Director.

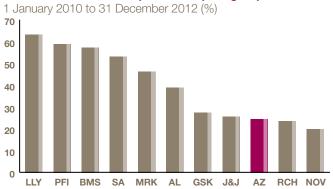
#### **Transactions with Directors**

There were no material recorded transactions between the Group and the Directors during 2012 or 2011.

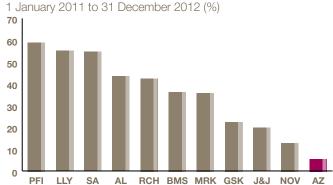
#### TSR over a five year period



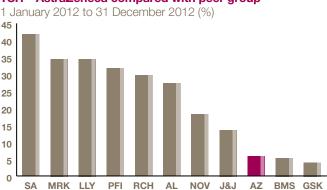
#### TSR - AstraZeneca compared with peer group



#### TSR - AstraZeneca compared with peer group



#### 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

#### 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 above, 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 above.

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 129). The graphs above 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 PSP award to 31 December 2012 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 above, over the last three months of 2012.

#### Directors' interests in shares

Beneficial interests

The table opposite 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 2012 to 31 December 2012 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 awards and/or AZIP awards, as well as Ordinary Shares or ADSs that are deferred under the annual bonus plan discussed in this Remuneration Report, are not included in the Directors' interests in shares table opposite but are shown in the relevant tables from page 135. 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 2012 and 31 January 2013, there was no change in the interests in Ordinary Shares shown in the table opposite.

	Beneficial interest in Ordinary Shares at 1 January 2012 or (if later) appointment date	Change to beneficial interest	Beneficial interest in Ordinary Shares at 31 December 2012 or (if earlier) resignation date
Leif Johansson <sup>1</sup>	25,509	3,000	28,509
Pascal Soriot <sup>2</sup>	_	3,500	3,500
Simon Lowth	54,226	2,734	56,960
Geneviève Berger <sup>1</sup>	_	900	900
Bruce Burlington	553	1,000	1,553
Graham Chipchase <sup>1</sup>	650	850	1,500
Jean-Philippe Courtois	2,635	-	2,635
Rudy Markham	2,452	_	2,452
Nancy Rothwell	1,832	573	2,405
Shriti Vadera	3,000	_	3,000
John Varley	1,744	3,700	5,444
Marcus Wallenberg	63,646	_	63,646
Former Directors			
Louis Schweitzer <sup>3</sup>	16,615	_	16,615
David Brennan <sup>3</sup>	246,174	60,430	306,604
Michele Hooper <sup>4</sup>	2,400	_	2,400

<sup>&</sup>lt;sup>1</sup> Appointed as a Director on 26 April 2012.

#### 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 2012	Net ADSs acquired during 2012	ADSs held at 1 June 2012 <sup>1</sup>
AstraZeneca Executive Deferral Plan	40,002	1,885	41,887
AstraZeneca Savings and Security Plan	9,022	391	9,413

<sup>&</sup>lt;sup>1</sup> David Brennan ceased to be a Director on 1 June and ceased to be an employee of the Company on 30 June.

#### Performance Share Plan

The interests of Directors at 31 December 2012 in Ordinary Shares that are the subject of awards under the PSP are shown below:

	Number of	Award price	Price on vesting			
	shares	(pence)	date (pence)	Grant date <sup>1</sup>		Performance period <sup>1</sup>
David Brennan						
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
2011 Share Award	131,075	2853		28.03.11	28.03.14	01.01.11 - 31.12.13
Total at 1 January 2012	391,942					
Partial vesting of 2009 Share Award <sup>2</sup>	(104,010) <sup>3,5</sup>		2854			
Partial lapse of 2009 Share Award <sup>2</sup>	(29,337)	-				
2012 Share Award	133,318	2805		30.03.12	30.03.15	01.01.12 - 31.12.14
Total at 1 June 2012 <sup>6</sup>	391,913 <sup>7</sup>					
Simon Lowth						
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
2011 Share Award	53,459	2853		28.03.11	28.03.14	01.01.11 - 31.12.13
Total at 1 January 2012	159,744					
Partial vesting of 2009 Share Award <sup>2</sup>	(42,335) <sup>4,5</sup>		2854			
Partial lapse of 2009 Share Award <sup>2</sup>	(11,941)					
2012 Share Award	70,588	2805		30.03.12	30.03.15	01.01.12 - 31.12.14
Total at 31 December 2012	176,056					

UK date convention applies.

Appointed as a Director on 1 October.

<sup>&</sup>lt;sup>3</sup> Ceased to be a Director on 1 June.

<sup>4</sup> Ceased to be a Director on 26 April 2012.

Share Awards granted in 2009 vested in 2012 at 78% based on the performance conditions and targets (which are set out in the Performance measures under the PSP section from page 129).

Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 49,571 Ordinary Shares.
 Following certain mandatory tax deductions, Simon Lowth became beneficially interested in a net number of 20,320 Ordinary Shares.

<sup>&</sup>lt;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 on page 133.

<sup>&</sup>lt;sup>6</sup> David Brennan ceased to be a Director on 1 June and ceased to be an employee of the Company on 30 June.

The Remuneration Committee determined that the Share Awards made to David Brennan in 2011 and 2012 under the PSP should be forfeited on his ceasing to be employed by the Company. The Share Award made in 2010 will vest on a pro rata basis to reflect the period worked since the award of the shares, but only if and to the extent that the relevant performance conditions are met.

#### AstraZeneca Investment Plan

The interests of Directors at 31 December 2012 in Ordinary Shares that are the subject of awards under the AZIP are shown below:

	Number of shares	Award price (pence)	Grant date <sup>1</sup>	Vesting date <sup>1</sup>	Performance period <sup>1</sup>
David Brennan		4		J	
2010 Share Award	21,253	2861	07.05.10	01.01.18	01.01.10 - 31.12.13
2011 Share Award	21,845	2853	28.03.11	01.01.19	01.01.11 - 31.12.14
Total at 1 January 2012	43,098				
2012 Share Award	22,219	2805	30.03.12	01.01.20	01.01.12 - 31.12.15
Total at 1 June 2012 <sup>2</sup>	65,317³				
Simon Lowth					
2010 Share Award	8,668	2861	07.05.10	01.01.18	01.01.10 - 31.12.13
2011 Share Award	8,909	2853	28.03.11	01.01.19	01.01.11 - 31.12.14
Total at 1 January 2012	17,577				
2012 Share Award	11,764	2805	30.03.12	01.01.20	01.01.12 - 31.12.15
Total at 31 December 2012	29,341				
Pascal Soriot					
Total at 1 October 2012⁴	-				
2012 Share Award	69,108	2894	26.10.12	01.01.20	01.01.12 - 31.12.15
Total at 31 December 2012	69,108				

UK date convention applies.

#### **Deferred Bonus Plan**

As described on page 129, 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 2012 in Ordinary Shares or ADSs that are the subject of awards under these arrangements are shown below:

			Price on		
	Number of shares	Award price (pence)	vesting date (pence)	Grant date <sup>1</sup>	Vesting date <sup>1</sup>
David Brennan					
2009 Award	17,992	2400		25.02.09	25.02.12
2010 Award	20,718	2817.5		25.02.10	25.02.13
2011 Award	17,725	2977		25.02.11	25.02.14
Total at 1 January 2012	56,435				
Vesting of 2009 Award	(17,992) <sup>2,4</sup>		2856		
2012 Award	15,498	2851		24.02.12	24.02.15
Total at 1 June 2012 <sup>5</sup>	53,941 <sup>6</sup>				
Simon Lowth					
2009 Award	9,775	2400		25.02.09	25.02.12
2010 Award	9,760	2817.5		25.02.10	25.02.13
2011 Award	10,281	2977		25.02.11	25.02.14
Total at 1 January 2012	29,816				
Vesting of 2009 Award	(9,775) <sup>3,4</sup>		2856		
2012 Award	9,001	2851		24.02.12	24.02.15
Total at 31 December 2012	29,042				

<sup>&</sup>lt;sup>1</sup> UK date convention applies

#### **Restricted share award**

On 26 October, Pascal Soriot was granted an award of 69,108 restricted shares at an award price of 2894 pence per share. His employment with the Company commenced on 1 October and the restricted shares will vest, subject to his continued employment with the Company, as follows:

- > 40% will vest on 1 October 2013
- > 30% will vest on 1 October 2014
- > 30% will vest on 1 October 2015.

<sup>&</sup>lt;sup>2</sup> David Brennan ceased to be a Director on 1 June and ceased to be an employee of the Company on 30 June.

<sup>3</sup> The Remuneration Committee determined that the Share Awards made to David Brennan in 2011 and 2012 under the AZIP should be forfeited on his ceasing to be employed by the Company. The Share Award made in 2010 will vest on a pro rata basis to reflect the period worked since the award of the shares, but only if and to the extent that the relevant performance conditions are met.

<sup>&</sup>lt;sup>4</sup> Pascal Soriot was appointed as a Director on 1 October.

<sup>&</sup>lt;sup>2</sup> Following certain mandatory tax deductions, David Brennan became beneficially interested in a net number of 8,583 Ordinary Shares.

<sup>&</sup>lt;sup>3</sup> Following certain mandatory tax deductions, Simon Lowth became beneficially interested in a net number of 4,692 Ordinary Shares

<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 on page 133.

David Brennan ceased to be a Director on 1 June and ceased to be an employee of the Company on 30 June.

The Remuneration Committee determined that the Share Awards made to David Brennan under the AstraZeneca Deferred Bonus Plan will vest in accordance with the normal vesting timetable at the end of the relevant three year retention periods.

#### Share option plans

The interests of Directors who served during 2012, 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 2012.

		Number of Ordinary Shares under option'	Exercise price per Ordinary Share <sup>2</sup>	First day exercisable <sup>3,4</sup>	Last day exercisable <sup>3,</sup>
David Brennan	At 1 January 2012 – options over Ordinary Shares	592,975	2375p	24.03.09	26.03.19
	- market price above option price (Ordinary Shares)	505,244	2271p	19.05.09	26.03.19
	- market price at or below option price (Ordinary Shares)	87,731	2975p	24.03.09	23.03.16
	At 1 June 2012⁵ – options over Ordinary Shares	592,975 <sup>6</sup>	2375p	24.03.09	26.03.19
	- market price above option price (Ordinary Shares)	353,872	2062p	28.03.11	26.03.19
	- market price at or below option price (Ordinary Shares)	239,103	2839p	24.03.09	29.03.17
	At 1 January 2012 – 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
	Lapsed 27 March 2012	(75,695)	\$49.59	28.03.05	27.03.12
	At 1 June 2012⁵ – options over ADSs	177,528 <sup>6</sup>	\$42.70	26.03.07	23.03.15
	- market price above option price (ADSs)	_	n/a	n/a	n/a
	- market price at or below option price (ADSs)	177,528	\$42.70	26.03.07	23.03.15
Simon Lowth	At 1 January 2012	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
	At 31 December 2012	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>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 132.

#### 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 \$
2012	-	-
2011	882,089	112,254
2010	260,182	11,454

During 2012, the market price of Ordinary Shares or ADSs was as follows:

Stock Exchange		Range of the Ordinary Share/ ADS market price during 2012
London	2909.5p	2591p to 3111.5p
Stockholm	306.4 SEK	286.2 SEK to 329.5 SEK
New York	\$47.27	\$40.03 to \$48.90

On behalf of the Board

#### A C N Kemp

Company Secretary 31 January 2013

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.

<sup>&</sup>lt;sup>5</sup> David Brennan ceased to be a Director on 1 June and ceased to be an employee of the Company on 30 June.

<sup>&</sup>lt;sup>6</sup> The Remuneration Committee determined that all unexercised options held by David Brennan should be exercised within two years of his ceasing to be employed by the Company with the exception of the option granted in 2009 which should be exercised before his cessation of employment.

# Innovation means



AstraZeneca's total contribution to the Russian economy will see over \$1.2 billion invested in the five years from 2011, supporting our goal to provide Russian patients access to our portfolio of life-saving prescription medicines.



### 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 31 January 2013

#### **Pascal Soriot**

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 2012 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 2012, the internal control over financial reporting is effective based on those criteria.

KPMG Audit Plc, an independent registered public accounting firm, has audited the effectiveness of internal control over financial reporting as at 31 December 2012 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 Plc has also issued reports in accordance with 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 2012

(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 2012 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 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 Financial Reporting Council's website at frc.org.uk/auditscopeukprivate.

#### **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 2012 and of its profit for the year then ended;
- > have been properly prepared in accordance with IFRSs as adopted by the EU; and
- > 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; or
- > 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 110 to 121 relating to the Company's compliance with the nine provisions of the UK Corporate Governance Code specified for our review; and
- > 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 2012 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
31 January 2013

### Financial Statements | Consolidated Statement of Comprehensive Income

## Consolidated Statement of Comprehensive Income for the year ended 31 December

		2012	2011	2010
D	Notes	\$m	\$m	\$m
Revenue	1	27,973	33,591	33,269
Cost of sales		(5,393)	(6,026)	(6,389)
Gross profit		22,580	27,565	26,880
Distribution costs		(320)	(346)	(335)
Research and development expense	2	(5,243)	(5,523)	(5,318)
Selling, general and administrative costs	2	(9,839)	(11,161)	(10,445)
Profit on disposal of subsidiary	2, 22		1,483	_
Other operating income and expense	2	970	777	712
Operating profit	2	8,148	12,795	11,494
Finance income	3	528	552	516
Finance expense	3	(958)	(980)	(1,033)
Profit before tax		7,718	12,367	10,977
Taxation	4	(1,391)	(2,351)	(2,896)
Profit for the period		6,327	10,016	8,081
Other comprehensive income:				
Foreign exchange arising on consolidation		106	(60)	26
Foreign exchange differences on borrowings designated in net investment hedges		(46)	24	101
Fair value movements on derivatives designated in net investment hedges		76	_	-
Amortisation of loss on cash flow hedge		1	2	1
Net available for sale gains taken to equity		72	31	4
Actuarial loss for the period	18	(85)	(741)	(46)
Income tax relating to components of other comprehensive income	4	(46)	198	(61)
Other comprehensive income for the period, net of tax		78	(546)	25
Total comprehensive income for the period		6,405	9,470	8,106
Profit attributable to:				
Owners of the Parent		6,297	9,983	8,053
Non-controlling interests		30	33	28
Total comprehensive income attributable to:				
Owners of the Parent		6,395	9,428	8,058
Non-controlling interests		10	42	48
Basic earnings per \$0.25 Ordinary Share	5	\$4.99	\$7.33	\$5.60
Diluted earnings per \$0.25 Ordinary Share	5	\$4.98	\$7.30	\$5.57
Weighted average number of Ordinary Shares in issue (millions)	5	1,261	1,361	1,438
Diluted weighted average number of Ordinary Shares in issue (millions)	5	1,264	1,367	1,446
Dividends declared and paid in the period	21	3,619	3,752	3,494

All activities were in respect of continuing operations.

\$m means millions of US dollars.

# Financial Statements | Consolidated Statement of Financial Position

# Consolidated Statement of Financial Position

at 31 December

	Notes	2012 \$m	2011 \$m	2010 \$m
Assets		——	ΦΙΙΙ	—
Non-current assets				
Property, plant and equipment	7	6,089	6,425	6,957
Goodwill	8	9,898	9,862	9,871
Intangible assets	9	16,448	10,980	12,158
Derivative financial instruments	15	389	342	324
Other investments	10	199	201	211
Other receivables	12	352	_	_
Deferred tax assets	4	1,111	1,514	1,475
		34,486	29,324	30,996
Current assets Inventories	11	2,061	1,852	1,682
Trade and other receivables	12	7,629	8,754	7,847
Other investments	10	823	4,248	1,482
Derivative financial instruments	15	31	25	9
Income tax receivable	10	803	1,056	3,043
Cash and cash equivalents	13	7,701	7,571	11,068
odon and odon oquivalonto	10	19,048	23,506	25,131
		53,534	52,830	56,127
Liabilities				,
Current liabilities				
Interest-bearing loans and borrowings	14	(901)	(1,990)	(125)
Trade and other payables	16	(9,221)	(8,975)	(8,661)
Derivative financial instruments	15	(3)	(9)	(8)
Provisions	17	(916)	(1,388)	(1,095)
Income tax payable		(2,862)	(3,390)	(6,898)
		(13,903)	(15,752)	(16,787)
Non-current liabilities			,	
Interest-bearing loans and borrowings	14	(9,409)	(7,338)	(9,097)
Deferred tax liabilities	4	(2,576)	(2,735)	(3,145)
Retirement benefit obligations	18	(2,265)	(2,674)	(2,472)
Provisions	17	(428)	(474)	(843)
Other payables	16	(1,001)	(385)	(373)
		(15,679)	(13,606)	(15,930)
Total liabilities		(29,582)	(29,358)	(32,717)
Net assets		23,952	23,472	23,410
Equity				
Capital and reserves attributable to equity holders of the Company Share capital	20	312	323	352
Share premium account		3,504	3,078	2,672
Capital redemption reserve		153	139	107
Merger reserve		433	433	433
Other reserves	19	1,374	1,379	1,377
Retained earnings	19	17,961	17,894	18,272
		23,737	23,246	23,213
Non-controlling interests		215	226	197
		23,952	23,472	23,410

The Financial Statements from page 142 to 191 were approved by the Board on 31 January 2013 and were signed on its behalf by

Pascal SoriotSimon LowthDirectorDirector

# Financial Statements | Consolidated Statement of Changes in Equity

# 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 attributable to owners \$m	Non- controlling interests \$m	Total equity \$m
At 1 January 2010	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
Profit for the period	-	-	-	-	-	6,297	6,297	30	6,327
Other comprehensive income	-	_	-	_	_	98	98	(20)	78
Transfer to other reserves <sup>1</sup>	_	_	_	_	(5)	5	_	_	
Transactions with owners									
Dividends	_	_	-			(3,619)	(3,619)	_	(3,619)
Issue of Ordinary Shares	3	426	-	-	-	-	429	-	429
Repurchase of Ordinary Shares	(14)	-	14	-	-	(2,635)	(2,635)	-	(2,635)
Share-based payments	-	-	-	-	-	(79)	(79)	_	(79)
Transfer from non-controlling interests to payables	-	-	-	-	-	-	-	(10)	(10)
Dividend paid by subsidiary to non-controlling interests	-	_	-	_	_	_	_	(11)	(11)
Net movement	(11)	426	14	-	(5)	67	491	(11)	480
At 31 December 2012	312	3,504	153	433	1,374	17,961	23,737	215	23,952

<sup>&</sup>lt;sup>1</sup> Amounts charged or credited to other reserves relate to exchange adjustments arising on goodwill.

# Financial Statements | Consolidated Statement of Cash Flows

# Consolidated Statement of Cash Flows for the year ended 31 December

		2012	2011	2010
	Notes	\$m	\$m	\$m
Cash flows from operating activities		7740	40.007	10.077
Profit before tax		7,718	12,367	10,977
Finance income and expense	3	430	428	517
Depreciation, amortisation and impairment		2,518	2,550	2,741
Decrease/(increase) in trade and other receivables		755 (150)	(1,108)	10 88
(Increase)/decrease in inventories		` '	(256)	
(Decrease)/increase in trade and other payables and provisions	00	(1,311)		(16)
Profit on disposal of subsidiary	22	(424)	(1,483)	(463)
Non-cash and other movements			(597)	
Cash generated from operations		9,536	12,368	13,854
Interest paid		(545)	(548)	(641)
Tax paid		(2,043)	(3,999)	(2,533)
Net cash inflow from operating activities		6,948	7,821	10,680
Cash flows from investing activities	00	(4.407)		(0.40)
Acquisitions of business operations	22	(1,187)	(0.740)	(348)
Movement in short-term investments and fixed deposits		3,619	(2,743)	(125)
Purchase of property, plant and equipment		(672)	(839)	(791)
Disposal of property, plant and equipment		199	102	83
Purchase of intangible assets		(3,947)	(458)	(1,390)
Disposal of intangible assets		-	_	210
Purchase of non-current asset investments		(46)	(11)	(34)
Disposal of non-current asset investments		43		5
Net cash received on disposal of subsidiary	22		1,772	
Dividends received		7	-	
Interest received		145	171	174
Payments made by subsidiaries to non-controlling interests		(20)	(16)	(10)
Net cash outflow from investing activities		(1,859)	(2,022)	(2,226)
Net cash inflow before financing activities		5,089	5,799	8,454
Cash flows from financing activities			100	40.4
Proceeds from issue of share capital		429	409	494
Repurchase of shares		(2,635)	(6,015)	(2,604)
Repayment of obligations under finance leases		(17)	_	
Issue of loans		1,980	_	
Repayment of loans		(1,750)		(1,741)
Dividends paid		(3,665)	(3,764)	(3,361)
Hedge contracts relating to dividend payments		48	3	(114)
Movement in short-term borrowings		687	46	(8)
Net cash outflow from financing activities		(4,923)	(9,321)	(7,334)
Net increase/(decrease) in cash and cash equivalents in the period		166	(3,522)	1,120
Cash and cash equivalents at the beginning of the period		7,434	10,981	9,828
Exchange rate effects		(4)	(25)	33
Cash and cash equivalents at the end of the period	13	7,596	7,434	10,981

# Financial Statements | Group Accounting Policies

# **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 amendments to IFRS 7 'Disclosures – Transfers of Financial Assets' and IAS 12 'Deferred Tax: Recovery of Underlying Assets'. The adoption of the 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, is included in the Directors' Report. Details of the product portfolio of the Group (including patent expiry dates for key marketed products), 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 86. 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 2012, the Group has \$9.8bn in financial resources (cash balances of \$7.7bn and undrawn committed bank facilities of \$3.0bn which are available until April 2017, with only \$0.9bn of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, recent government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, 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, 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.

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.

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.

#### **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 2012, no amounts have met recognition criteria.

Payments to in-licence products and compounds from 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, 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.

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.

#### Jointly controlled operations

The Group has one arrangement over which it has joint control. The form of this arrangement is a jointly controlled operation under IAS 31 'Interests in Joint Ventures'. The Group recognises its share of income that it earns from the jointly controlled operation and

its share of expenses incurred. The Group also recognises the assets associated with the jointly controlled operation that it controls and the liabilities it incurs under the jointly controlled operation collaboration agreement.

#### **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 surplus 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 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 liability 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 plan awards is calculated using a modified version of the binomial model. In accordance with IFRS 2 'Share-based Payment', the resulting cost is recognised in profit over the vesting period of the awards, 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.

# Financial Statements | Group Accounting Policies

### 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 over its estimated useful life on a straight-line basis. 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

Leases are classified as finance leases if they transfer substantially all the risks and rewards incidental to ownership, otherwise they are classified as operating leases. Assets and liabilities arising on finance leases are initially recognised at fair value or, if lower, the present value of the minimum lease payments. The discount rate used in calculating the present value of the minimum lease payments is the interest rate implicit in the lease. Finance charges under finance leases are allocated to each reporting period so as to produce a constant periodic rate of interest on the remaining balance of the finance liability. Rentals under operating leases are charged to profit on a straight-line basis.

#### **Subsidiaries**

A subsidiary is an entity controlled, directly or indirectly, by AstraZeneca PLC. Control is regarded as the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities.

The financial results of subsidiaries are consolidated from the date control is obtained until the date that control ceases.

#### **Inventories**

Inventories are stated at the lower of cost and net realisable value. The first in, first out or an average method of valuation is used. For finished goods and work in progress, cost includes directly attributable costs and certain overhead expenses (including depreciation). Selling expenses and certain other overhead expenses (principally central administration costs) are excluded. Net realisable value is determined as estimated selling price less all estimated costs of completion and costs to be incurred in selling and distribution.

Write-downs of inventory occur in the general course of business and are recognised in cost of sales.

#### Trade and other receivables

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, trade and other receivables and payables and rights and obligations under employee benefit plans which are dealt with in specific accounting policies.

The Group's other financial instruments include:

- > cash and cash equivalents
- > fixed deposits
- > other investments
- > bank and other borrowings
- > derivatives.

#### Cash and cash equivalents

Cash and cash equivalents comprise cash in hand, current balances with banks and similar institutions and highly liquid investments with maturities of three months or less when acquired. They are readily convertible into known amounts of cash and are held at amortised cost.

#### **Fixed deposits**

Fixed deposits, comprising principally funds held with banks and other financial institutions, are initially measured at fair value, plus direct transaction costs, and are subsequently remeasured to amortised cost using the effective interest rate method at each reporting date. Changes in carrying value are recognised in profit.

#### Other investments

Where investments have been classified as held for trading, they are measured initially at fair value and subsequently remeasured to fair value at each reporting date. Changes in fair value are recognised in profit.

In all other circumstances, the investments are 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).

Other interest-bearing loans are initially measured at fair value (with direct transaction costs being amortised over the life of the bond) 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 recognised in 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 recognised in other comprehensive income.

If certain criteria are met, non-US dollar denominated loans or derivatives 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 in the Consolidated Financial Statements. Foreign exchange derivatives hedging net investments in foreign operations are carried at fair value. Effective fair value movements are recognised in other comprehensive income, with any ineffectiveness taken to the income statement. 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 'Disclosure 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'. The new and revised standards were endorsed by the EU in December 2012, with an effective date of 1 January 2014 (except for IFRS 13 which has an effective date of 1 January 2013) but with early adoption permitted. The Group intends to adopt the new and revised standards from 1 January 2013. The adoption is not expected to have a significant impact upon the Group's net results, net assets or disclosures.

The amendments to IAS 19 'Employee Benefits' are effective for accounting periods beginning on or after 1 January 2013 and were endorsed by the EU in June 2012. The amendments result in a change to the methodology used in calculating the expected return on pension assets, reported as finance income. Finance income will be lower as a result. On adoption, prior period finance income will be restated with decreases of approximately \$70m for 2012 and \$85m for 2011. The adoption of the IAS 19 amendments is not expected to have a significant impact on the Group's net assets.

The amendments to IAS 1 'Presentation of Items in Other Comprehensive Income' 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 2012, 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. These amendments were endorsed by the EU in 2012.

# Notes to the Group Financial Statements

#### 1 Product revenue information

11 Todact Teveride information			
	2012 \$m	2011 \$m	2010 \$m
Cardiovascular:	0.050	0.000	F 004
Crestor	6,253	6,622	5,691
Atacand	1,009	1,450	1,483
Seloken/Toprol-XL	918	986	1,210
<u>Onglyza</u>	323	211	69
Plendil Plendi	252	256	255
Zestril	115	144	157
Brilinta/Brilique	89	21	
Byetta	74	_	_
Bydureon	37	_	_
Others	461	522	538
Total Cardiovascular	9,531	10,212	9,403
Gastrointestinal:	2044	4.400	4.000
Nexium	3,944	4,429	4,969
Losec/Prilosec	710	946	986
Others	198	161	133
Total Gastrointestinal	4,852	5,536	6,088
Respiratory & Inflammation:		0.140	0.740
Symbicort	3,194	3,148	2,746
Pulmicort	866	892	872
Rhinocort	177	212	227
Others	178	216	254
Total Respiratory & Inflammation	4,415	4,468	4,099
Neuroscience:			
Seroquel	2,803	5,828	5,302
Local anaesthetics	540	602	605
Diprivan	291	294	322
Zomig	182	413	428
Vimovo	65	34	5
Others	42	33	42
Total Neuroscience	3,923	7,204	6,704
Oncology:			
Zoladex	1,093	1,179	1,115
Faslodex	654	546	345
Iressa	611	554	393
Arimidex	543	756	1,512
Casodex	454	550	579
Others	134	120	101
Total Oncology	3,489	3,705	4,045
Infection and Other:			
Synagis	1,038	975	1,038
Merrem	396	583	817
FluMist	181	161	174
Other Products	100	137	147
Total Infection and Other	1,715	1,856	2,176
Astra Tech	-	386	535
Aptium Oncology	48	224	219
Total	27,973	33,591	33,269

#### 2 Operating profit

Operating profit includes the following items:

#### Research and development expense

In 2012, research and development includes a \$50m impairment following the decision by AstraZeneca not to pursue a regulatory filing for TC-5214. In 2011, research and development includes a \$285m impairment charge related to the termination of development of the investigational compound olaparib for the maintenance treatment of serous ovarian cancer and \$150m impairment charge related to the intangible assets held in relation to TC-5214. In 2010, research and development included a \$445m impairment of intangible assets related specifically to motavizumab. Further details of impairment charges for 2012, 2011 and 2010 are included in Notes 7 and 9.

#### Selling, general and administrative costs

In 2012, selling, general and administrative costs includes net legal provisions of \$72m, in respect of net legal provision charges relating to ongoing *Seroquel* franchise legal matters, Average Wholesale Price litigation in the US, the *Toprol-XL* antitrust litigation and *Nexium* commercial litigation. In 2011, selling, general and administrative costs included \$135m of net legal provision charges, all of which were in respect of the ongoing *Seroquel* franchise legal matters, Average Wholesale Price litigation in the US and the *Toprol-XL* antitrust litigation. In 2010, selling, general and administrative costs included legal provision charges of \$617m, of which \$592m was in respect of *Seroquel* franchise 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.

#### 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

	2012 \$m	2011 \$m	2010 \$m
Royalties	***	•	¥
Income	659	610	522
Amortisation	(92)	(51)	(59)
Impairment	_	_	(123)
Net gain on disposal of property, plant and equipment	8	33	66
Gains on disposal of product rights	255	_	_
Net loss on disposal of other intangible assets	_	_	(1)
Other income	140	226	307
Other expense	_	(41)	_
Other operating income and expense	970	777	712

Royalty amortisation and impairment relates to income streams acquired with Medlmmune, and, from 2012, amounts relating to our arrangements with Merck.

#### Restructuring costs

During 2012, the Group announced the third phase of its restructuring programme, as approved by the SET. The tables below show the costs that have been charged in respect of restructuring programmes by cost category and type. Severance provisions are detailed in Note 17.

	2012 \$m	2011 \$m	2010 \$m
Cost of sales	136	54	144
Research and development expense	791	468	654
Selling, general and administrative costs	631	639	404
Total charge	1,558	1,161	1,202

Total charge	1,558	1,161	1,202
Other	411	468	398
Accelerated depreciation and impairment	328	290	299
Severance costs	819	403	505
	2012 \$m	2011 \$m	2010 \$m

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.

#### Financial instruments

Included within operating profit are the following net gains and losses on financial instruments.

	2012 \$m	2011 \$m	2010 \$m
Gains/(losses) on forward foreign exchange contracts	139	(75)	29
(Losses)/gains on receivables and payables	(153)	68	(80)
Gains/(losses) on available for sale current investments	12	(22)	(2)
	(2)	(29)	(53)

#### 3 Finance income and expense

	2012 \$m	2011 \$m	2010 \$m
Finance income			
Returns on fixed deposits and equity securities	18	9	9
Returns on short-term deposits	24	37	33
Expected return on post-employment defined benefit plan assets	486	502	451
Fair value gains on debt, interest rate swaps and investments	-	4	23
Total	528	552	516
Finance expense			
Interest on debt and commercial paper	(404)	(404)	(450)
Interest on overdrafts, finance leases and other financing costs	(22)	(29)	(29)
Interest on post-employment defined benefit plan liabilities	(507)	(539)	(543)
Fair value charges on debt, interest rate swaps and investments	(10)	_	_
Net exchange losses	(15)	(8)	(11)
Total	(958)	(980)	(1,033)
Net finance expense	(430)	(428)	(517)

#### Financial instruments

Included within finance income and expense are the following net gains and losses on financial instruments.

	2012 \$m	2011 \$m	2010 \$m
Interest and fair value adjustments in respect of debt designated at fair value through profit or loss, net of derivatives	(18)	(6)	(5)
Interest and changes in carrying values of debt designated as hedged items, net of derivatives	(16)	(17)	(18)
Interest and fair value changes on fixed and short-term deposits and equity securities	37	45	61
Interest on debt, overdrafts, finance leases and commercial paper held at amortised cost	(397)	(405)	(452)
Exchange losses on financial assets and liabilities	(15)	(8)	(11)
	(409)	(391)	(425)

\$22m fair value losses (2011: \$10m fair value gains; 2010: \$29m fair value gains) on interest rate fair value hedging instruments and \$21m fair value gains (2011: \$9m fair value losses; 2010: \$29m fair value losses) 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.

\$27m fair value losses (2011: \$29m fair value gains; 2010: \$33m fair value gains) on derivatives related to debt instruments designated at fair value through profit or loss and \$18m fair value gains (2011: \$26m fair value losses; 2010: \$28m 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. Ineffectiveness on the net investment hedge taken to profit was \$nil (2011: \$nil; 2010: \$nil).

#### 4 Taxation

Taxation recognised in the profit for the period in the consolidated statement of comprehensive income is as follows:

	2012 \$m	2011 \$m	2010 \$m
Current tax expense	·	****	<b>*</b> ····
Current year	1,761	2,680	3,065
Adjustment for prior years	(79)	(102)	370
	1,682	2,578	3,435
Deferred tax expense Origination and reversal of temporary differences	(155)	(141)	(369)
Adjustment to prior years	(136)	(86)	(170)
	(291)	(227)	(539)
Taxation recognised in the profit for the period	1,391	2,351	2,896

Taxation relating to components of other comprehensive income is as follows:

	2012 \$m	2011 \$m	2010 \$m
Current and deferred tax Foreign exchange arising on consolidation	14	12	(29)
Actuarial loss for the period	28	214	(18)
Share-based payments	7	21	9
Net available for sale gains recognised in other comprehensive income	(18)	_	_
Deferred tax impact of reduction in Sweden and UK tax rates	(84)	(53)	(23)
Other	7	4	_
Taxation relating to components of other comprehensive income	(46)	198	(61)

#### 4 Taxation continued

Taxation has been provided at current rates on the profits earned for the periods covered by the Group Financial Statements. The 2012 prior period current tax adjustment relates to a benefit of \$259m arising from a number of tax settlements (including settlement of a transfer pricing matter), partially offset by an increase in provisions for other tax contingencies and tax accrual to tax return adjustments. The 2011 prior period current tax adjustment relates to a benefit of \$520m arising from a number of tax settlements, 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 2012 prior period deferred tax adjustment relates to a benefit of \$102m arising from a number of tax settlements (including settlement of a transfer pricing matter) and tax accrual to tax return adjustments. 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.

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 \$8,655m at 31 December 2012 (2011: \$9,155m; 2010: \$16,768m).

#### 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 Statutory Corporation Tax to 21% by 2014. In 2012, the UK government also enacted legislation as part of its programme of corporate tax reforms including the introduction of a patent box regime, under which UK profits arising from certain UK owned patents will be subject to a reduced rate of UK Statutory Corporation Tax effective 1 April 2013. The Swedish government has enacted legislation to reduce the Sweden Statutory Corporation Tax rate from 26.3% to 22% effective 1 January 2013. 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 below reconciles the UK statutory tax charge to the Group's total tax charge.

	2012 \$m	2011 \$m	2010 \$m
Profit before tax	7,718	12,367	10,977
Notional taxation charge at UK corporation tax rate of 24.5% (2011: 26.5%; 2010: 28%)	1,891	3,277	3,074
Differences in effective overseas tax rates	(83)	(340)	(333)
Deferred tax credit relating to reduction in Sweden, UK and other tax rates¹	(271)	(53)	(21)
Unrecognised deferred tax asset	(18)	5	_
Items not deductible for tax purposes	116	71	12
Items not chargeable for tax purposes	(29)	(32)	(36)
Non-taxable gain arising from the Astra Tech disposal	-	(389)	_
Adjustments in respect of prior periods	(215)	(188)	200
Total tax charge for the year	1,391	2,351	2,896

<sup>&</sup>lt;sup>1</sup> The 2012 item relates to the reduction in the Sweden Statutory Corporation Tax rate from 26.3% to 22% effective 1 January 2013 and the UK Statutory Corporation Tax rate from 25% (the tax rate which was substantively enacted as effective from 1 April 2012 as at 31 December 2011) to the tax rate of 23% effective from 1 April 2013. 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 18% for the year ended 31 December 2012 is lower than the UK Statutory Corporation Tax rate of 24.5% mainly as a result of the \$230m adjustment to deferred tax balances following substantive enactment of a reduction in the Sweden Statutory Corporation Tax rate from 26.3% to 22% effective 1 January 2013, the \$240m release of a tax provision following the settlement of a transfer pricing matter and the difference in effective overseas tax rates as discussed below. Excluding the effects of the one-off benefits totalling \$470m mentioned above, the tax rate is 24.1%.

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.

#### 4 Taxation continued

#### 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 reserves <sup>1</sup> \$m	Accrued expenses	Share schemes \$m	Deferred capital gains \$m	Losses and tax credits carried forward <sup>5</sup> \$m	Other \$m	Total \$m
Net deferred tax balance at 1 January 2010	(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)
Additions through business combinations <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)
Taxation expense	30	11	(115)	(83)	333	(30)	(69)	5	180	29	291
Other comprehensive income	_	_	(46)	_	_	_	(10)	_	_	5	(51)
Additions through business combinations <sup>4</sup>	_	(527)	_	_	_	2	30	-	98	_	(397)
Exchange	(21)	(17)	23	5	(84)	3	4	(3)	_	3	(87)
Net deferred tax balance at 31 December 2012	229	(2,917)	553	921	(1,284)	600	57	(59)	411	24	(1,465)

Untaxed reserves relate to taxable profits where the tax liability is deferred to later periods.

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 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)
Deferred tax assets at 31 December 2012	353	44	561	961	_	656	57	_	411	36	3,079
Deferred tax liabilities at 31 December 2012	(124)	(2,961)	(8)	(40)	(1,284)	(56)	-	(59)	_	(12)	(4,544)
Net deferred tax balance at 31 December 2012	229	(2,917)	553	921	(1.284)	600	57	(59)	411	24	(1.465)

Analysed in the statement of financial position, after offset of balances within countries, as:

	2012 \$m	2011 \$m	2010 \$m
Deferred tax assets	1,111	1,514	1,475
Deferred tax liabilities	(2,576)	(2,735)	(3,145)
Net deferred tax balance	(1,465)	(1,221)	(1,670)

#### Unrecognised deferred tax assets

Deferred tax assets of \$120m have not been recognised in respect of deductible temporary differences (2011: \$169m; 2010: \$128m) 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

	2012	2011	2010
Profit for the year attributable to equity holders (\$m)	6,297	9,983	8,053
Basic earnings per Ordinary Share	\$4.99	\$7.33	\$5.60
Diluted earnings per Ordinary Share	\$4.98	\$7.30	\$5.57
Weighted average number of Ordinary Shares in issue for basic earnings (millions)	1,261	1,361	1,438
Dilutive impact of share options outstanding (millions)	3	6	8
Diluted weighted average number of Ordinary Shares in issue (millions)	1,264	1,367	1,446

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.

The deferred tax liability of \$143m relates to the acquisition of Novexel.

The deferred tax adjustment of \$37m relates to the Astra Tech disposal.

<sup>&</sup>lt;sup>4</sup> The deferred tax liability of \$397m relates to the acquisition of Ardea.
<sup>5</sup> Includes losses and tax credits carried forward which will expire within 15 to 20 years.

#### **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 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.

#### 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 where the legal entity resides and from which those sales were made.

			Revenue
	2012 \$m	2011 \$m	2010 \$m
UK			
External	1,843	1,980	1,952
Intra-Group	6,939	9,901	9,957
	8,782	11,881	11,909
Continental Europe Belgium	293	343	331
France	1,393	1,799	1,929
Germany	763	1,121	1,151
Italy	773	951	1,000
Spain	506	688	762
Sweden	466	964	1,157
Others	2,003	2,363	2,440
Intra-Group	5,067	5,101	5,144
	11,264	13,330	13,914
The Americas			
Canada	1,069	1,589	1,492
US	11,074	13,745	14,010
Others	1,326	1,452	1,387
Intra-Group	2,353	2,819	2,341
	15,822	19,605	19,230
Asia, Africa & Australasia Australia	1,050	1,166	981
Japan	2,748	2,905	2,458
China	1,511	1,261	1,047
Others	1,155	1,264	1,172
Intra-Group	70	70	67
ilita-Group	6,534	6,666	5,725
Continuing operations	42,402	51,482	50,778
Intra-Group eliminations	(14,429)	(17,891)	(17,509)
and Group ourningtions	27,973	33,591	33,269
	21,913	00,001	00,208

Export sales from the UK totalled \$8,072m for the year ended 31 December 2012 (2011: \$11,056m; 2010: \$10,944m). Intra-Group pricing is determined on an arm's length basis.

#### 6 Segment information continued

		С	perating profit		Profit before tax	
Profit from	2012 \$m	2011 \$m	2010 \$m	2012 \$m	2011 \$m	2010 \$m
UK	397	2,221	3,258	4	1,803	3,098
Continental Europe <sup>1</sup>	3,539	5,210	4,591	3,522	5,202	4,581
The Americas	3,705	4,813	3,278	3,687	4,828	2,932
Asia, Africa & Australasia	507	551	367	505	534	366
Continuing operations	8,148	12,795	11,494	7,718	12,367	10,977

		Non-current assets <sup>2</sup>				Total assets
	2012 \$m	2011 \$m	2010 \$m	2012 \$m	2011 \$m	2010 \$m
UK	2,743	2,941	3,397	12,316	15,752	17,171
Continental Europe	3,673	3,785	4,470	6,796	6,811	7,596
The Americas	25,767	20,090	20,808	30,708	26,673	28,175
Asia, Africa & Australasia	803	652	522	3,714	3,594	3,185
Continuing operations	32,986	27,468	29,197	53,534	52,830	56,127

	Assets acquired <sup>3</sup>				Net op	erating assets4
	2012 \$m	2011 \$m	2010 \$m	2012 \$m	2011 \$m	2010 \$m
UK	350	414	314	2,519	3,361	3,273
Continental Europe	379	344	1,053	4,006	4,113	4,827
The Americas <sup>5</sup>	6,760	314	1,125	22,940	18,395	18,795
Asia, Africa & Australasia	229	177	107	2,328	2,380	2,021
Continuing operations	7,718	1,249	2,599	31,793	28,249	28,916

<sup>&</sup>lt;sup>1</sup> 2011 includes profit on disposal of Astra Tech (see Note 22).

		Property, plant a	nd equipment
	2012 \$m	2011 \$m	2010 \$m
UK	1,353	1,387	1,628
Sweden	1,183	1,408	1,647
US	2,197	2,309	2,381
Rest of the world	1,356	1,321	1,301
Continuing operations	6,089	6,425	6,957

#### Geographic markets

The table below shows revenue in each geographic market in which customers are located.

	2012 \$m	2011 \$m	2010 \$m
UK	668	866	1,033
Continental Europe	7,042	8,896	9,315
The Americas	13,075	16,484	16,629
Asia, Africa & Australasia	7,188	7,345	6,292
Continuing operations	27,973	33,591	33,269

Revenue is recognised at the point of delivery, which is usually when title passes to the wholesaler. Transactions with two wholesalers (2011: two; 2010: two) individually represented greater than 10% of total revenue. The values of these transactions recorded as revenue were \$3,517m and \$3,155m (2011: \$4,298m and \$4,170m; 2010: \$4,164m and \$4,129m).

<sup>2011</sup> includes profit on disposal of Astra Tech (see Note 22).
21 Non-current assets' exclude deferred tax assets and derivative financial instruments.
3 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).
4 'Net operating assets' exclude short-term investments, cash, short-term borrowings, loans, derivative financial instruments, retirement benefit obligations and non-operating receivables and payables.
5 Assets acquired in 2012 include those related to Amylin and Ardea (see Notes 9 and 22).

#### 7 Property, plant and equipment

	Land and buildings \$m	Plant and equipment \$m	Assets in course of construction \$m	Total property, plant and equipment \$m
Cost At 1 January 2010	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
Capital expenditure	37	229	502	768
Additions through business combinations	-	4	-	4
Transfer of assets into use	123	391	(514)	_
Disposals and other movements	(370)	(1,050)	(49)	(1,469)
Exchange adjustments	149	292	17	458
At 31 December 2012	5,850	8,645	576	15,071
Depreciation At 1 January 2010	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
Charge for year	280	743	_	1,023
Disposals and other movements	(129)	(1,116)	-	(1,245)
Exchange adjustments	82	237	-	319
At 31 December 2012	2,668	6,314	-	8,982
Net book value At 31 December 2010	3,425	2,941	591	6,957
At 31 December 2011	3,476	2,329	620	6,425
At 31 December 2012	3.182	2,331	576	6,089

There were no impairment charges in 2012 or 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.

	2012 \$m	2011 \$m	2010 \$m
The net book value of land and buildings comprised: Freeholds	3,122	3,449	3,395
Leaseholds	60	27	30

Included within plant and equipment are Information Technology assets held under finance leases with a net book value of \$79m (2011 and 2010: \$nil).

#### 8 Goodwill

	2012 \$m	2011 \$m	2010 \$m
Cost At 1 January	10,186	10,206	10,228
Exchange and other adjustments	7	(20)	(22)
Additions through business combinations	30	_	_
At 31 December	10,223	10,186	10,206
Amortisation and impairment losses At 1 January	324	335	339
Exchange and other adjustments	1	(11)	(4)
At 31 December	325	324	335
Net book value at 31 December	9,898	9,862	9,871

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 which is considered by the Board as a reasonable period given the long development and life-cycle of a medicine. 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 2012, 2011 and 2010) 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% (2011: 10%; 2010: 10%).

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 2012 (and 31 December 2011 and 31 December 2010).

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 distribution rights \$m	Other intangibles \$m	Software development costs \$m	Total \$m
Cost At 1 January 2010	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
Additions through business combinations	1,464	-	-	1,464
Additions – separately acquired	5,228	12	212	5,452
Exchange and other adjustments	271	(65)	59	265
At 31 December 2012	22,862	2,135	1,905	26,902
Amortisation and impairment losses At 1 January 2010	3,727	1,148	768	5,643
Amortisation for year	573	121	116	810
Impairment	699	131	3	833
Disposals	_	(1)	_	(1)
Exchange and other adjustments	89	26	(20)	95
At 31 December 2010	5,088	1,425	867	7,380
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
Amortisation for year	1,039	95	162	1,296
Impairment	192	1	6	199
Exchange and other adjustments	182	8	28	218
At 31 December 2012	7,659	1,578	1,217	10,454
Net book value				
At 31 December 2010	10,716	910	532	12,158
At 31 December 2011	9,653	714	613	10,980
At 31 December 2012	15,203	557	688	16,448

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 2010 Cost of sales	87	_	_	87
Research and development expense	_	24	-	24
Selling, general and administrative costs	486	22	116	624
Other operating income and expense	_	75	-	75
	573	121	116	810
Year ended 31 December 2011 Cost of sales	129	_	_	129
Research and development expense	-	27		27
Selling, general and administrative costs	523	24	140	687
Other operating income and expense	_	68	_	68
	652	119	140	911
Year ended 31 December 2012 Cost of sales	325	_	_	325
Research and development expense	-	25	_	25
Selling, general and administrative costs	673	13	162	848
Other operating income and expense	41	57	_	98
	1,039	95	162	1,296

#### 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 2010				
Cost of sales	128	-	-	128
Research and development expense	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 expense	548	1	_	549
Selling, general and administrative costs	4	_	_	4
	552	1	_	553
Year ended 31 December 2012				
Research and development expense	185	1	-	186
Selling, general and administrative costs	7	_	6	13
	192	1	6	199

#### Amortisation and impairment charges

The 2012 impairment of product, marketing and distribution rights includes a charge of \$50m following the decision by AstraZeneca not to pursue a regulatory filing for TC-5214, based on the final results of 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 remaining \$149m charge relates to the termination of other development projects during the year.

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 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. 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 licence 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 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 2012, 2011 and 2010) 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% (2011: 14%; 2010: 14%).

#### Significant assets

	Description	Carrying value \$m	Remaining amortisation period
Advance payment <sup>1</sup>	Product, marketing and distribution rights	386	6 years
Partial retirement <sup>1</sup>	Product, marketing and distribution rights	610	2-15 years
First Option <sup>1</sup>	Product, marketing and distribution rights	1,428	14-18 years
Second Option <sup>1</sup>	Product, marketing and distribution rights	1,652	3-4 years
Intangible assets arising from the acquisition of CAT	Product, marketing and distribution rights	251	3 and 8 years
RSV franchise assets arising from the acquisition of MedImmune	Product, marketing and distribution rights	3,618	13 years
Intangible assets arising from the acquisition of MedImmune	Licensing and contractual income	398	6-7 years
Intangible assets arising from the acquisition of MedImmune	Product, marketing and distribution rights	548	19 years
Intangible assets arising from the collaboration with BMS <sup>2</sup>	Product, marketing and distribution rights	540	10-11 years
Bydureon (weekly) asset arising from the Amylin collaboration with BMS <sup>3</sup>	Product, marketing and distribution rights	2,502	18 years
Other intangible assets arising from the Amylin collaboration with BMS <sup>3</sup>	Product, marketing and distribution rights	779	10-18 years
Intangible assets arising from the acquisition of Novexel <sup>4</sup>	Product, marketing and distribution rights	300	Not amortised
Intangible assets arising from the acquisition of Ardea <sup>4</sup>	Product, marketing and distribution rights	1,464	Not amortised

These assets are associated with the restructuring of the joint venture with Merck & Co., Inc.

These assets arise from the collaboration agreement with BMS for Onglyza and Forxiga.
 These assets arise from the collaboration agreement with BMS for the related Amylin products.
 Assets in development are not amortised but are tested annually for impairment.

#### 9 Intangible assets continued

#### Collaboration with BMS on Amylin products

On 8 August 2012, BMS completed its acquisition of Amylin. On that date, AstraZeneca and BMS entered into collaboration arrangements, based substantially on the framework of the existing diabetes alliance, regarding the development and commercialisation of Amylin's portfolio of products. Under the terms of the collaboration, the companies will jointly undertake the global selling and marketing activities in relation to the collaboration products. BMS will undertake all manufacturing activities with AstraZeneca receiving collaboration product at cost. Profits and losses arising from the collaboration will be shared equally.

The total consideration for AstraZeneca's participation in the collaboration is \$3.7bn, including an amount of \$135m relating to an option of AstraZeneca contained in the collaboration agreement to acquire certain additional governance rights in respect of the collaboration. The Group notified BMS of its decision to exercise the option in August 2012 and the balance of \$135m will be payable once applicable anti-trust and competition approvals are received by AstraZeneca. The Group expects to make this payment in the first half of 2013. Upon such payment, the additional governance rights of AstraZeneca granted by the option will become legally effective.

AstraZeneca considers that the key strategic and financial decisions over which the collaboration agreement and the governance rights that are subject to the option grant joint control, represent the activities most relevant in affecting the success of the collaboration. AstraZeneca accounts for the collaboration as a jointly controlled operation. The Group has recognised a 50% share of collaboration revenues amounting to \$128m, cost of sales of \$36m and other costs, excluding amortisation, of \$133m, in its income statement from 9 August 2012. An amount of \$165m was owed to BMS under this arrangement, recorded within trade and other payables, at 31 December 2012.

AstraZeneca's payment to BMS for its participation in the collaboration primarily results in the purchase of intangible assets, valued at \$3,358m, related to the collaboration products: *Byetta* (exenatide) injection and *Bydureon* (exenatide extended-release for injectable suspension/exenatide 2mg powder and solvent for prolonged release suspension for injection) that are approved for use in both the US and Europe, *Symlin* (pramlinitide acetate) injection that is approved for use in the US, and metreleptin, a leptin analogue currently under review at the US Food and Drug Administration (FDA) for the treatment of diabetes and/or hypertriglyceridaemia in patients with rare forms of inherited or acquired lipodystrophy. In addition, a prepayment of \$0.4bn has been recognised representing payments in advance for collaboration products.

#### Arrangements with Merck

In 1982, Astra 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 (the 'Restructuring'). Under the agreements relating to the Restructuring (the 'Agreements'), a US limited partnership (the '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 provide, in part, for:

- > Annual contingent payments; and
- > 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.

The termination arrangements and payments include:

- > the Advance Payment
- > the Partial Retirement
- > the True-Up
- > the Loan Note Receivable
- > the First Option
- > the Second Option.

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). Once all 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 from:

- > The substantial freedom over products acquired or discovered after the merger of Astra and Zeneca in 1999; and
- > 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 and other cost efficiencies, together with the strategic advantages of increased freedom to operate.

The intangible assets relating to purchased product rights 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.

### **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). Contingent payments on all other agreement products have ceased as discussed under First Option below.

#### 9 Intangible assets 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 of \$967m was made. The Advance Payment has been accounted for as an intangible asset and is being amortised over 20 years. Although the rights obtained apply in perpetuity, the period of amortisation of 20 years is used to reflect the typical timescale of development and marketing of a product.

#### Partial Retirement, True-Up and Loan Note Receivable

On 17 March 2008, AstraZeneca made a net cash payment to Merck of approximately \$2.6bn in connection with the Partial Retirement, the True-Up and the Loan Note Receivable. This payment resulted in AstraZeneca acquiring Merck's interests in certain AstraZeneca products (including *Pulmicort*, *Rhinocort*, *Symbicort* and *Toprol-XL*), AstraZeneca ceasing contingent payments on these products and AstraZeneca obtaining the ability to exploit these products and other opportunities in the Respiratory therapy area. Intangible assets of \$994m were recognised at the time with the balance of the net payment (\$1,656m) representing payments on account for future product rights associated with the First Option and the Second Option as detailed below. These 'non-refundable deposits' were classified as intangible assets.

#### **First Option**

On 26 February 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 certain products in development at the time (principally *Brilinta* and lesogaberan; development of lesogaberan subsequently was discontinued). Also on 30 April 2010, contingent payments on these products 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. These rights were valued at \$1,829m and were recognised as intangible assets from 26 February 2010 (\$1,182m having been transferred from non-refundable deposits to supplement the payment of \$647m to Merck). Of these rights, \$689m was allocated to contingent payment relief and \$1,140m to intangible assets reflecting the ability to fully exploit the products in the Cardiovascular and Neuroscience Therapy Areas. The remaining non-refundable deposits of \$474m relate to benefits that would be secured upon AstraZeneca exercising the Second Option.

#### **Second Option**

The Agreements provided that 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 was exercisable by AstraZeneca in May to October of 2012, or in 2017, or if combined annual sales of the two products fell below a minimum amount.

On 26 June 2012, AstraZeneca and Merck agreed to amend certain provisions of the Agreements with respect to the Second Option.

The principal areas covered by the amendments are a change in the timing for AstraZeneca to exercise the Second Option, and agreement on the valuation methodology for setting certain aspects of the option exercise price. Under the amended Agreements, Merck has granted to AstraZeneca a new Second Option exercisable by AstraZeneca between 1 March 2014 and 30 April 2014, with closing on 30 June 2014. Options exercisable in 2017 or if combined annual sales fall below a minimum amount also remain available to AstraZeneca. In addition to this revised timing for the Second Option, AstraZeneca and Merck have also reached agreement on the valuation methodology for setting certain components of the option exercise price for a 2014 exercise. In lieu of third-party appraisals, the valuation for a 2014 exercise is now a fixed sum of \$327m, based on a shared view by AstraZeneca and Merck of the forecasts for sales of *Nexium* and *Prilosec* in the US market. The agreed amount that would be payable on 30 June 2014 is subject to a true-up in 2018 that replaces a shared forecast with actual sales for the period from closing in 2014 to June 2018. In addition, the exercise price for the Second Option also includes a multiple of ten times Merck's average 1% annual profit allocation in the Partnership for the three years prior to exercise. AstraZeneca currently expects this amount to be around \$80m. The component of the exercise price of the Second Option that includes the net present value of up to 5% of future US sales of *Vimovo*, with the precise amount dependent on an annual sales threshold that has not yet been achieved and the timing of the option exercise, will continue.

AstraZeneca believes that the amendments provide a greater degree of certainty to the valuation of the Second Option that is preferable to the previous arrangements and, barring unforeseen circumstances, AstraZeneca now intends to exercise the Second Option in 2014.

Under the amendments, if AstraZeneca exercises in 2014, Merck's existing rights to manufacture *Nexium* and *Prilosec* would cease upon closing. In connection with the amendments, Merck also granted AstraZeneca flexibility to exploit certain commercial opportunities with respect to *Nexium*.

AstraZeneca now considers that exercise of the Second Option is virtually certain. This judgement is supported by management's view that: AstraZeneca is fully committed to exercising the Second Option in 2014, barring unforeseen circumstances; external announcements of that intention constructively oblige AstraZeneca to exercise in 2014, barring unforeseen circumstances; and the Second Option price is highly favourable, giving economic compulsion for AstraZeneca to exercise in 2014. As such, AstraZeneca has applied an accounting treatment to reflect the Second Option as if the date of exercise were 26 June 2012 (the date of amendment of the Agreements), resulting in liabilities to Merck of approximately \$1.5bn (\$1.1bn of which will be paid by way of monthly contingent payments between 1 July 2012 and 30 June 2014 and the balance as a lump sum on 30 June 2014), and a corresponding increase to intangible assets, from that date. These intangible assets, and the \$474m from the First Option (detailed above), in aggregate, reflect the value of the ability to exploit opportunities in the Gastrointestinal Therapy Area and relief from contingent payments.

#### 10 Other investments

	2012 \$m	2011 \$m	2010 \$m
Non-current investments			
Equity securities available for sale	199	201	211
	199	201	211
Current investments			
Equity securities and bonds available for sale	748	296	355
Equity securities held for trading	29	25	20
Fixed deposits	46	3,927	1,107
	823	4,248	1,482

The equity securities and bonds available for sale in current investments of \$748m (2011: \$296m; 2010: \$355m) are held in an escrow account. Further details of this escrow account are included in Note 18.

Impairment charges of \$2m in respect of available for sale securities are included in other operating income and expense in profit (2011: \$3m; 2010: \$2m).

Equity securities and bonds available for sale, and equity securities held for trading, are held on the consolidated statement of financial position at fair value. The fair value of listed investments is based on year end quoted market prices. For unlisted investments, cost is considered to approximate to fair value, as detailed below. Fixed deposits are held at amortised cost with carrying value being a reasonable approximation of fair value given their short-term nature.

None of the financial assets or liabilities have been reclassified in the year.

#### Fair value hierarchy

The table below analyses financial instruments, contained within other investments and carried at fair value, by valuation method. The different levels have been defined as follows:

- > Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- > Level 2: inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (ie as prices) or indirectly (ie derived from prices).
- > Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

	Level 1 \$m	Level 2 \$m	Level 3 \$m	Total \$m
2010				
Equity securities and bonds available for sale	399	_	167	566
Equity securities held for trading	20	_	_	20
Total	419	_	167	586
2011				
Equity securities and bonds available for sale	338	_	159	497
Equity securities held for trading	25	_	_	25
Total	363	_	159	522
2012				
Equity securities and bonds available for sale	809	-	138	947
Equity securities held for trading	29	-	-	29
Total	838	_	138	976

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.

#### 11 Inventories

	2012 \$m	2011 \$m	2010 \$m
Raw materials and consumables	620	588	539
Inventories in process	876	645	665
Finished goods and goods for resale	565	619	478
	2,061	1,852	1,682

The Group recognised \$3,019m (2011: \$3,447m; 2010: \$3,547m) of inventories as an expense within cost of sales during the year. Inventory write-offs in the year amounted to \$120m (2011: \$51m; 2010: \$69m).

#### 12 Trade and other receivables

#### Non-current other receivables

Non-current other receivables of \$352m (2011: \$nil; 2010: \$nil) consist of prepayments in relation to our jointly controlled operation with BMS. Further details of this prepayment are included in Note 9.

#### Current trade and other receivables

	2012	2011	2010
	\$m	\$m	\$m
Amounts due within one year			
Trade receivables	5,760	6,696	6,328
Less: Amounts provided for doubtful debts (Note 23)	(64)	(66)	(81)
	5,696	6,630	6,247
Other receivables	750	1,172	607
Prepayments and accrued income	923	725	733
	7,369	8,527	7,587
Amounts due after more than one year			
Other receivables	85	65	64
Prepayments and accrued income	175	162	196
	260	227	260
Trade and other receivables	7,629	8,754	7,847

With the exception of a receivable of \$nil (2011: \$nil; 2010: \$25m) held within other receivables, that arose on the acquisition of Novexel and the subsequent transaction with Forest, and which is held at fair value (see Note 22), all other financial assets are held on the consolidated statement of financial position at amortised costs with carrying value being a reasonable approximation of fair value. The Novexel-related receivable falls within level 3 of the fair value hierarchy as defined in Note 10.

#### 13 Cash and cash equivalents

	2012 \$m	2011 \$m	2010 \$m
Cash at bank and in hand	1,304	1,488	1,750
Short-term deposits	6,397	6,083	9,318
Cash and cash equivalents	7,701	7,571	11,068
Unsecured bank overdrafts	(105)	(137)	(87)
Cash and cash equivalents in the cash flow statement	7,596	7,434	10,981

The Group holds \$301m (2011: \$543m; 2010: \$370m) of cash and cash equivalents which is required to meet insurance solvency, capital and security requirements and which, as a result, is not readily available for the general purposes of the Group.

Cash and cash equivalents are held on the consolidated statement of financial position at amortised cost. Fair value approximates to carrying value.

#### 14 Interest-bearing loans and borrowings

		Repayment dates	2012 \$m	2011 \$m	2010 \$m
Current liabilities		dates	ΨΠ	ψιτι	ψΠ
Bank overdrafts		On demand	105	137	87
Finance leases			22	_	_
5.4% Callable bond	US dollars	2012	_	1,769	_
Other loans		Within one year	774	84	38
			901	1,990	125
Non-current liabilities			,		
Finance leases			62	_	_
5.4% Callable bond	US dollars	2012	_	_	1,800
5.4% Callable bond	US dollars	2014	805	834	837
5.125% Non-callable bond	euros	2015	990	969	993
5.9% Callable bond	US dollars	2017	1,895	1,896	1,855
1.95% Callable bond	US dollars	2019	995	_	_
7% Guaranteed debentures	US dollars	2023	399	387	359
5.75% Non-callable bond	pounds sterling	2031	561	536	535
6.45% Callable bond	US dollars	2037	2,717	2,716	2,718
4% Callable bond	US dollars	2042	985	_	_
			9,409	7,338	9,097

All loans and borrowings above are unsecured, except for finance leases which are secured against the Information Technology assets to which they relate (see Note 7).

#### 14 Interest-bearing loans and borrowings continued

Set out below is a comparison by category of carrying values and fair values of all the Group's interest-bearing loans and borrowings at 31 December 2012, 31 December 2011 and 31 December 2010.

	Instruments in a fair value hedge relationship <sup>†</sup> \$m	Instruments designated at fair value <sup>2</sup> \$m	Amortised cost <sup>a</sup> \$m	Total carrying value \$m	Fair value \$m
2010					
Overdrafts		_	87	87	87
Loans due within one year	_	-	38	38	38
Loans due after more than one year	1,659	1,196	6,242	9,097	10,022
Total	1,659	1,196	6,367	9,222	10,147
2011					
Overdrafts	_	_	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	7,338	8,765
Total	1,669	1,221	6,438	9,328	10,793
2012					
Overdrafts	<u> </u>	-	105	105	105
Finance leases due within one year	-	-	22	22	22
Finance leases due after more than one year	-	_	62	62	62
Loans due within one year	-	-	774	774	774
Loans due after more than one year	900	1,204	7,243	9,347	10,897
Total	900	1,204	8,206	10,310	11,860

Instruments designated as hedged items in fair value hedge relationships with respect to interest rate risk include a designated portion of the US dollars 5.9% callable bond repayable in 2017.

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, this falls within the Level 1 valuation method as defined in Note 10. 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.

A loss of \$10m was made during the year on the fair value of bonds designated at fair value through profit or loss, due to decreased credit risk. A gain of \$34m 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 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:

	2012	2011	2010
Loans and borrowings	0.6% to 2.0%	0.9% to 2.3%	0.7% to 4.0%

Instruments designated at fair value through profit or loss include the US dollar 5.4% callable bond repayable in 2014 and the US dollar 7% guaranteed debentures repayable in 2023. Included within borrowings held at amortised cost are amounts designated as hedges of net investments in foreign operations of \$1,551m (2011: \$1,505m; 2010: \$1,528m) held at amortised cost. The fair value of these borrowings was \$1,808m at 31 December 2012 (2011: \$1,752m; 2010: \$1,687m).

#### 15 Derivative financial instruments

Derivative financial instruments consist 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), cross-currency swaps (included in instruments designated in net investment hedges) and forward foreign exchange contracts (included below in other derivatives).

	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	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	151	_	_	151
Related to instruments designated at fair value through profit or loss	162	-	_	162
Designated as a net investment hedge	76	-	_	76
Other derivatives	_	31	(3)	28
31 December 2012	389	31	(3)	417

All derivatives are held at fair value and fall within Level 2 of the fair value hierarchy as defined in Note 10. None of the derivatives have been reclassified in the year.

The fair value of interest rate swaps and cross-currency swaps is estimated using appropriate zero coupon curve valuation techniques to discount future contractual cash flows based on rates at current 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. The majority of forward foreign exchange contracts for existing transactions had maturities of less than one month from year end.

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:

	2012	2011	2010
Derivatives	0.6% to 2.0%	0.9% to 2.3%	0.7% to 4.0%

#### 16 Trade and other payables

	2012 \$m	2011 \$m	2010 \$m
Current liabilities		ψ	ψ
Trade payables	2,449	2,155	2,257
Value added and payroll taxes and social security	231	343	323
Rebates and chargebacks	2,486	3,285	2,839
Accruals	3,200	2,474	2,297
Other payables	855	718	945
	9,221	8,975	8,661
Non-current liabilities			
Accruals	710	113	104
Other payables	291	272	269
	1,001	385	373

With the exception of a payable of \$nil (2011: \$nil; 2010: \$50m) held within other payables, that arose on the acquisition of Novexel and the subsequent transaction with Forest, and which is held at fair value (see Note 22), all other financial liabilities are held on the consolidated statement of financial position at amortised cost with carrying value being a reasonable approximation of fair value. The Novexel-related payable falls within Level 3 of the fair value hierarchy as defined in Note 10.

#### 17 Provisions for liabilities and charges

	Severance \$m	Environmental \$m	Employee benefits \$m	Legal \$m	Other provisions \$m	Total \$m
At 1 January 2010	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
Charge for year	873	22	19	90	92	1,096
Cash paid	(853)	(27)	(20)	(513)	(63)	(1,476)
Reversals	(65)	_	_	(18)	(91)	(174)
Exchange and other movements	18	1	7	1	9	36
At 31 December 2012	637	88	148	100	371	1,344

	2012 \$m	2011 \$m	2010 \$m
Due within one year	916	1,388	1,095
Due after more than one year	428	474	843
	1,344	1,862	1,938

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 contractual 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**

97% of the Group's defined benefit obligations at 31 December 2012 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.

#### 18 Post-retirement benefits continued

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, lower value on the liabilities than IAS 19.

#### ΙΙΚ

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. The next valuation is due at 31 March 2013.

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 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). 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 from existing investments held in escrow and the balance will be paid in due course. 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 2012, £462m (\$748m) 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 profit in 2010.

#### **Rest of Group**

The IAS 19 positions as at 31 December 2012 are shown below for each of the other countries with significant defined benefit plans. These plans account for 92% 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 2012, when plan obligations were \$1,917m and plan assets were \$1,679m. 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 2012, when plan obligations were estimated to amount to \$1,889m and plan assets were \$1,125m.
- > The German defined benefits programme was actuarially revalued at 31 December 2012, when plan obligations amounted to \$355m and plan assets were \$23m.

On current bases, it is expected that contributions (excluding those in respect of past service cost) during the year ending 31 December 2013 to the four main countries will be \$537m.

#### 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 2012, some 3,528 retired employees and covered dependants currently benefit from these provisions and some 8,893 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 2012 was \$16m (2011: \$12m; 2010: \$18m). Plan assets were \$301m and plan obligations were \$363m at 31 December 2012. These benefit plans have been included in the disclosure of post-retirement benefits under IAS 19.

#### 18 Post-retirement benefits continued

#### 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 2012. 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:

		2012		2011
	UK	Rest of Group	UK	Rest of Group
Inflation assumption	3.1%	2.2%	3.2%	2.3%
Rate of increase in salaries	_1	3.4%	_1	3.4%
Rate of increase in pensions in payment	2.9%	1.1%	3.1%	0.9%
Discount rate	4.5%	3.6%	4.8%	4.1%
Long-term rate of return expected at 31 December				
Equities	7.5%	7.4%	7.5%	7.4%
Bonds	4.2%	3.3%	4.5%	3.8%
Others	2.8%	4.0%	2.8%	3.8%
Rate of increase in medical costs (initial rate)	10.0%	8.2%	10.0%	9.0%

<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 2012 and members expected to retire in 2032 (2011: 2011 and 2031 respectively).

	Life exp	Life expectancy assumption for a male member retiring at age 6		
Country	2012	2032	2011	2031
UK	23.1	24.8	22.9	24.7
US	20.1	21.5	20.0	21.4
Sweden	20.4	22.4	20.4	22.4
Germany	18.6	21.3	18.3	21.0

#### Post-retirement scheme deficit

The assets and obligations of the defined benefit schemes operated by the Group at 31 December 2012, 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.

		2012				2011
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Scheme assets Equities	2,828	1,147	3,975	2,221	1,084	3,305
Bonds	3,280	1,660	4,940	2,961	1,382	4,343
Others	742	336	1,078	506	365	871
Total fair value of scheme assets	6,850	3,143	9,993	5,688	2,831	8,519
Present value of scheme obligations	(7,740)	(4,524)	(12,264)	(7,042)	(4,157)	(11,199)
Past service cost not yet recognised	_	6	6	_	6	6
Deficit in the scheme as recognised in the statement of financial position	(890)	(1,375)	(2,265)	(1,354)	(1,320)	(2,674)

#### 18 Post-retirement benefits continued

#### Fair value of scheme assets

			2012			2011
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
At beginning of year	5,688	2,831	8,519	5,149	2,618	7,767
Expected return on scheme assets	342	144	486	340	162	502
Expenses	(5)	-	(5)	(7)	_	(7)
Actuarial gains/(losses)	275	207	482	(4)	35	31
Settlements	-	(61)	(61)	_	_	_
Exchange	289	26	315	_	(38)	(38)
Employer contributions	584	262	846	487	246	733
Participant contributions	8	-	8	9	3	12
Benefits paid	(331)	(266)	(597)	(286)	(195)	(481)
Scheme assets' fair value at end of year	6,850	3,143	9,993	5,688	2,831	8,519

The actual return on the plan assets was a gain of \$968m (2011: gain of \$533m).

#### Movement in post-retirement scheme obligations

			2012			2011
<del>-</del>	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Present value of obligation in scheme at beginning of year	(7,042)	(4,157)	(11,199)	(6,554)	(3,691)	(10,245)
Current service cost	(41)	(108)	(149)	(49)	(110)	(159)
Past service cost	(77)	(50)	(127)	(32)	(37)	(69)
Participant contributions	(8)	-	(8)	(9)	(3)	(12)
Benefits paid	331	266	597	286	195	481
Other finance expense	(343)	(164)	(507)	(364)	(175)	(539)
Expenses	5	-	5	7	_	7
Actuarial loss	(224)	(343)	(567)	(328)	(444)	(772)
Settlements and curtailments	-	111	111	_	53	53
Exchange	(341)	(79)	(420)	1	55	56
Present value of obligations in scheme at end of year	(7,740)	(4,524)	(12,264)	(7,042)	(4,157)	(11,199)

The obligation arises from the following plans:

			2012			2011
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Funded	(7,709)	(3,961)	(11,670)	(7,016)	(3,689)	(10,705)
Unfunded	(31)	(563)	(594)	(26)	(468)	(494)
Total	(7,740)	(4,524)	(12,264)	(7,042)	(4,157)	(11,199)

#### 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 2012, are set out below:

			2012			2011
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
Operating profit						
Current service cost	(41)	(108)	(149)	(49)	(110)	(159)
Past service cost	(77)	(50)	(127)	(32)	(37)	(69)
Settlements and curtailments	-	50	50	_	53	53
Total charge to operating profit	(118)	(108)	(226)	(81)	(94)	(175)
Finance expense						
Expected return on post-retirement scheme assets	342	144	486	340	162	502
Interest on post-retirement scheme obligations	(343)	(164)	(507)	(364)	(175)	(539)
Net return	(1)	(20)	(21)	(24)	(13)	(37)
Charge before taxation	(119)	(128)	(247)	(105)	(107)	(212)
Other comprehensive income Difference between the actual return and the expected return on						
the post-retirement scheme assets	275	207	482	(4)	35	31
Experience losses arising on the post-retirement scheme obligations	(12)	(147)	(159)	(11)	(10)	(21)
Changes in assumptions underlying the present value of the						
post-retirement scheme obligations	(212)	(196)	(408)	(317)	(434)	(751)
Actuarial gains/(losses) recognised	51	(136)	(85)	(332)	(409)	(741)

#### 18 Post-retirement benefits continued

Included in total assets and obligations for the UK is \$427m (2011: \$388m) in respect of members' defined contribution sections of the scheme. Group costs in respect of defined contribution schemes during the year were \$249m (2011: \$262m). \$127m past service cost in 2012 relates predominantly to enhanced pensions on early retirement in the UK and Sweden. \$50m settlements and curtailments credit in 2012 predominantly relate to a settlement credit of \$30m recognised in the US, where a proportion of deferred inactive participants who are not yet eligible for retirement elected to exchange their plan benefit for immediate cash lump sums, and a \$25m curtailment credit recognised in Sweden as a consequence of the Södertälje site closure. During 2011, the Group disposed of Astra Tech (see Note 22) resulting in a curtailment gain of \$44m.

#### Actuarial gains and losses

	2012	2011	2010	2009	2008
UK					
Present value of obligations (\$m)	(7,740)	(7,042)	(6,554)	(7,055)	(5,029)
Fair value of scheme assets (\$m)	6,850	5,688	5,149	4,853	3,835
Deficit in the scheme (\$m)	(890)	(1,354)	(1,405)	(2,202)	(1,194)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	275	(4)	244	293	(1,185)
Percentage of scheme assets	4.0%	0.1%	4.7%	6.0%	30.9%
Scheme obligations					
Amount (\$m)	(224)	(328)	(221)	(1,218)	972
Percentage of scheme obligations	2.9%	4.7%	3.4%	17.3%	19.3%
Rest of Group					
Present value of obligations (\$m)	(4,524)	(4,157)	(3,691)	(3,591)	(3,591)
Fair value of scheme assets (\$m)	3,143	2,831	2,618	2,402	2,013
Deficit in the scheme (\$m)	(1,381)	(1,326)	(1,073)	(1,189)	(1,578)
Experience adjustments on:					
Scheme assets					
Amount (\$m)	207	35	(4)	180	(700)
Percentage of scheme assets	6.6%	1.2%	0.2%	7.5%	34.8%
Scheme obligations					
Amount (\$m)	(343)	(444)	(65)	176	(319)
Percentage of scheme obligations	7.6%	10.7%	1.8%	4.9%	8.9%
Total	(10.064)	(11.100)	(10.045)	(10.646)	(0,000)
Present value of obligations (\$m)  Fair value of scheme assets (\$m)	(12,264) 9,993	(11,199) 8,519	(10,245) 7,767	(10,646) 7,255	(8,620)
Deficit in the scheme (\$m)	(2,271)				5,848
	(2,211)	(2,680)	(2,478)	(3,391)	(2,772)
Experience adjustments on:					
Scheme assets Amount (\$m)	482	31	040	470	(4.005)
			240	473	(1,885)
Percentage of scheme assets	4.8%	0.4%	3.1%	6.5%	32.2%
Scheme obligations	(507)	(770)	(000)	(4.0.40)	050
Amount (\$m)	(567)	(772)	(286)	(1,042)	653
Percentage of scheme obligations	4.6%	6.9%	2.8%	9.8%	7.6%

#### Transactions with pension schemes

In 2011, 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 2012 was \$1m and the amount outstanding at 31 December 2012 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:

	2012 \$m	2011 \$m	2010 \$m
At 1 January	(2,447)	(1,865)	(1,800)
Actuarial losses	(85)	(741)	(46)
Deferred tax	(46)	159	(19)
At 31 December	(2,578)	(2,447)	(1,865)

The cumulative amount of actuarial losses before deferred tax recognised in other comprehensive income is \$3,308m (2011: \$3,223m; 2010: \$2,482m).

#### 18 Post-retirement benefits continued

#### 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 benefit pension obligation countries.

		2012		2011
	+1%	-1%		-1%
UK (\$m)	1,028	(1,201)	934	(1,088)
US (\$m)	224	(257)	229	(262)
Sweden (\$m)	370	(466)	299	(374)
Germany (\$m)	63	(77)	41	(49)
Total (\$m)	1,685	(2,001)	1,503	(1,773)

#### Sensitivity of medical cost assumptions

	Effect of change in medical cost assumption increase/(decrease)				
	2012			2011	
	+1%			-1% .	
Current service and interest cost of net periodic post-employment medical costs (\$m)	1	(1)	1	(1)	
Accumulated post-employment benefit obligation for medical costs (\$m)	11	(12)	10	(10)	

#### 19 Reserves

#### Retained earnings

The cumulative amount of goodwill written off directly to reserves resulting from acquisitions, net of disposals, amounted to \$685m (2011: \$680m; 2010: \$682m) using year end rates of exchange. At 31 December 2012, 55,555 shares, at a cost of \$4m, have been deducted from retained earnings (2011: 36,177 shares, at a cost of \$2m; 2010: 57,717 shares, at a cost of \$3m).

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).

	2012 \$m	2011 \$m	2010 \$m
Cumulative translation differences included within retained earnings			
Balance at beginning of year	1,760	1,798	1,656
Foreign exchange arising on consolidation	106	(60)	26
Exchange adjustments on goodwill (recorded against other reserves)	5	(2)	15
Foreign exchange differences on borrowings designated in net investment hedges	(46)	24	101
Fair value movement on derivatives designated in net investment hedges	76	_	_
Net exchange movement in retained earnings	141	(38)	142
Balance at end of year	1,901	1,760	1,798

#### Other reserves

The other reserves arose from the cancellation of £1,255m of share premium account by the Company in 1993 and the redenomination of share capital (\$157m) in 1999. The reserves are available for writing off goodwill arising on consolidation and, subject to guarantees given to preserve creditors at the date of the court order, are available for distribution.

#### 20 Share capital of the Company

		Allotted, called-up and fully paid			
	2012 \$m	2011 \$m	2010 \$m		
Issued Ordinary Shares (\$0.25 each)	312	323	352		
Redeemable Preference Shares (£1 each – £50,000)	_	_	_		
	312	323	352		

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		
	2012	2011	2010	
At 1 January	1,292,355,052	1,409,023,452	1,450,958,562	
Issues of shares	12,241,784	10,739,989	11,756,397	
Repurchase of shares	(57,817,288)	(127,408,389)	(53,691,507)	
At 31 December	1,246,779,548	1,292,355,052	1,409,023,452	

#### 20 Share capital of the Company continued

#### Share repurchases

During the year, the Company repurchased 57.8m Ordinary Shares at an average price of 2879 pence per share (2011: 127.4m Ordinary Shares at an average price of 3111 pence per share). These shares were subsequently cancelled.

#### Share schemes

A total of 12.2m Ordinary Shares were issued during the year in respect of share schemes (2011: 10.7m Ordinary Shares; 2010: 11.8m 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 122.

#### Shares held by subsidiaries

No shares in the Company were held by subsidiaries in any year.

#### 21 Dividends to shareholders

	2012 Per share	2011 Per share	2010 Per share	2012 \$m	2011 \$m	2010 \$m
Final	\$1.95	\$1.85	\$1.71	2,495	2,594	2,484
Interim	\$0.90	\$0.85	\$0.70	1,124	1,158	1,010
	\$2.85	\$2.70	\$2.41	3,619	3,752	3,494

The second interim dividend, to be confirmed as final, is \$1.90 per Ordinary Share and \$2,369m in total. This will be payable on 18 March 2013.

On payment of the dividends, exchange gains of \$3m (2011: gains of \$3m; 2010: gains of \$19m) arose. These exchange gains are included in Note 3.

#### 22 Acquisitions and disposals

#### 2012 acquisitions

#### Ardea

On 19 June 2012, AstraZeneca completed the acquisition of Ardea. Ardea is a US (San Diego, California) based biotechnology company focused on the development of small molecule therapeutics for the treatment of serious diseases. AstraZeneca acquired 100% of Ardea's shares for cash consideration of \$1,268m. The acquisition strengthens our research and development capabilities in the respiratory and inflammation therapy area.

In most business acquisitions, there is a part of the cost that is not capable of being attributed in accounting terms to identifiable assets and liabilities acquired and is therefore recognised as goodwill. In the case of the acquisition of Ardea, this goodwill is underpinned by a number of elements, which individually cannot be quantified. Most significant among these is the premium attributable to a highly-skilled workforce and established experience in the field of gout.

Ardea's results have been consolidated into the Group's results from 20 June 2012. For the period from acquisition to 31 December 2012, Ardea's revenues were immaterial, in the context of the Group's revenue, and its loss after tax was \$43m. If the acquisition had taken effect at the beginning of the reporting period (1 January 2012), on a *pro forma* basis, the revenue of the combined Group for 2012 would have been unchanged and the profit after tax would have been \$6,245m. This *pro forma* information has been prepared taking into account any amortisation, interest costs and related tax effects but does not purport to represent the results of the combined Group that actually would have occurred had the acquisition taken place on 1 January 2012 and should not be taken to be representative of future results.

	Book value \$m	Fair value adjustment \$m	Fair value \$m
Non-current assets:			
Intangible assets	-	1,464	1,464
Other	4	-	4
	4	1,464	1,468
Current assets	199	-	199
Current liabilities	(31)	(1)	(32)
Non-current liabilities:			
Deferred tax liabilities	-	(397)	(397)
Total assets acquired	172	1,066	1,238
Goodwill			30
Consideration			1,268
Less: Cash and cash equivalents acquired			(81)
Net cash outflow		-	1,187

Acquisition costs arising on the acquisition of \$12m were expensed within selling, general and administrative costs in 2012.

#### 22 Acquisitions and disposals continued

#### 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 in 2011 (2010: \$535m) in revenue and \$16m in 2011 (2010: \$55m) 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
Consideration	1,795
Less: Cash held in disposed undertaking	(23)
Net cash consideration	1,772

The gain on disposal of Astra Tech is non-taxable.

#### 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 2010 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
Less: Cash and cash equivalents acquired			(79)
Net cash outflow			348

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 was no profit impact from this divestment.

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.

#### 23 Financial risk management objectives and policies

The Group's principal financial instruments, other than derivatives, comprise bank overdrafts, finance leases, 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, cross-currency swaps and interest rate swaps for the purpose of hedging its foreign currency and interest rate risks. The Group may designate certain financial instruments as either fair value hedges or net investment hedges in accordance with IAS 39. Key controls applied to transactions in derivative financial instruments are: to use only instruments where good market liquidity exists, to revalue all financial instruments regularly using current market rates and to sell options only to offset previously purchased options. The Group does not use derivative financial instruments for speculative purposes.

#### Capital management

The capital structure of the Group consists of shareholders' equity (Note 20), debt (Note 14) and cash (Note 13). For the foreseeable future, the Board will maintain a capital structure that supports the Group's strategic objectives through:

- > managing funding and liquidity risk
- > optimising shareholder return
- > maintaining a strong, investment-grade credit rating.

Funding and liquidity risk are reviewed regularly by the Board and managed in accordance with policies described below.

The Board's distribution policy comprises a regular cash dividend, and subject to business needs, a share repurchase component. The Board regularly reviews its shareholders' return strategy and in 2012 decided to suspend share repurchases in order to retain strategic flexibility. In addition, we are restating our dividend cover target in terms of reported earnings adjusted for restructuring costs, intangible asset amortisation and impairments and other items as determined by the Group, and are targeting two times cover on this measure.

The Group's net funds position (loans and borrowings net of cash and cash equivalents, current investments and derivative financial instruments) has decreased from \$2,849m at the beginning of the year to a net debt position of \$1,369m at 31 December 2012 as a result of reduced operating cash inflows, substantial investment activities and share repurchases in 2012, offset by reduced tax cash outflows and fixed deposits maturing in the year.

#### 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 is assigned short-term credit ratings of P-1 by Moody's and A-1+ by Standard and Poor's. The Group's long-term credit rating is A1 negative outlook by Moody's and AA- stable outlook by Standard and Poor's.

In addition to cash and cash equivalents of \$7,701m, fixed deposits of \$46m, less overdrafts of \$105m at 31 December 2012, the Group has committed bank facilities of \$3.0bn available to manage liquidity. At 31 December 2012, the Group has issued \$1,551m under a Euro Medium Term Note programme and \$7,796m 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 \$3.0bn mature in April 2017 and were undrawn at 31 December 2012.

#### 23 Financial risk management objectives and policies continued

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	Finance leases \$m	Trade and other payables \$m	Total non-derivative financial instruments \$m	Interest rate swaps \$m	Cross- 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	Finance leases \$m	Trade and other payables \$m	Total non-derivative financial instruments \$m	Interest rate swaps \$m	Cross- 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	Finance leases \$m	Trade and other payables \$m	Total non-derivative financial instruments \$m	Interest rate swaps \$m	Cross- currency swaps \$m	Total derivative financial instruments \$m	Total \$m
Within one year	881	484	23	9,221	10,609	(85)	(12)	(97)	10,512
In one to two years	_	1,214	23	1,001	2,238	(67)	(12)	(79)	2,159
In two to three years	_	1,435	23	_	1,458	(49)	(12)	(61)	1,397
In three to four years	_	393	21	-	414	(49)	(12)	(61)	353
In four to five years	_	2,143	11	_	2,154	(48)	(12)	(60)	2,094
In more than five years	_	10,766	_	_	10,766	(90)	(96)	(186)	10,580
	881	16,435	101	10,222	27,639	(388)	(156)	(544)	27,095
Effect of interest	(2)	(7,340)	(17)	_	(7,359)	388	86	474	(6,885)
Effect of discounting, fair values and									
issue costs	-	252	-	-	252	(313)	(6)	(319)	(67)
31 December 2012	879	9,347	84	10,222	20,532	(313)	(76)	(389)	20,143

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 2012, the Group held interest rate swaps with a notional value of \$1.8bn, converting the 5.4% callable bond maturing in 2014, and the 7% guaranteed debentures payable in 2023 to floating rates and partially converting the 5.9% callable bond maturing in 2017 to floating rates. No new interest rate swaps were entered into during 2012 or 2011. At 31 December 2012, swaps with a notional value of \$0.75bn were designated in fair value hedge relationships 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 dollar liquidity funds earning floating rates of interest.

#### 23 Financial risk management objectives and policies continued

The interest rate profile of the Group's interest-bearing financial instruments, as at 31 December 2012, 31 December 2011 and 31 December 2010 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.

	2012					2011			2010
	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	901	22	879	1,990	999	991	125	_	125
Non-current	9,409	7,306	2,103	7,338	5,215	2,123	9,097	6,242	2,855
	10,310	7,328	2,982	9,328	6,214	3,114	9,222	6,242	2,980
Financial assets Fixed deposits	46	_	46	3,927	_	3,927	1,107	_	1,107
Cash and cash equivalents	7,701	-	7,701	7,571	_	7,571	11,068	_	11,068
	7,747	_	7,747	11,498	_	11,498	12,175	_	12,175

In addition to the financial assets above, there are \$7,924m (2011: \$8,747m; 2010: \$7,829m) 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 62% of Group external sales in 2012 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 2012, 5.4% of interest-bearing loans and borrowings were denominated in pounds sterling and 9.6% 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.

During 2012, the Group entered into a cross-currency swap to convert \$750m of the 1.95% 2019 maturing bond into fixed Japanese yen debt. This instrument was designated in a net investment hedge against the foreign currency risk of the Group's Japanese yen net assets. Fair value movements on the revaluation of the cross-currency swap are recognised in other comprehensive income to the extent that the hedge is effective. Any ineffectiveness would be 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.

The table below sets out the principal foreign exchange contracts outstanding at 31 December 2012, 31 December 2011 and 31 December 2010 along with the underlying gross exposure as defined above.

	GBP	SEK	EUR \$m	AUD \$m	JPY \$m	CAD	RON \$m	RUB
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
2010								
Gross exposure	732	(806)	478	117	133	33	82	129
Forward exchange contracts	(38)	806	(478)	(117)	(133)	(33)	(83)	(129)
Net exposure	6941	_	_	-	-	_	(1)	_
2011								
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	_	_	_	_	-	_	_	_
2012								
Gross exposure	(889)	(1,055)	472	65	257	54	112	259
Forward exchange contracts	889	1,055	(472)	(65)	(257)	(54)	(112)	(259)
Net exposure	-	-	-	-	_	-	-	_

<sup>&</sup>lt;sup>1</sup> The sterling hedge position as at 31 December 2010 was updated in early January 2011.

# 23 Financial risk management objectives and policies continued Sensitivity analysis

The sensitivity analysis set out below summarises the sensitivity of the market value of our financial instruments to hypothetical changes in market rates and prices. The range of variables chosen for the sensitivity analysis reflects our view of changes which are reasonably possible over a one-year period. Market values are the present value of future cash flows based on market rates and prices at the valuation date. For long-term debt, an increase in interest rates results in a decline in the fair value of debt.

The sensitivity analysis assumes an instantaneous 100 basis point change in interest rates in all currencies from their levels at 31 December 2012, with all other variables held constant. Based on the composition of our long-term debt portfolio as at 31 December 2012, a 1% increase in interest rates would result in an additional \$30m in interest expense being incurred per year. The exchange rate sensitivity analysis assumes an instantaneous 10% change in foreign currency exchange rates from their levels at 31 December 2012, 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 2010

		Interest rates		Exchange rates	
				-10%	
Increase/(decrease) in fair value of financial instruments (\$m)	595	(684)	36	(36)	
Impact on profit: (loss)/gain (\$m)	_	_	(133)	133	
Impact on equity: gain/(loss) (\$m)	_	_	169	(169)	

#### 31 December 2011

		Interest rates		Exchange rates
				-10%
Increase/(decrease) in fair value of financial instruments (\$m)	654	(777)	(15)	15
Impact on profit: (loss)/gain (\$m)	_	_	(190)	190
Impact on equity: gain/(loss) (\$m)	_	_	175	(175)

#### 31 December 2012

		Interest rates	Exchange rate		
				-10%	
Increase/(decrease) in fair value of financial instruments (\$m)	853	(1,005)	12	(12)	
Impact on profit: (loss)/gain (\$m)	-	_	(231)	231	
Impact on equity: gain/(loss) (\$m)	-	_	243	(243)	

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.

#### 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 73% of US sales (2011: three wholesalers accounted for approximately 75%; 2010: three wholesalers accounted for approximately 73%).

#### 23 Financial risk management objectives and policies continued

The ageing of trade receivables at the reporting date was:

	2012 \$m	2011 \$m	2010 \$m
Not past due	5,322	6,249	5,953
Past due 0-90 days	288	177	104
Past due 90-180 days	41	82	67
Past due > 180 days	45	122	123
	5,696	6,630	6,247

	2012 \$m	2011 \$m	2010 \$m
Movements in provisions for trade receivables Balance at beginning of year	66	81	81
Income statement credit	_	(10)	(1)
Amounts utilised, exchange and other movements	(2)	(5)	1
Balance at end of year	64	66	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 US dollar AAA-rated liquidity funds and short-term bank deposits.

The most significant concentration of financial credit risk at 31 December 2012 was \$6,589m invested in five US dollar AAA-rated liquidity funds. 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. 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 2012 was \$230m (2011: \$21m; 2010: \$13m).

#### 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.

	2012	2011	2010
Employees			
UK	7,900	8,700	10,100
Continental Europe	16,100	19,200	20,100
The Americas	15,300	18,000	18,300
Asia, Africa & Australasia	14,200	13,900	13,200
Continuing operations	53,500	59,800	61,700

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 2012 was 51,700 (2011: 57,200; 2010: 61,100).

The costs incurred during the year in respect of these employees were:

	2012 \$m	2011 \$m	2010 \$m
Salaries	4,192	4,631	4,837
Social security costs	664	783	693
Pension costs	525	490	501 <sup>1</sup>
Other employment costs	362	496	408
	5,743	6,400	6,439

<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 \$846m are not included above (2011: \$431m; 2010: \$531m).

### Financial Statements | Notes to the Group Financial Statements

#### 24 Employee costs and share plans for employees continued

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 2012 will be paid in cash, as they were in 2011 and 2010. The Company also offers UK employees the opportunity to buy Partnership Shares (Ordinary Shares). 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. In 2010, the Company introduced a Matching Share element in respect of Partnership Shares, the first award of which was made in 2011. Partnership Shares and Matching Shares are held in the HM Revenue & Customs (HMRC)-approved All-Employee Share Plan. At the Company's AGM in 2002, shareholders approved the issue of new shares for the purposes of the All-Employee Share Plan.

#### The AstraZeneca Executive Annual Bonus Scheme

This scheme is a performance bonus scheme for Directors and senior employees who do not participate in the AstraZeneca UK Performance Bonus Plan. Annual bonuses are paid in cash and reflect both corporate and individual performance measures. The Remuneration Committee has discretion to reduce or withhold bonuses if business performance falls sufficiently short of expectations in any year such as to make the payment of bonuses inappropriate.

#### The AstraZeneca Deferred Bonus Plan

This plan was introduced in 2006 and is used to defer a portion of the bonus earned under the AstraZeneca Executive Annual Bonus Scheme into Ordinary Shares in the Company for a period of three years. The plan currently operates only in respect of Executive Directors and members of the SET. Awards of shares under this plan are typically made in February each year, the first award having been made in February 2006.

#### Sweden

In Sweden, an all-employee performance bonus plan is in operation, which rewards strong individual performance. Bonuses are paid 50% into a fund investing in AstraZeneca equities and 50% in cash. The AstraZeneca Executive Annual Bonus Scheme, the AstraZeneca Performance Share Plan and the AstraZeneca Global Restricted Stock Plan all operate in respect of relevant AstraZeneca employees in Sweden.

#### US

In the US, there are two all-employee short-term or annual performance bonus plans in operation to differentiate and reward strong individual performance. Annual bonuses are paid in cash. There is also one senior staff long-term incentive scheme, under which 76 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 \$139m (2011: \$153m; 2010: \$120m). 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 2012 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 2012, 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. Further details of this plan can be found in the Directors' Remuneration Report from page 122.

	Shares '000	WAFV <sup>1</sup> pence	WAFV <sup>1</sup>
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
Shares awarded in March 2012	3,283	1403	22.41
Shares awarded in August 2012	38	1480	23.50

<sup>&</sup>lt;sup>1</sup> Weighted average fair value.

#### 24 Employee costs and share plans for employees continued

#### The AstraZeneca Investment Plan

This plan was introduced in 2010 and approved by shareholders at the 2010 AGM. The main grant of awards in 2012 under the plan was in March, with a further smaller grant in October. 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 2012, 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. Further details of this plan can be found in the Directors' Remuneration Report from page 122.

	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
Shares awarded in March 2012	113	2805	44.82
Shares awarded in October 2012	69	2894	n/a

#### The AstraZeneca Global Restricted Stock Plan

This plan was introduced in 2010. The main grant of awards in 2012 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
Shares awarded in March 2012	2,916	2805	44.82
Shares awarded in August 2012	26	2959	47.00

#### The AstraZeneca Restricted Share Plan

This plan was introduced in 2008 and provides for the grant of restricted share awards to key employees, excluding Executive Directors. Awards are made on an *ad hoc* basis with variable vesting dates. The plan has been used five times in 2012 to make awards to 161 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 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
Shares awarded in February 2012	10	3067	48.20
Shares awarded in March 2012	371	2805	44.82
Shares awarded in July 2012	5	n/a	46.94
Shares awarded in August 2012	188	2959	47.00
Shares awarded in October 2012 <sup>1</sup>	69	2894	n/a

<sup>1</sup> This is an award of restricted shares, granted to Pascal Soriot under an arrangement, the details of which are identical to the rules of the AstraZeneca Restricted Share Plan.

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.

### Financial Statements | Notes to the Group Financial Statements

#### 24 Employee costs and share plans for employees continued

#### Share option plans

The charge for share-based payments in respect of share options is \$7m (2011: \$37m; 2010: \$53m) which is comprised entirely of equity-settled transactions. At 31 December 2012, the only significant options outstanding were under the AstraZeneca Share Option Plan.

#### 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 for a period of 10 years. The first grant of options occurred in August 2000. The final grant of options under the plan was in August 2009, since when no further grants have been or will be made. Options are not transferable. Options were granted over AstraZeneca Ordinary Shares or ADSs.

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.

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.

	AstraZeneca Share	e Option Plan
	Options '000	WAEP pence
Options outstanding at 1 January 2010	62,398	2601
Options exercised	(10,144)	2538
Options forfeited	(3,189)	2470
Options outstanding at 31 December 2010	49,065	2439
Options exercised	(10,408)	2125
Options forfeited	(3,435)	2933
Options outstanding at 31 December 2011	35,222	2484
Options exercised	(11,648)	2219
Options forfeited	(3,861)	3128
Options outstanding at 31 December 2012	19,713	2513
Range of exercise prices	18	82 to 3335
Weighted average remaining contractual life		1468 days
Options exercisable	19,713	2513

<sup>&</sup>lt;sup>1</sup> Weighted average exercise price.

The fair value of options was estimated at the date of grant, being prior to 1 January 2010, using the Black-Scholes option pricing model based on weighted average exercise price, expected volatility, dividend yield, risk-free interest rates and expected lives. Expectations of early exercise were incorporated into the model.

The expected volatility was 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

	2012 \$m	2011 \$m	2010 \$m
Commitments			
Contracts placed for future capital expenditure on property, plant and equipment			
and software development costs not provided for in these accounts	245	190	259

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	3,129	296	584	699	1,550
Future potential revenue milestone payments	4,337	_	5	40	4,292

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 expensed as the associated sale is recognised. The table excludes any payments already capitalised in the financial statements for the year ended 31 December 2012.

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 75, 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.

#### 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 2010, 2011 or 2012.

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 28 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 2012 in the aggregate of \$88m (2011: \$92m; 2010: \$119m), 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 (2011: \$50m to \$90m; 2010: \$20m to \$40m) which relates solely to the US.

### Financial Statements | Notes to the Group Financial Statements

### 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. Further details of the legal provisions taken during the year are provided in Note 17.

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 or loss of exclusivity 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 2012, 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

In March 2012, the Canadian Federal Court of Appeal dismissed Mylan Pharmaceuticals ULC's appeal against a decision prohibiting the Canadian Minister of Health from issuing it with a marketing authorisation. There is no remaining *Arimidex* litigation in Canada.

### Atacand Plus (candesartan cilexetil/hydrochlorothiazide) Patent/regulatory proceedings outside the US

In Canada, in February and May 2012, AstraZeneca settled notice of compliance proceedings with Cobalt Pharmaceuticals Inc., and Apotex Inc. respectively allowing each company to enter the Canadian market on 23 September 2012, or earlier, in certain circumstances. Generic candesartan cilexetil/hydrochlorothiazide entered the Canadian market in September 2012. There is no remaining *Atacand Plus* litigation in Canada.

#### Crestor (rosuvastatin calcium)

#### US patent litigation/regulatory proceedings

In December 2012, the US Court of Appeals for the Federal Circuit affirmed the decision of the US District Court for the District of Delaware that the substance patent protecting *Crestor* is valid and enforceable. The Federal Circuit also held that Apotex Corp. (Apotex) was liable as a submitter and is therefore bound by the District Court's decision. In January 2013, defendants Aurobindo Pharma Limited, Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals Inc., Sun Pharmaceutical Industries, LTD., and, separately, Apotex, filed petitions for rehearing and rehearing *en banc* of aspects of the Federal Circuit's decision.

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 for *Crestor* tablets. In March 2012, the Court ruled that, based on the NDA application alone, it did not have subject matter jurisdiction over AstraZeneca's claims for infringement of its patents relating to methods of using rosuvastatin compounds to treat certain cardiovascular conditions. In November 2012, the Court ruled that

#### 25 Commitments and contingent liabilities continued

defendant Watson Laboratories, Inc. (Watson) was precluded from relitigating its defence of invalidity. In December 2012, defendant EGIS Pharmaceuticals PLC was dismissed from the case by stipulation where it conceded the validity and enforceability of the *Crestor* substance patent and also agreed to be bound by any judgment against Watson. Trial took place in December 2012 on the sole remaining issue of infringement of the substance patent. The Court will render a decision after submission of post-trial briefs from both parties.

As previously reported, 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. In May 2012, the FDA denied the Petition.

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.

#### Patent proceedings outside the US

AstraZeneca is engaged in proceedings in Australia, Brazil, Canada, Malaysia, 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, Canada, Malaysia and Mexico.

In Australia, as previously reported in 2011, AstraZeneca instituted proceedings against Apotex Pty Ltd asserting infringement of various formulation and method patents for *Crestor*. In January 2012, AstraZeneca instituted similar proceedings against Watson Pharma Pty Ltd. and Actavis Australia Pty Ltd. AstraZeneca was granted preliminary injunctions against all three parties. A trial was held in October 2012 and a decision is pending.

In Canada, in February 2012, AstraZeneca reached settlement with Pharmascience Inc. (PMS) resolving the litigation regarding AstraZeneca's *Crestor* substance patent and, as part of the agreement, PMS was permitted to enter the Canadian market on 2 April 2012, or earlier, in certain circumstances. Generic rosuvastatin calcium entered the Canadian market in April 2012.

#### Entocort EC (budesonide)

#### US patent litigation

In April 2012, the US Court of Appeals for the Federal Circuit affirmed the US District Court for the District of Delaware's decision that Mylan Pharmaceuticals Inc.'s generic budesonide product does not infringe AstraZeneca's patent protecting *Entocort EC*.

#### Losec/Prilosec (omeprazole)

#### **US** patent litigation

AstraZeneca continues litigation to recover patent infringement damages against Andrx Pharmaceuticals, Inc., and Apotex Corp. and Apotex Inc.

#### Patent proceedings outside the US

In Canada, the AstraZeneca patent infringement proceeding against Apotex Inc. regarding omeprazole capsules and tablets remains pending.

In May 2012, in Canada, the Federal Court found AstraZeneca liable to Apotex Inc. for section 8 damages arising from notice of compliance proceedings that had been finally dismissed in December 2003. The actual amount of damages owing, if any, will be determined at a future date by a court reference procedure. AstraZeneca has appealed the Federal Court's decision.

### Nexium (esomeprazole magnesium) US patent litigation

In 2012, AstraZeneca entered into separate agreements with three generic companies settling AstraZeneca's patent infringement action against each generic company's ANDA product. As part of each settlement, each generic company was granted a licence to enter the US market with its proposed ANDA version of generic esomeprazole magnesium on 27 May 2014, subject to regulatory approval, or earlier, in certain circumstances.

In January 2012, AstraZeneca received a Paragraph IV notice letter from Mylan Laboratories Ltd. (Mylan Laboratories). In March 2012, AstraZeneca commenced a patent infringement action in the US District Court for the District of New Jersey against Mylan Laboratories regarding its generic ANDA product. Trial against Mylan Laboratories may be scheduled in 2013.

In 2011, AstraZeneca commenced a patent infringement action in the US District Court for the District of New Jersey against Hanmi USA Inc., et al. (Hanmi) in response to the filing of an NDA under §505(b)(2) for FDA approval to market 20mg and 40mg esomeprazole strontium capsules. Trial against Hanmi may be scheduled in 2013.

#### Patent 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, Malaysia, Mexico, the Netherlands, Norway, Philippines, Poland, Portugal, Singapore, Slovenia, Sweden, Switzerland and Turkey. There is generic entry in many European markets.

In the European Patent Office (EPO), in June and July 2011, the Opposition Division revoked EP 1020461 (the '461 patent) (which relates to *Nexium*) and EP 1020460 (the '460 patent) (which relates to *Nexium* i.v.). AstraZeneca appealed the Opposition Division's decision. In November 2012, separate EPO Technical Boards of Appeal granted AstraZeneca's appeals and maintained both the '461 patent and the '460 patent.

In Canada, in March 2012, AstraZeneca discontinued its notice of compliance proceeding pending with Mylan Pharmaceuticals ULC (Mylan) with respect to the Canadian *Nexium* substance patent number 2.290.963 after Mylan withdrew its notice of allegation.

Also, in Canada, in October 2012, the Federal Court prohibited Pharmascience Inc. from receiving a marketing authorisation for its esomeprazole magnesium product until May 2018.

# 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 formulation and form of active ingredient for *Pulmicort Respules* began trial on 7 November 2012 in the US District Court for the District of New Jersey. Closing arguments are scheduled for 8 February 2013 and AstraZeneca expects a decision shortly thereafter.

### Seroquel IR (quetiapine fumarate) US regulatory proceedings

In March 2012, in response to the FDA's notice that generic *Seroquel IR* had been granted final approval, AstraZeneca filed a lawsuit in the US District Court for the District of Columbia seeking a temporary restraining order to vacate these approvals, and an injunction to enjoin any further approvals of generic quetiapine. In June 2012, the Court denied AstraZeneca's motion for summary judgment and granted the FDA's cross motion for summary judgment on the issue of exclusivity for *Seroquel IR*. In July 2012, AstraZeneca appealed that ruling to the US Court of Appeals for the District of Columbia Circuit. Generic quetiapine fumarate (*Seroquel IR*) entered the US market in March 2012.

### Financial Statements | Notes to the Group Financial Statements

# **25 Commitments and contingent liabilities** continued *Seroquel XR* (an extended release formulation of quetiapine fumarate)

#### US patent litigation/regulatory proceedings

In October 2011, the US District Court for the District of New Jersey conducted a trial in the patent infringement actions involving the *Seroquel XR* formulation patent against certain generic drug manufacturers. In March 2012, the Court found the *Seroquel XR* formulation patent to be valid. The Court also found that Anchen Pharmaceuticals, Inc., Osmotica Pharmaceutical Corporation, Torrent Pharmaceuticals Limited, Torrent Pharma Inc., Mylan Pharmaceuticals Inc. and Mylan Inc. have infringed the *Seroquel XR* formulation patent. The decision has been appealed.

In July 2012, AstraZeneca settled its patent infringement action against Intellipharmaceutics Corp. and Intellipharmaceutics International Inc. (together, Intellipharmaceutics) pending in the US District Court for the Southern District of New York by granting a licence to the *Seroquel XR* product patent, effective 1 November 2016, or earlier, in certain circumstances.

In July 2012, AstraZeneca received a Paragraph IV notice letter from Amneal Pharmaceuticals, LLC (Amneal) relating to *Seroquel XR*. In August 2012, AstraZeneca commenced a patent infringement action against Amneal and related Amneal entities in the US District Court for the District of New Jersey. In January 2013, AstraZeneca settled its patent infringement action against Amneal by granting a licence to the *Seroquel XR* product patent, effective 1 November 2016, or earlier, in certain circumstances.

In September 2012, AstraZeneca received a Paragraph IV notice letter from Lupin Ltd. (Lupin) relating to *Seroquel XR*. In November 2012, AstraZeneca commenced a patent infringement action against Lupin in the US District Court for the District of New Jersey.

#### Patent proceedings outside the US

In the Netherlands, in March 2012, the District Court in the Hague upheld the validity of the formulation patent protecting *Seroquel XR*.

In the UK, in March 2012, the UK High Court found the Seroquel XR formulation patent invalid.

In Spain, in July 2012, the Commercial Court in Barcelona found the *Seroquel XR* formulation patent valid.

In Germany, in September 2012, the Regional Court in Düsseldorf affirmed preliminary injunctions against Heumann Pharma GmbH & Co, Heumann Verwaltungs GmbH, Ratiopharm GmbH, CT Arzneimittel GmbH and AbZ Pharma GmbH. However, in November 2012, the Federal Patent Court found the Seroquel XR patent invalid and outstanding injunctions have been lifted.

Generic versions of *Seroquel XR* have been launched in Austria, Denmark, Germany, Italy, Portugal, UK, Romania and elsewhere. While AstraZeneca continues to have confidence in the patent protecting *Seroquel XR* and will continue to take appropriate legal action, additional generic launches and adverse court rulings are possible.

### Symbicort (budesonide/formoterol) US patent litigation

AstraZeneca is defending a complaint alleging patent infringement filed 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*.

### Vimovo (naproxen/esomeprazole magnesium) US patent litigation

In January 2013, AstraZeneca and Pozen commenced a patent-infringement action in the US District Court for the District of New Jersey in response to an ANDA challenge to seven patents listed in the Orange Book including the patent in-licensed from Pozen. Three additional patent-infringement actions regarding generic versions of *Vimovo* are also pending in the Court.

#### Zestril (lisinopril dihydrate)

#### 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 and that damages claim remains pending.

## Product Liability Litigation Crestor (rosuvastatin calcium)

AstraZeneca is defending 15 lawsuits in California state courts involving a total of 263 plaintiffs claiming physical injury from treatment with *Crestor*. The lawsuits allege multiple types of injuries including diabetes mellitus, various cardiac injuries, rhabdomyolysis, and liver and kidney injuries. Fourteen cases have been consolidated into one co-ordinated proceeding in Los Angeles, California.

#### Iressa (gefitinib)

Between 2004 and 2008, seven claims were filed against AstraZeneca in Japan, in the Osaka and Tokyo District Courts alleging that *Iressa* caused a fatal incidence of interstitial lung disease in Japanese patients. As previously reported, 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 (MHLW), had any liability for any of the claims. Following that decision, on 25 May 2012, the Osaka High Court reversed the Osaka District Court decision and ruled that neither AstraZeneca, nor the MHLW, had any liability for any of the claims. The plaintiffs have appealed both decisions to the Japanese Supreme Court.

#### Nexium (esomeprazole magnesium)

As previously disclosed, 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 various federal and state courts in the US. Currently, there are approximately 1,900 plaintiffs. In December 2012, the US Judicial Panel on Multi-District Litigation ordered that the federal cases be co-ordinated for proceedings in the US District Court for the Central District of California.

#### Seroquel IR (quetiapine fumarate)

With regard to Seroquel IR product liability litigation in the US, AstraZeneca is aware of approximately 10 cases in active litigation in various jurisdictions. Provisions associated with diabetes-related claims were reduced by approximately \$18m in 2012.

Four putative class actions were initiated in Canada in the provinces of Alberta, British Columbia, Ontario and Quebec, alleging that AstraZeneca failed to provide adequate warnings in connection with an alleged association between *Seroquel IR* and the onset of diabetes. Class certification was denied in the Ontario proceedings in 2012 and in Quebec in 2011. Both decisions were appealed. On 12 December 2012, the Quebec Court of Appeal approved plaintiff's motion to abandon the appeal of the lower court's decision to deny class certification.

#### 25 Commitments and contingent liabilities continued

With regard to insurance coverage for the substantial legal defence costs and settlements that have been incurred in connection with the *Seroquel IR* product liability claims in the US related to alleged diabetes and/or other related injuries (which now exceed the total amount of insurance coverage available), disputes continue with insurers and legal proceedings have commenced in the UK about the availability of coverage under certain 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**

#### Crestor (rosuvastatin calcium)

On 29 November 2012, a Motion to Certify a Claim as a Class Action and Related Statement of Claim were filed in Israel in the District Court in Tel Aviv – Jaffa, against AstraZeneca and four other pharmaceutical companies. With respect to AstraZeneca, in addition to other causes of action, the Statement of Claim alleges that AstraZeneca engaged in deception and failed to disclose material facts to consumers of *Crestor* regarding certain adverse events associated with the drug.

#### 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 one case remains pending. In the Massachusetts State Court case, AstraZeneca reached an agreement in principle to settle the matter in September 2012, and a provision has been taken. Plaintiffs' motion for preliminary approval of the settlement will be heard by the Court on 5 February 2013. The Delaware State Court case has been stayed since May 2005.

#### Seroquel (quetiapine fumarate)

Of the various state law claims brought by state Attorneys General generally alleging that AstraZeneca made false and/or misleading statements in marketing and promoting *Seroquel*, AstraZeneca remains in litigation with the Attorney General of Mississippi. In 2012, AstraZeneca settled the cases brought by the Attorneys General of the states of Montana, New Mexico, South Carolina and Utah, and also finalised previously reported agreements in principle with Alaska and Arkansas. In December 2012, AstraZeneca also agreed in principle to a settlement of similar claims with the Attorney General of Kentucky, which was finalised in January 2013. Provisions for the foregoing settlements were taken in 2012.

#### Synagis (palivizumab)

In September 2011, MedImmune, filed an action against Abbott International, LLC (Abbott) in the Circuit Court for Montgomery County, Maryland, seeking a declaratory judgment in a contract dispute. Abbott's motion to dismiss was granted. In September 2011, Abbott filed a parallel action against MedImmune in the Illinois State Court. Abbott's motion to hold the disputed funds in escrow was rejected. In February 2012, the Court denied MedImmune's motion to dismiss and is expected to set a trial date for 2013.

#### Toprol-XL (metoprolol succinate)

AstraZeneca is defending anti-trust claims in the US regarding the listing and enforcement of patents protecting *Toprol-XL*. In March 2013, the US District Court for the District of Delaware will hold a hearing to review the agreement in principle to settle the remaining claims alleged by the end-payers, for which a provision was taken in 2012.

#### Other Commercial Litigation

#### **Co-Payment Subsidy Litigation**

In March 2012, the New England Carpenters Health and Welfare Fund, on behalf of a proposed class of payers that reimbursed consumers for *Nexium* and *Crestor* prescriptions as to which AstraZeneca subsidised the consumer's co-payment obligation, brought an action against AstraZeneca in the US District Court for the Eastern District of Pennsylvania. On 5 September 2012, the plaintiffs voluntarily dismissed their complaint against AstraZeneca while reserving the right to file a new complaint against AstraZeneca in the future.

#### Shionogi Arbitration Crestor Royalty Calculation

In July 2012, Shionogi & Co. Ltd initiated arbitration proceedings to resolve issues relating to the treatment of certain excise taxes and other specific items in the calculation of royalties on *Crestor* sales.

#### **Nexium Settlement Anti-trust Litigation**

AstraZeneca is a defendant in numerous nearly identical putative class actions alleging that AstraZeneca's settlements of patent litigation relating to *Nexium* violated US anti-trust law and various state laws. In December 2012, the US Judicial Panel on Multi-District Litigation ordered that the cases be co-ordinated for proceedings in the US District Court for the District of Massachusetts.

#### Average Wholesale Price (AWP) 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 Utah, Wisconsin, and, as discussed below, with the Commonwealth of Kentucky.

During 2012, settlements were reached with the Attorneys General of the states of Louisiana and Oklahoma and provisions were taken.

AstraZeneca prevailed in its appeal before the Commonwealth of Kentucky Court of Appeals. In that case, AstraZeneca sought reversal of 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. On 12 October 2012, the Kentucky Court of Appeals reversed the trial court's decision and held that AstraZeneca was not liable for damages. The Court of Appeals remanded the case to the trial court for entry of judgment in favour of AstraZeneca. On 13 November 2012, the Commonwealth filed its Motion for Discretionary Review (appeal) in the Kentucky Supreme Court.

There are no remaining AWP cases pending against MedImmune.

#### 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 false pricing information reported to the government and 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. On 25 January 2013, the Court granted AstraZeneca's motion and dismissed the case with prejudice.

### Financial Statements | Notes to the Group Financial Statements

### 25 Commitments and contingent liabilities continued 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 Medicare and Medicaid 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. As to AstraZeneca, the Court dismissed plaintiffs' claims, both state and federal, for all Average Manufacturer Price submissions made before 1 January 2007 but denied AstraZeneca's motion to dismiss all claims regarding submissions made after 1 January 2007.

#### Drug importation and anti-trust litigation

As previously disclosed, in August 2004, Californian retail pharmacy plaintiffs filed an action in the Superior Court of California alleging a conspiracy by AstraZeneca and other pharmaceutical manufacturer defendants to set the price of drugs sold in California at or above the Canadian sales price for those drugs and otherwise restrict the importation of pharmaceuticals into the US. After the court granted the defendants' motion for summary judgment, and that decision was affirmed on appeal, in October 2012, the plaintiffs filed a petition for review by the California Supreme Court, which was denied.

#### Employment - wage/hour litigation

On 18 June 2012, the US Supreme Court in Christopher vs. SmithKline Beecham Corporation (GSK) handed down a decision concerning whether pharmaceutical sales representatives are exempt from overtime pay regulations under the US Department of Labor's outside sales exemption. The decision favoured GSK and by implication AstraZeneca and the pharmaceutical industry as a whole. As a result of the Christopher decision, the final wage and hour class action lawsuits against AstraZeneca were dismissed in October 2012.

#### 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

In December 2012, the Court of Justice of the EU ruled 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. The Court of Justice dismissed all of the cross-appeals and confirmed the judgment of the General Court in all material respects. No further appeals are possible.

#### Nexium (esomeprazole magnesium)

#### 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. The Department of Justice has filed a notice of non-intervention in the federal case. The Attorney General of Texas has stated that it plans to file a similar notice in the Texas False Claims Act case pending in state court in Texas. AstraZeneca and counsel for relator are currently negotiating the language of stipulations of dismissal. AstraZeneca expects these cases to be formally dismissed shortly.

#### **Dutch National Competition Authority investigation**

In the Dutch National Competition Authority (NMa) investigation into alleged abuse of a dominant position, the investigation team issued a report alleging foreclosure of generic versions of certain proton pump inhibitors other than esomeprazole. The file has now been passed to the Legal Department of the NMa. AstraZeneca completed its defence in April 2012 and awaits a decision by the Board of the NMa later in 2013.

#### **Federal Trade Commission inquiry**

In 2012, AstraZeneca 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.

#### Seroquel (quetiapine fumarate)

#### Attorney General of Texas investigation

In July 2012, AstraZeneca received a civil investigative demand from the Office of the Attorney General for the State of Texas in connection with an investigation related to sales and marketing activities potentially involving *Seroquel*.

#### Synagis (palivizumab)

As previously disclosed, on 30 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*. On 1 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 pursuant to what the government attorneys advised was a joint investigation. MedImmune has accepted receipt of these requests and is co-ordinating with the government offices to provide the appropriate responses and co-operate with any related investigation.

In May 2012, MedImmune, received a subpoena *duces tecum* from the Office of Attorney General for the State of Florida Medicaid and Fraud Control Unit requesting certain documents related to the sales and marketing activities of *Synagis*. MedImmune has accepted receipt of the request and is co-ordinating with the Florida government to provide the appropriate responses and co-operate with any related investigation. AstraZeneca is unaware of the nature or focus of the investigation, however, based on the nature of the requests it appears to be similar to the inquiries from the State of New York and Department of Justice (which is mentioned above).

## 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 and other government officials in several countries. AstraZeneca is co-operating with these inquiries. AstraZeneca is investigating indications of inappropriate conduct in certain countries, including China. Resolution of this matter could involve the payment of fines and/or other remedies.

### 25 Commitments and contingent liabilities continued Serbia

In August 2011, AstraZeneca'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. The indictment was subsequently amended. In March 2012, the Court denied AstraZeneca's request to dismiss the amended indictment and joined the proceedings against AstraZeneca and the other named pharmaceutical companies with the pending proceedings against the allegedly involved individual defendants. AstraZeneca has filed an appeal with the Serbian Constitutional Court.

#### India

On 23 February 2012, the Indian Central Bureau of Investigation filed a First Information Report in the court in Delhi against AstraZeneca and public officials of the Central Procurement Agency of the Delhi Directorate of Health Services (DHS) in connection with circumstances surrounding the submission by AstraZeneca of an alleged false affidavit in relation to pricing as part of a tender for *Meronem* entered into by AstraZeneca with the DHS in 2009. AstraZeneca is co-operating with the investigation.

#### Other US Attorney's Offices 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*, *Prilosec* and *Toprol-XL*.

#### Additional government inquiries

As is true for most, if not all, major prescription pharmaceutical companies operating in the US, AstraZeneca is currently involved in multiple US federal and state inquiries into drug marketing and pricing practices. In addition to the investigations described above, various federal and state law enforcement offices have, from time to time, requested information from the Company. There have been no material developments in those matters.

#### 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 \$423m, a reduction of \$226m compared to 2011 primarily due to the settlement of a transfer pricing matter as detailed in Note 4.

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 \$522m (2011: \$375m); 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 \$1,846m relating to a number of other tax contingencies, an increase of \$174m mainly due to the impact of an additional year of transactions relating to contingencies for which accruals had already been established and exchange rate effects. For these tax exposures, AstraZeneca does not expect material additional losses. It is, however, possible that some of these contingencies may reduce in the future if any tax authority challenge is unsuccessful or matters lapse following expiry of the relevant statutes of limitation resulting in a reduction in the tax charge in future periods.

#### Timing of cash flows and interest

It is not possible to estimate the timing of tax cash flows in relation to each outcome, however, it is anticipated that a number of significant disputes may be resolved over the next one to two years. Included in the provision is an amount of interest of \$248m (2011: \$291m). Interest is accrued as a tax expense.

### Financial Statements | Notes to the Group Financial Statements

#### 26 Operating leases

Total rentals under operating leases charged to profit were as follows:

	2012	2011	2010
	\$m	\$m	\$m
Operating leases	197	215	212

The future minimum lease payments under operating leases that have initial or remaining terms in excess of one year at 31 December 2012 were as follows:

	2012 \$m	2011 \$m	2010 \$m
Obligations under leases comprise: Not later than one year	102	92	161
Later than one year and not later than five years	223	178	242
Later than five years	109	122	103
Total future minimum lease payments	434	392	506

#### 27 Statutory and other information

	2012 \$m	2011 \$m	2010 \$m
Fees payable to KPMG Audit Plc and its associates:			
Group audit fee	2.2	2.4	2.3
Fees payable to KPMG Audit Plc and its associates for other services:			
The audit of subsidiaries pursuant to legislation	5.0	5.5	6.5
Audit-related assurance services	2.2	2.4	3.3
Tax compliance services	0.8	0.8	0.6
Tax advisory services	0.1	0.1	0.5
Other assurance services	1.1	2.5	0.1
Fees payable to KPMG Audit Plc in respect of the Group's pension schemes:			
The audit of subsidiaries' pension schemes	0.5	0.6	0.6
	11.9	14.3	13.9

Audit-related assurance services include fees of \$1.7m (2011: \$1.9m; 2010: \$2.4m) in respect of section 404 of the Sarbanes-Oxley Act. Other assurance services include assurance services provided in relation to the Group's long-term debt issuance in 2012.

#### 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.

	2012 \$000	2011 \$000	2010 \$000
Short-term employee benefits	19,451	19,973	21,925
Post-employment benefits	2,137	2,155	1,793
Termination benefits	1,672	_	_
Share-based payments	15,304	16,064	11,563
	38,564	38,192	35,281

Total remuneration is included within employee costs (see Note 24). Further details of Directors' emoluments are included in the Directors' Remuneration Report from pages 122 to 137.

#### Subsequent events

There were no material subsequent events.

### Financial Statements | Principal Subsidiaries

### Principal Subsidiaries

At 31 December 2012	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		100	Many first vision
AstraZeneca Dunkerque Production SCS	France	100	Manufacturing
AstraZeneca SAS	France	100	Research, manufacturing, marketing
Novexel SA	France	100	Research
AstraZeneca GmbH	Germany	100	Development, manufacturing, marketing
AstraZeneca Holding GmbH	Germany	100	Manufacturing, marketing
AstraZeneca SpA	Italy	100	Marketing
AstraZeneca Farmaceutica Spain SA	Spain	100	Marketing
AstraZeneca AB	Sweden	100	Research and development, manufacturing, marketing
AstraZeneca BV	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
Ardea Biosciences, Inc.	US	100	Research and development
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. AstraZeneca operates through 217 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 2012.

### Financial Statements | Independent Auditor's Report to the Members of AstraZeneca PLC

### 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 2012 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 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 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 Financial Reporting Council's website at frc.org.uk/auditscopeukprivate.

#### **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 2012;
- > have been properly prepared in accordance with UK Generally Accepted Accounting Practice; and
- > 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; and
- > 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; or
- > the Parent Company Financial Statements and the part of the Directors' Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- > certain disclosures of Directors' Remuneration specified by law are not made; or
- > we have not received all the information and explanations we require for our audit.

#### Other matter

We have reported separately on the Group Financial Statements of AstraZeneca PLC for the year ended 31 December 2012.

#### **Jimmy Daboo**

Senior Statutory Auditor
For and on behalf of KPMG Audit Plc, Statutory Auditor
Chartered Accountants
15 Canada Square, London, E14 5GL

31 January 2013

### Financial Statements | Company Balance Sheet

# Company Balance Sheet at 31 December

#### AstraZeneca PLC

	Notes	2012 \$m	2011 \$m
Fixed assets		<b>4</b>	<b>\$111</b>
Fixed asset investments	1	25,349	23,421
Current assets			
Debtors – other		3	1
Debtors – amounts owed by Group undertakings		6,589	1,937
		6,592	1,938
Creditors: Amounts falling due within one year			
Non-trade creditors	2	(956)	(3,217)
Interest-bearing loans and borrowings	3	-	(1,749)
		(956)	(4,966)
Net current assets/(liabilities)		5,636	(3,028)
Total assets less current liabilities		30,985	20,393
Creditors: Amounts falling due after more than one year			
Amounts owed to Group undertakings	3	(283)	(283)
Interest-bearing loans and borrowings	3	(8,742)	(6,714)
		(9,025)	(6,997)
Net assets		21,960	13,396
Capital and reserves			
Called-up share capital	6	312	323
Share premium account	4	3,504	3,078
Capital redemption reserve	4	153	139
Other reserves	4	2,904	2,983
Profit and loss account	4	15,087	6,873
Shareholders' funds	5	21,960	13,396

\$m means millions of US dollars.

The Company Financial Statements from page 193 to 197 were approved by the Board on 31 January 2013 and were signed on its behalf by

Pascal SoriotSimon LowthDirectorDirector

Company's registered number 2723534

### Financial Statements | Company Accounting Policies

### 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 IFRS 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 29 (IFRS 7) 'Disclosures – Transfers of Financial Assets' during the year. The adoption had no impact on the net results or net assets of 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.

### Financial Statements | Notes to the Company Financial Statements

### Notes to the Company Financial Statements

#### 1 Fixed asset investments

		Investments in subsidiaries		
	Shares \$m	Loans \$m	Total \$m	
Cost and net book value at 1 January 2012	16,427	6,994	23,421	
Additions	-	1,980	1,980	
Impairment	(21)	-	(21)	
Capital contribution	(79)	-	(79)	
Exchange	-	45	45	
Amortisation	-	3	3	
Cost and net book value at 31 December 2012	16,327	9,022	25,349	

During the year management conducted an impairment review of the Company's investment in AstraZeneca Holding GmbH because of a deterioration in the trading outlook in Germany. The review indicated that AstraZeneca Holding GmbH's carrying amount exceeded its value by \$21m and consequently the carrying amount has been written down by this amount. The impairment loss has been recognised in operating costs within the profit and loss account.

A list of principal subsidiaries is included on page 191.

#### 2 Non-trade creditors

	2012 \$m	2011 \$m
Amounts due within one year Short-term borrowings (unsecured)	792	14
Other creditors	158	170
Amounts owed to Group undertakings	6	3,033
	956	3,217

#### 3 Loans

		Repayment dates	2012 \$m	2011 \$m
Amounts due within one year Interest-bearing loans and borrowings (unsecured)				
5.4% Callable bond	US dollars	2012	_	1,749
Amounts due after more than one year Amounts owed to subsidiaries (unsecured)				
7.2% Loan	US dollars	2023	283	283
Interest-bearing loans and borrowings (unsecured)				
5.4% Callable bond	US dollars	2014	749	749
5.125% Non-callable bond	euros	2015	990	969
5.9% Callable bond	US dollars	2017	1,745	1,744
1.95% Callable bond	US dollars	2019	995	_
5.75% Non-callable bond	pounds sterling	2031	561	536
6.45% Callable bond	US dollars	2037	2,717	2,716
4% Callable bond	US dollars	2042	985	_
			8,742	6,714

	2012 \$m	2011 \$m
Loans or instalments thereof are repayable:		
After five years from balance sheet date	5,541	5,279
From two to five years	2,735	1,718
From one to two years	749	_
Within one year	-	1,749
Total unsecured	9,025	8,746

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.

### Financial Statements | Notes to the Company Financial Statements

#### **4 Reserves**

	Share premium account \$m	Capital redemption reserve \$m	Other reserves \$m	Profit and loss account \$m	2012 Total \$m	2011 Total \$m
At beginning of year	3,078	139	2,983	6,873	13,073	19,476
Profit for the year	-	-	-	14,467	14,467	2,961
Dividends	_	-	-	(3,619)	(3,619)	(3,752)
Amortisation of loss on cash flow hedge	-	-	-	1	1	2
Share-based payments	-	-	(79)	_	(79)	(37)
Share repurchases	_	14	_	(2,635)	(2,621)	(5,983)
Issue of AstraZeneca PLC Ordinary Shares	426	_	_	_	426	406
At end of year	3,504	153	2,904	15,087	21,648	13,073
Distributable reserves at end of year	_	-	1,841	15,087	16,928	8,714

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 2012, \$15,087m (2011: \$6,873m) 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 2012 is \$1,063m (2011: \$1,142m) in respect of cumulative share-based payment awards. These amounts are not available for distribution.

#### 5 Reconciliation of movement in shareholders' funds

	2012 \$m	2011 \$m
At beginning of year	13,396	19,828
Net profit for the financial year	14,467	2,961
Dividends	(3,619)	(3,752)
Amortisation of loss on cash flow hedge	1	2
Share-based payments	(79)	(37)
Issue of AstraZeneca PLC Ordinary Shares	429	409
Repurchase of AstraZeneca PLC Ordinary Shares	(2,635)	(6,015)
Net increase/(decrease) in shareholders' funds	8,564	(6,432)
Shareholders' funds at end of year	21,960	13,396

Details of dividends paid and payable to shareholders are given in Note 21 to the Group Financial Statements.

#### 6 Share capital

	Allotted, called	d-up and fully paid
	2012 \$m	2011 \$m
Issued Ordinary Shares (\$0.25 each)	312	323
Redeemable Preference Shares (£1 each – £50,000)	-	_
	312	323

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
At 1 January 2012	1,292,355,052	323
Issues of shares	12,241,784	3
Repurchase of shares	(57,817,288)	(14)
At 31 December 2012	1,246,779,548	312

#### Share repurchases

During the year, the Company repurchased 57.8m Ordinary Shares at an average price of 2879 pence per share (2011: 127.4m Ordinary Shares at an average price of 2932 pence per share).

#### Share schemes

A total of 12.2m Ordinary Shares were issued during the year in respect of share schemes (2011: 10.7m Ordinary Shares). 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 IR product liability litigation and the Nexium product liability litigation 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 and other government officials in several countries. AstraZeneca is co-operating with these inquiries. AstraZeneca is investigating indications of inappropriate conduct in certain countries, including China. Resolution of this matter could involve the payment of fines and/or other remedies.

#### **Dutch National Competition Authority investigation**

In the Dutch National Competition Authority (NMa) investigation into alleged abuse of a dominant position, the investigation team issued a report alleging foreclosure of generic versions of certain proton pump inhibitors other than esomeprazole. The file has now been passed to the Legal Department of the NMa. AstraZeneca completed its defence in April 2012 and awaits a decision by the Board of the NMa later in 2013.

#### 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 2012 and 2011.

### Financial Statements | Group Financial Record

### **Group Financial Record**

For the year ended 31 December	2008 \$m	2009 \$m	2010 \$m	2011 \$m	2012 \$m
Revenue and profits				00.77	
Revenue	31,601	32,804	33,269	33,591	27,973
Cost of sales	(6,598)	(5,775)	(6,389)	(6,026)	(5,393)
Distribution costs	(291)	(298)	(335)	(346)	(320)
Research and development expense	(5,179)	(4,409)	(5,318)	(5,523)	(5,243)
Selling, general and administrative costs	(10,913)	(11,332)	(10,445)	(11,161)	(9,839)
Profit on disposal of subsidiary				1,483	
Other operating income and expense	524	553	712	777	970
Operating profit	9,144	11,543	11,494	12,795	8,148
Finance income	854	462	516	552	528
Finance expense	(1,317)	(1,198)	(1,033)	(980)	(958)
Profit before tax	8,681	10,807	10,977	12,367	7,718
Taxation	(2,551)	(3,263)	(2,896)	(2,351)	(1,391)
Profit for the period	6,130	7,544	8,081	10,016	6,327
Other comprehensive income for the period, net of tax	(1,906)	(54)	25	(546)	78
Total comprehensive income for the period	4,224	7,490	8,106	9,470	6,405
Profit attributable to:					
Equity holders of the Company	6,101	7,521	8,053	9,983	6,297
Non-controlling interests	29	23	28	33	30
Earnings per share	<b>A</b> 4.00	ΦΕ 40	ΦΕ 00	Φ7.00	04.00
Earnings per \$0.25 Ordinary Share (basic)	\$4.20	\$5.19	\$5.60	\$7.33	\$4.99
Earnings per \$0.25 Ordinary Share (diluted)	\$4.20	\$5.19	\$5.57	\$7.30	\$4.98
Dividends	\$1.90	\$2.09	\$2.41	\$2.70	\$2.85
Return on revenues Operating profit as a percentage of revenues	28.9%	35.2%	34.5%	38.1%	29.1%
Ratio of earnings to fixed charges	13.5	19.9	24.0	28.5	19.9
Take of carrings to fixed ortaines	10.0	10.0	27.0	20.0	10.0
At 31 December	2008 \$m	2009 \$m	2010 \$m	2011 \$m	2012 \$m
Statement of Financial Position					
Property, plant and equipment, goodwill and intangible assets	29,240	29,422	28,986	27,267	32,435
Other investments and non-current receivables	605	446	535	543	940
Deferred tax assets	1,236	1,292	1,475	1,514	1,111
Current assets	15,869	23,760	25,131	23,506	19,048
Total assets	46,950	54,920	56,127	52,830	53,534
Current liabilities	(13,415)	(17,640)	(16,787)	(15,752)	(13,903)
Non-current liabilities	(17,475)	(16,459)	(15,930)	(13,606)	(15,679)
Net assets	16,060	20,821	23,410	23,472	23,952
Share capital	362	363	352	323	312
Reserves attributable to equity holders	15,550	20,297	22,861	22,923	23,425
Non-controlling interests	148	161	197	226	215
Total equity and reserves	16,060	20,821	23,410	23,472	23,952
For the year ended 31 December	2008 \$m	2009 \$m	2010 \$m	2011 \$m	2012 \$m
Cash flows					
Net cash inflow/(outflow) from:					
Operating activities	8,742	11,739	10,680	7,821	6,948
Investing activities <sup>1</sup>	(3,881)	(2,444)	(2,226)	(2,022)	(1,859)
Financing activities <sup>1</sup>	(6,377)	(3,661)	(7,334)	(9,321)	(4,923)
	(1,516)	5,634	1,120	(3,522)	166

<sup>1</sup> Investing activities and Financing activities were restated in 2011 to reclassify cash paid in hedge contracts relating to dividend payments from Investing activities to Financing activities.

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.

### Additional Information | Development Pipeline

### Development Pipeline

as at 31 December 2012

Throughout the development process, we strive to obtain patent protection consistent with our patent process (as described in the Intellectual Property section from page 35). 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 74), 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 from page 35.

#### **Line Extensions**

				Date	Estimated Filing			
Compound	Mechanism	Area Under Investigation	Phase	Commenced Phase	US	EU	Japan	China
Cardiovascular								
Axanum	proton pump inhibitor + low dose aspirin FDC	low dose aspirin associated peptic ulcer in high-risk CV patients	III		Withdrawn	Launched	2016	
Brilinta/Brilique EUCLID	ADP receptor antagonist	outcomes study in patients with peripheral artery disease	III	4Q 2012	2016	2016	2016	2017
Brilinta/Brilique PEGASUS-TIMI 54	ADP receptor antagonist	outcomes study in patients with prior myocardial infarction	III	4Q 2010	2015	2015	2015	2017
Bydureon EXSCEL#	GLP-1 receptor agonist	outcomes study	III	2Q 2010	2018			
Bydureon Dual Chamber Pen#	GLP-1 receptor agonist	diabetes	III		3Q 2013			
Forxiga (dapagliflozin)/ metformin FDC#	SGLT2 inhibitor + metformin FDC	diabetes	III	3Q 2007		Filed		
Forxiga (dapagliflozin)#	SGLT2 inhibitor	diabetes – add on to DPP-4	III	1Q 2010		Filed		
Forxiga (dapagliflozin)#	SGLT2 inhibitor	diabetes – add on to insulin and add on to metformin long-term data	III	2Q 2008		Filed		
Forxiga (dapagliflozin)#	SGLT2 inhibitor	diabetes – in patients with high CV risk – Study 18 and 19 long-term data	III	1Q 2010		1H 2014		
Forxiga (dapagliflozin)#	SGLT2 inhibitor	diabetes – triple therapy (dapa+met+SU)	III	1Q 2011		1Q 2013		
Kombiglyze XR/ Komboglyze FDC#*	DPP-4 inhibitor + metformin FDC	diabetes	III		Launched	Launched		1H 2014
SaxaDapa FDC#	DPP-4 inhibitor/SGLT2 inhibitor	diabetes	III	2Q 2012	2015	2015		
Onglyza SAVOR-TIMI 53#	DPP-4 inhibitor	outcomes study	III	2Q 2010	4Q 2013	4Q 2013		2H 2014
Gastrointestinal								
Entocort	glucocorticoid steroid	Crohn's disease/ulcerative colitis	III		Launched	Launched	2015	
Nexium	proton pump inhibitor	peptic ulcer bleeding	III		Filed**	Launched	n/a	Launched
Neuroscience								
Diprivan#	sedative and anaesthetic	conscious sedation	III			Launched	1H 2014	Launched
Oncology								
Faslodex	oestrogen receptor antagonist	1st line advanced breast cancer	III	4Q 2012	2016	2016	2016	2016
Iressa	EGFR tyrosine kinase inhibitor	treatment beyond progression	III	1Q 2012		2015	2015	2015
Respiratory & Inflammati								
Symbicort***	inhaled steroid/long-acting beta <sub>2</sub> -agonist	Breath Actuated Inhaler asthma/COPD	III	4Q 2011	1H 2014			

Kombiglyze XR in the US; Komboglyze FDC in the EU. 2<sup>nd</sup> CRL received from FDA in 2011. AstraZeneca response submitted to FDA in December 2012.

<sup>\*\*\*</sup> Excludes Symbicort pMDI post marketing LABA in December.

# Additional Information | Development Pipeline as at 31 December 2012

#### **NCEs**

#### Phase III/Registration

				Date		Estimate	d Filing	
Compound	Mechanism	Area Under Investigation	Phase	Commenced Phase	US	EU	Japan	China
Cardiovascular								
Brilinta/Brilique	ADP receptor antagonist	arterial thrombosis	III		Launched	Launched	2Q 2013	Approved
Forxiga (dapagliflozin)#	SGLT2 inhibitor	diabetes	III		Filed*	Launched	1Q 2013	1Q 2013
metreleptin#	leptin analogue	lipodystrophy	III		2Q 2013		n/a	
Infection								
CAZ AVI# (CAZ104)	beta lactamase inhibitor/ cephalosporin	serious infections	III	1Q 2012	n/a	2H 2014	2H 2014	2016
Q-LAIV Flu Vaccination**	live, attenuated, intranasal influenza virus vaccine (quadrivalent)	seasonal influenza	III		Approved	Filed		
Zinforo# (ceftaroline)	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections	III		n/a	Launched		1H 2014
Neuroscience								
naloxegol (NKTR-118)#	oral peripherally-acting mu-opioid receptor antagonist	opioid-induced constipation	III	2Q 2011	3Q 2013	3Q 2013		
Oncology								
Caprelsa	VEGFR/EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer	III		Launched	Launched	2015	Filed
Respiratory & Inflamma	tion							
brodalumab#	anti-IL-17R MAb	psoriasis	III	3Q 2012	2015	2015		
fostamatinib#	spleen tyrosine kinase (SYK) inhibitor	rheumatoid arthritis	III	3Q 2010	4Q 2013	4Q 2013		
lesinurad	selective inhibitor of URAT1	chronic management of hyperuricaemia in patients with gout	III	4Q 2011	1H 2014	1H 2014	2017	2017

#### Phases I and II

				Date Commenced ——	Estimated Filing			
Compound	Mechanism	Area Under Investigation	Phase	Phase	US	EU	Japan	China
Cardiovascular								
AZD1722#	NHE3 inhibitor	end stage renal disease/chronic kidney disorder	I	4Q 2010				
Gastrointestinal								
tralokinumab	anti-IL-13 MAb	ulcerative colitis	II	2Q 2012				
Infection							,	
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	4Q 2012				
CXL#	beta lactamase inhibitor/ cephalosporin	MRSA	II	4Q 2010				
ATM AVI	BL/BLI	targeted serious bacterial infections	I	4Q 2012				
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	2Q 2006				
MEDI-557	anti-RSV MAb – extended half-life	RSV prevention in high-risk adults (COPD/CHF/other)	I	3Q 2007				
MEDI-559	paediatric RSV vaccine	RSV prophylaxis	I	4Q 2008				
Neuroscience								
AZD3241	myeloper-oxidase (MPO) inhibitor	Parkinson's disease	II	2Q 2012				
AZD3480#	alpha <sub>4</sub> /beta <sub>2</sub> neuronal nicotinic receptor agonist	Alzheimer's disease	II	3Q 2007				
AZD5213	histamine-3 receptor antagonist	Alzheimer's disease	II	2Q 2012				
AZD6765	NMDA receptor antagonist	major depressive disorder	II	3Q 2007				
AZD1446#	alpha <sub>4</sub> /beta <sub>2</sub> neuronal nicotinic receptor agonist	Alzheimer's disease	I	4Q 2008				
AZD3293#	beta-secretase	Alzheimer's disease	I	4Q 2012				
MEDI5117	anti-IL6 MAb	rheumatoid arthritis	- 1	2Q 2012				

<sup>\*</sup> Partnered product.
\* CRL received in January 2012.
\*\* sBLA in US; MAA in EU.

#### **NCEs**

#### Phases I and II continued

				Date Commenced ——		Estimated I	-iling	
Compound	Mechanism	Area Under Investigation	Phase	Phase	US	EU	Japan	Chin
Oncology								
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	4Q 2011				
ostamatinib#	spleen tyrosine kinase (SYK) inhibitor	haematological malignancies	II	1Q 2012				
MEDI-551#	anti-CD19 MAb	haematological malignancies	II	1Q 2012				
MEDI-573#	anti-IGF MAb	metastatic breast cancer	II	4Q 2011				
MEDI-575#	anti-PDGFR-alpha MAb	non-small cell lung cancer	II	2Q 2011				
olaparib	PARP inhibitor	gBRCAm ovarian cancer, gBRCAm breast cancer, gastric cancer	II	1Q 2012				
selumetinib# (AZD6244) (ARRY-142886)	MEK inhibitor	solid tumours	II	4Q 2006				
remelimumab	anti-CTLA4 MAb	solid tumours	II	3Q 2004				
AZD1208	PIM kinase inhibitor	haematological malignancies	I	1Q 2012				
AZD2014	TOR kinase inhibitor	solid tumours	I	1Q 2010				
AZD5363#	AKT inhibitor	solid tumours	I	4Q 2010				
AZD8330# (ARRY 424704)	MEK inhibitor	solid tumours	- 1	1Q 2007				
AZD9150	STAT3 inhibitor	haematological malignancies	I	1Q 2012				
MEDI0639#	anti-DLL-4 MAb	solid tumours	-	2Q 2012				
MEDI3617#	anti-ANG-2 MAb	solid tumours	1	4Q 2010				
MEDI4736#	anti-PD-L1 MAb	solid tumours	-	3Q 2012				
MEDI-565#	anti-CEA BiTE	solid tumours	I	1Q 2011				
MEDI6469#	murine anti-OX40 MAb	solid tumours	I	1Q 2006				
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	haematological malignancies	I	2Q 2007				
volitinib#	MET inhibitor	solid tumours	1	1Q 2012				
Respiratory & Inflammat								
AZD2115#	MABA	COPD		2Q 2012				
AZD5069	CXCR2	asthma	11	4Q 2010				
AZD5423#	inhaled SGRM	COPD		4Q 2010				
benralizumab#	anti-IL-5R MAb	asthma/COPD		4Q 2008				
mavrilimumab#	anti-GM-CSFR MAb	rheumatoid arthritis		1Q 2010				
MEDI-546#	anti-IFN-alphaR MAb	SLE.	II	1Q 2012				
MEDI7183#	anti-a4b7 MAb	Crohn's disease/ulcerative colitis		4Q 2012				
MEDI8968#	anti-IL-1R MAb	COPD		4Q 2011				
sifalimumab#	anti-IFN-alpha MAb	SLE		3Q 2008				
tralokinumab	anti-IL-13 MAb	asthma/IPF		1Q 2008				
AZD8848#	inhaled TLR7	asthma		2Q 2012				
AZD7594#	inhaled SGRM	COPD	<u> </u>	4Q 2012				
MEDI2070#	anti-IL-23 MAb	Crohn's disease	<u> </u>	2Q 2010				
MEDI4212	anti-IgE MAb	asthma	i	1Q 2012				
MEDI-551#	anti-CD19 MAb	multiple sclerosis	<u> </u>	3Q 2012				
MEDI5872#	anti-B7RP1 MAb	SLE	<u> </u>	4Q 2008				
MEDI7814	anti-C5/C5a MAb	COPD	<u> </u>	1Q 2012				
MEDI9929#	anti-TSLP MAb	asthma	<u></u>	4Q 2008				
RDEA3170	selective inhibitor of URAT1	chronic management of hyperuricaemia in patients with gout	1	3Q 2011				

<sup>\*</sup> Partnered product.

#### Comments

Submission dates shown for assets in Phase III and beyond.

### Additional Information | Development Pipeline

as at 31 December 2012

#### Discontinued Projects between 31 December 2011 and 31 December 2012

NCE/Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
Cardiovascular			
NCE	AZD2820	Safety/Efficacy	obesity
NCE	AZD4017	Safety/Efficacy	glaucoma
NCE	AZD2927	Safety/Efficacy	atrial fibrillation
Infection			
NCE	AZD9773	Safety/Efficacy	severe sepsis
NCE	AZD5099	Safety/Efficacy	serious infections
NCE	MEDI-534	Safety/Efficacy	RSC/PIV prophylaxis
Neuroscience			
NCE	AZD2423	Safety/Efficacy	chronic neuropathic pain
NCE	AZD3839	Safety/Efficacy	Alzheimer's disease
NCE	MEDI-578	Regulatory	OA pain
NCE	TC-5214	Safety/Efficacy	major depressive disorder (monotherapy)
NCE	TC-5214	Safety/Efficacy	major depressive disorder (adjunct)
Oncology		,	
NCE	AZD1480	Safety/Efficacy	solid tumours
NCE	AZD3514	Safety/Efficacy	prostate cancer
NCE	AZD8931	Safety/Efficacy	breast cancer chemo. combi./solid tumours
NCE	selumetinib (AZD6244) (ARRY-142886)/MK2206#	Study completed	solid tumours
Respiratory & Inflammation			
NCE	AZD8683	Safety/Efficacy	COPD
NCE	MEDI-570	Safety/Efficacy	SLE
NCE	AZD1981	Safety/Efficacy	asthma/COPD
NCE	AZD2423	Safety/Efficacy	COPD

<sup>#</sup> Partnered product.

#### **Completed Projects**

			Launch Status				
Compound	Mechanism	Area Under Investigation	US	EU		China	
Cardiovascular							
Crestor#	statin	outcomes in subjects with elevated CRP	Launched	Launched		Launched	
Gastrointestinal							
Nexium	proton pump inhibitor	GERD	Launched	Launched	Launched	Launched	
Infection							
FluMist/Fluenz	live, attenuated, intranasal influenza virus vaccine	influenza	Launched	Launched			
Neuroscience							
EMLA	local anaesthetic	topical anaesthesia		Launched	Launched		
Oncology							
Iressa	EGFR tyrosine kinase inhibitor	1st line EGFR mut+ NSCLC		Launched	Launched	Launched	
Faslodex	oestrogen receptor antagonist	high dose (500mg) 2 <sup>nd</sup> line advanced breast cancer	Launched	Launched	Launched		
Ranmark# (denosumab)	anti-RANKL MAb	bone disorders stemming from bone metastasis			Launched		
Respiratory & Inflamma	ition						
Oxis	long-acting beta <sub>2</sub> -agonist	COPD		Launched	Launched	Launched	
Symbicort	inhaled steroid/long-acting beta2-agonist	COPD	Launched	Launched	Launched	Launched	
Symbicort	inhaled steroid/long-acting beta2-agonist	SMART		Launched	Launched	Launched	

<sup>#</sup> Partnered product.

#### 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.

### Additional Information | Shareholder Information

### Shareholder Information

#### AstraZeneca PLC share listings and prices

	2008	2009	2010	2011	2012
Ordinary Shares in issue – millions					
At year end	1,447	1,451	1,409	1,292	1,247
Weighted average for year	1,453	1,448	1,438	1,361	1,261
Stock market price – per Ordinary Share					
Highest (pence)	2888	2947	3385	3194	3111.5
Lowest (pence)	1748	2147	2732	2543.5	2591
At year end (pence)	2807	2910.5	2922	2975	2909.5

#### Percentage analysis of issued share capital at 31 December

By size of account Number of Ordinary Shares	2008 %	2009 %		2011 %	2012 %
1 – 250	0.5	0.5	0.5	0.6	0.6
251 – 500	0.7	0.7	0.6	0.7	0.7
501 – 1,000	0.9	0.8	0.8	0.8	0.8
1,001 – 5,000	1.2	1.1	1.1	1.2	1.1
5,001 – 10,000	0.2	0.2	0.2	0.2	0.2
10,001 – 50,000	1.0	1.1	1.0	1.0	1.0
50,001 – 1,000,000	13.6	13.0	12.8	13.8	12.6
Over 1,000,000 <sup>1</sup>	81.9	82.6	83.0	81.7	83.0

<sup>&</sup>lt;sup>1</sup> Includes Euroclear and ADR holdings

At 31 December 2012, the Company had 111,111 registered holders of 1,246,779,548 Ordinary Shares. There were 122,617 holders of Ordinary Shares held under the Euroclear Services Agreement, representing 12.9% of the issued share capital of the Company and approximately 235,000 holders of ADRs, representing 11.0% 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 2012, under AstraZeneca's share repurchase programme, which was introduced in 1999, 57.8 million Ordinary Shares were repurchased and subsequently cancelled at a total cost of \$2,635 million, representing 4.6% of the total issued share capital of the Company at 31 December 2012. The average price paid per Ordinary Share in 2012 was 2879 pence. This brings the total number of Ordinary Shares repurchased to date since the beginning of the repurchase programme in 1999, to 615.2 million Ordinary Shares (at an average price of 2777 pence per Ordinary Share) for a consideration, including expenses, of \$29,352 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 in 2012 totalled 12.2 million. The Company suspended its share repurchase programme effective 1 October.

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.

### Additional Information | Shareholder Information

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 2011 and 2012, the reported high and low share prices of the Company, on the following bases:

- > For shares listed on the LSE, the reported high and low middle market closing quotations are derived from the Daily Official List.
- > For shares listed on the SSE, the high and low closing sales prices are as stated in the Official List.
- > For ADSs listed on the NYSE, the reported high and low sales prices are as reported by Dow Jones (ADR quotations).

		Ordinar	y LSE	Ordinary	SSE	ADS	
		High (pence)	Low (pence)	High (SEK)	Low (SEK)	High (US\$)	Low (US\$)
2011	- Quarter 1	3073.5	2801.5	320.6	289.0	49.38	45.40
	- Quarter 2	3194.0	2895.0	328.5	294.2	52.40	46.60
	- Quarter 3	3166.5	2543.5	324.5	269.3	51.08	40.95
	- Quarter 4	3080.5	2731.5	319.0	293.7	49.89	42.53
2012	- Quarter 1	3111.5	2778.5	329.5	294.5	48.58	44.18
	- Quarter 2	2867.0	2591.0	309.3	286.2	46.22	40.03
	- Quarter 3	3096.0	2882.0	326.4	307.3	48.36	45.01
	- Quarter 4	3042.5	2792.5	326.3	300.8	48.90	44.34
	– July	3002.5	2882.0	326.4	311.8	47.34	45.01
	- August	3096.0	2936.5	324.8	309.0	48.21	46.79
	- September	2976.0	2888.5	316.9	307.3	48.36	46.34
	- October	2951.0	2860.0	313.2	307.0	47.63	45.82
	- November	2966.5	2792.5	316.7	300.8	47.55	44.34
	- December	3042.5	2909.5	326.3	306.4	48.90	46.88

#### **Major shareholdings**

At 31 January 2013, 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	8.08
Invesco Limited	72,776,277	6 October 2009	5.83
Axa SA	56,991,117	3 February 2009	4.57
Investor AB	51,587,810	2 February 2012	4.13
Legal & General Investment Management Limited	57,675,232	5 August 2010	4.62

<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).

So far as the Company is aware, 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 capital		
Shareholder	31 Jan 2013	2 Feb 2012	27 Jan 2011	28 Jan 2010
BlackRock, Inc.	8.08	7.87	7.18	6.94
Invesco Limited	5.83	5.67	5.18	5.01
Axa SA	4.57	4.44	4.06	3.92
Investor AB	4.13	4.02	3.67	3.55
Legal & General Investment Management Limited	4.62	4.50	4.10	4.64

ADSs evidenced by ADRs issued by JPMorgan, as depositary, are listed on the NYSE. At 31 January 2013, the proportion of Ordinary Shares represented by ADSs was 11.17% of the Ordinary Shares outstanding.

Number of registered holders of Ordinary Shares at 31 January 2013:

> In the US 743 > Total 110,421

Number of record holders of ADRs at 31 January 2013:

> In the US 2,103 > Total 2,122

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 31 January 2013, 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	274,159	0.02

The Company does not know of any arrangements, the operation of which might result in a change in the control of the Company.

#### **Related party transactions**

During the period 1 January 2013 to 31 January 2013, 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 31 January 2013, options outstanding to subscribe for Ordinary Shares were:

Number of shares	Subscription price (pence)	Normal expiry date
19,572,351	1882 – 3335	2013 - 2019

The weighted average subscription price of options outstanding at 31 January 2013 was 2542 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
299,060	1882 – 3335	2014 - 2019

(c) Included in paragraph (b) are options granted to individually named Directors. Details of these option holdings at 31 December 2012 are shown in the Share option plans table on page 137.

During the period 1 January 2013 to 31 January 2013, 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 2012, payable on 18 March 2013, is 15 February 2013 and the ex-dividend date is 13 February 2013.

The record date for the first interim dividend for 2013, payable on 16 September 2013, is 16 August 2013.

Future dividends will normally be paid as follows:

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

#### **Shareview**

The Company's shareholders with internet access may visit the website, shareview.co.uk, and register their details to create a portfolio. Shareview is a free and secure online service from the Company's registrars, Equiniti Limited, which gives access to shareholdings, including balance movements, indicative share prices and information about recent dividends.

#### **ShareGift**

The Company welcomes and values all of its shareholders, no matter how many or how few shares they own. However, shareholders who have only a small number of shares whose value makes it uneconomic to sell them, either now or at some stage in the future, may wish to consider donating them to charity through ShareGift, an independent charity share donation scheme. One feature of the scheme is that there is no gain or loss for UK capital gains tax purposes on gifts of shares through ShareGift, and it may now also be possible to obtain UK income tax relief on the donation. Further information about ShareGift can be found on its website, sharegift.org, or by contacting ShareGift on 020 7930 3737 or at 17 Carlton House Terrace, London SW1Y 5AH. ShareGift is administered by The Orr Mackintosh Foundation, registered charity number 1052686. More information about the UK tax position on gifts of shares to ShareGift can be obtained from HM Revenue & Customs on their website, hmrc.gov.uk.

#### **The Unclaimed Assets Register**

The Company supplies unclaimed dividend data to the Unclaimed Assets Register (UAR), which provides investors who have lost track of shareholdings with an opportunity to search the UAR's database of unclaimed financial assets on payment of a small fixed fee. The UAR donates part of the search fee to charity. The UAR can be contacted on 0870 241 1713 or at PO Box 9501, Nottingham NG80 1WD.

#### Results

Unaudited trading results of AstraZeneca in respect of the first three months of 2013 will be published on 25 April 2013 and results in respect of the first six months of 2013 will be published on 1 August 2013.

### Additional Information | 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 US). 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 the 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 converted into US dollars after 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 may be taxable at favourable US federal income tax rates. 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 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 2012. 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 may be subject to information reporting and 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 Internal Revenue Service (IRS) on time.

Certain US resident holders who are individuals (and under proposed US Treasury regulations, certain entities), may be required to report information relating to securities issued by non-US persons (or foreign accounts through which the securities are held), generally on IRS Form 8938, subject to certain exceptions (including an exception for securities held in accounts maintained by 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 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 charge to UK stamp duty or UK stamp duty reserve tax (SDRT) may arise on the deposit of Ordinary Shares in connection with the creation of ADRs. The rate of stamp duty or SDRT will generally be 1.5% of the value of the consideration or, in some circumstances, the value of the Ordinary Shares. However, following a recent ruling in the UK, there is no 1.5% SDRT charge on the issue of Ordinary Shares (or, where it is integral to the raising of new capital, the transfer of Ordinary Shares) into the ADR arrangement.

No UK stamp duty will be payable on the acquisition or transfer of existing ADRs provided that any instrument of transfer or written agreement to transfer is executed outside the UK and remains at all times outside the UK. An agreement for the transfer of ADRs will not give rise to a liability for SDRT.

A transfer of or an agreement to transfer Ordinary Shares will generally be subject to UK stamp duty or SDRT at 0.5% of the amount or value of any consideration, provided, in the case of stamp duty, it is rounded to the nearest £5.

Transfers of Ordinary Shares into CREST will generally not be subject to stamp duty or SDRT unless such a transfer is made for a consideration in money or money's worth, in which case a liability to SDRT will arise, usually at the rate of 0.5% of the value of the consideration. Paperless transfers of Ordinary Shares within CREST are generally liable to SDRT at the rate of 0.5% of the value of the consideration. CREST is obliged to collect SDRT from the purchaser on relevant transactions settled within the system.

#### 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)		
2010	7.2504	1.5453
2011	6.5059	1.5996
2012	6.7782	1.5834
End of year spot rates (statement of financial position)		
2010	6.7511	1.5422
2011	6.9050	1.5443
2012	6.5176	1.6171

### Additional Information | Corporate Information

### 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.

In 2007, the Group acquired MedImmune, a biologics and vaccines business based in the US.

The Group owns and operates numerous R&D, production and marketing facilities worldwide. Its corporate office is at 2 Kingdom Street, London W2 6BD.

#### Articles Objects

The Company's objects are 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 at least \$125, which currently represents 500 shares.

## Rights, preferences and restrictions attaching to shares

As at 31 December 2012, the Company had 1,246,779,548 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 2012 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 are fit for their purpose.

### Additional Information | Glossary

### Glossary

#### **Market definitions**

United States of America	Other Established Markets		Emerging Markets		
US	Western Europe	Japan	Emerging Europe	China	Other Emerging ROW
	Austria		Albania*		Egypt
	Belgium	Canada	Belarus*	Emerging Asia Pacific	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\*.

\*\*MIS Health, IMS Midas Quantum Q3 2012 data is not available or AstraZeneca does not subscribe for IMS Health quarterly data for these countries. The above table is not an exhaustive list of all the countries in which AstraZeneca operates.

#### **US** equivalents

Terms used in this Annual Report	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

### Additional Information | Glossary

#### **Glossary**

The following abbreviations and expressions have the following meanings when used in this Annual Report:

**Abbott** – Abbott Laboratories, Inc. with respect to *Crestor* and *Synagis*.

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.

Amgen - Amgen, Inc.

**Amylin** – Amylin Pharmaceuticals, LLC (formerly Amylin Pharmaceuticals, Inc.).

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 2012.

API - active pharmaceutical ingredient.

Ardea - Ardea Biosciences, Inc.

Ardelyx - Ardelyx, Inc.

Articles – the Articles of Association of the Company. 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.

**biologic(s)** – a class of drugs based on large protein molecules that have a therapeutic effect.

**biosimilar(s)** – a copy of a biologic that is sufficiently similar to meet regulatory requirements, which can compete with patented biologics once they have come off patent.

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.

 $\ensuremath{\text{CFO}}$  – 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 (CIA) – the agreement described in the US Corporate Integrity Agreement reporting section on page 39.

**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.

**EFPIA** – European Federation of Pharmaceutical Industries and Associations.

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.

GAAP – Generally Accepted Accounting Principles.

 $\label{eq:GERD-gastro} \textbf{GERD}-\text{gastro oesophageal reflux disease}.$ 

**GI** – gastrointestinal.

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.

HR - human resources.

IAS - International Accounting Standards.

IAS 19 - IAS 19 Employee Benefits.

IAS 32 – IAS 32 Financial Instruments: Presentation. IAS 39 – IAS 39 Financial Instruments: Recognition and Measurement.

IASB – International Accounting Standards Board. IFRS – International Financial Reporting Standards or International Financial Reporting Standard, as the context requires.

IFRS 8 - IFRS 8 Operating Segments.

IP - intellectual property.

Ironwood - Ironwood Pharmaceuticals, Inc.

IS - information services.

IT – information technology.

**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.).

**NDA** – a new drug application to the FDA for approval to market a new medicine in the US.

NCE - new chemical entity.

Novartis - Novartis Pharma A.G.

Novexel - Novexel S.A.

NSAID - a non-steroidal anti-inflammatory drug.

 $\label{eq:NYSE-the-New York Stock Exchange} \textbf{NYSE-} the New York Stock Exchange.$ 

n/m - not meaningful.

**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).

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 begin to determine the safety profile of the drug. Phase II studies are typically conducted in a relatively small number of patients and can be divided into Phase IIa studies, which tend to be designed to assess dosing requirements, and Phase IIb studies, which tend to assess safety and efficacy.

Phase III – the phase of clinical research which is performed to gather additional information about effectiveness and safety of the drug, often in a comparative setting, to evaluate the overall benefit/risk profile of the drug. Phase III studies usually include between several hundred and several thousand patients.

pounds sterling, £, GBP, pence or p – references to the currency of the UK.

Pozen - POZEN INC.

**primary care** – general healthcare provided by physicians who generally have first contact with patients and who may have continuing care for them.

**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. **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 35.

Regulatory Exclusivity – any of the IP rights arising from generation of clinical data and includes Regulatory Data Protection, Paediatric Exclusivity and Orphan Drug status.

Responsible Business Plan – the plan described in the Responsible Business section from page 48, further details of which can be found at our website, astrazeneca.com/responsible/management-and-measurement/responsible-business-plan.

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 franchise – Seroquel IR and Seroquel XR.

SET - 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.

SOP – AstraZeneca Share Option Plan. specialty care – specific healthcare provided by medical specialists who do not generally have first contact with patients.

Targacept - Targacept, Inc.

Teva – Teva Pharmaceuticals USA, Inc.

TKI - tyrosine kinase inhibitor.

**TSR** – total shareholder return, being the total return on a share over a period of time, including dividends reinvested

**UK** – United Kingdom of Great Britain and Northern Ireland

**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 - United States of America.
US dollar, US\$, USD or \$ - references to the currency of the US

**WHO** – the World Health Organization, the United Nations' specialised agency for health.

### Additional Information | Trade marks

#### **Trade marks**

AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trade marks of the AstraZeneca group of companies.

The following brand names which appear in italics in this Annual Report are trade marks of the Group:

Trade mark	Comments
Accolate	
Arimidex	
Atacand	Atacand Plus in rest of world (not in the US or the EU)
Axanum	Not in the US
Brilinta	In the US and rest of world (not in the EU)
Brilique	In the EU
Caprelsa	
Casodex	
Crestor	
Diprivan	
EMLA	Not in the US or the EU
Entocort	
Faslodex	
FluMist	In the US and the rest of world. Fluenz in the EU.
Iressa	
Merrem	Meronem in the EU and rest of world (not in the US)
Naropin	Not in the US or the EU
Nexium	
Nolvadex	
Oxis Turbuhaler	Not in the US or the EU
Plendil	
Losec/Prilosec	In the EU and rest of world (not in the US). Prilosec in the US
Pulmicort	
Pulmicort Respules	
Pulmicort Turbuhaler	
Rhinocort	
Seloken Zoc	Not in the US. Seloken, Seloken XL, Seloken Zoc or Seloken Zok in rest of world (not in the US or the EU)
Seroquel	
Seroquel IR	
Seroquel XR	
Symbicort	
Symbicort SMART	Not in the US
Symbicort Turbuhaler	Not in the US or the EU
Synagis	In the US. Abbott owns the trade mark for Synagis in rest of world (not in the US or the EU)
Tenormin	
Toprol-XL	In the US. Seloken/Betaloc Zok in rest of world (not in the US or the EU)
Vimovo	
Xylocaine	Not in the US or the EU
Zestril	
Zoladex	
Zomig	Not in the US
The following brand name	s which appear in italics in this Annual Report are trade marks licensed to the Group by the entities set out below:

Trade mark	Owner	Comments
Bydureon	Amylin – North & South Americas; AstraZeneca – rest of world (not in the US or the EU)	Ownership dependent upon geography
Byetta	Amylin – North & South Americas; AstraZeneca – rest of world (not in the US or the EU)	Ownership dependent upon geography
Cubicin	Cubist Pharmaceuticals, Inc.	
Forxiga	BMS	
Kombiglyze XR	BMS	
Kombiglyze	BMS	
Komboglyze	BMS	
Linzess	Ironwood	Brand name for linaclotide in the US
Onglyza	BMS	
Ranmark	Daiichi Sankyo Company, Limited	
Symlin	Amylin – North & South Americas; AstraZeneca Pharmaceuticals LP – rest of world (not in the US or the EU)	Ownership dependent upon geography
Teflaro	Forest	Brand name for ceftaroline in the US
Zinforo	Forest	Ownership of Zinforo trade mark was assigned from AstraZeneca to Forest in April 2012

The following brand names which appear in italics throughout this Annual Report are not owned by or licensed to the Group and are owned by the entities set out below:

Trade mark	Owner
Lipitor	Pfizer Ireland Pharmaceuticals
Plavix	Sanofi

### Additional Information | Index

2012 performance summary	24
Accounting policies	146, 194
Acquisitions and disposals	173
Amgen	31, 55, 68, 93
	31, 55, 71, 93, 161
Annual general meeting	121, 208
Ardea	31, 69, 90, 173
Articles of association	206, 208
Astra Tech	174
Audit Committee	75, 115
Biologics Board	17, 19, 30 106, 110
Branches	120
Business background	120
and results overview	86
Capitalisation	94
Cardiovascular	52
Cash and cash equivalents	148, 164
Chairman's Statement	6
Chief Executive Officer's Review	8
Clinical Trials	33, 34
Code of Conduct	47
Commitments and contingent liabilitie	s 183
Community Investment	49
Company history	203, 208
Competition	16, 78
Compliance and	
Group Internal Audit	47, 75, 115
Consolidated statement of Cash Flows	1/15
Consolidated statement	145
of Changes in Equity	144
Consolidated statement	
of Comprehensive Income	142
Consolidated statement	
of Financial Position	143
Corporate governance	104
Diabetes	52, 54
Directors' interest in shares	134
Directors' remuneration	122
Directors' responsibility statement	140
Diversity	43, 44
Dividends	7, 94, 173, 205
Earnings per ordinary share	5, 154
Emerging Markets	13, 73, 77, 209
Employee costs and share plans for employees	179
Established Markets	38, 72, 209
Ethics	33, 39, 47
Finance income and expense	152
Financial instruments	148, 166
Financial position 2011	97
Financial position 2012	92
Financial risk management	99, 175
Financial summary	2
Gastrointestinal	56
Glossary	209
	2, 97, 101, 147, 158
Group Financial Record	198
Group Financial Statements	140
Growth drivers	16
Human Rights	45
Independent auditor's report	141, 192
Infection	58
Inflammation see Respirat	ory & Inflammation

Intaliable assets         92, 97, 101, 159           Intellectual Property         35           Interest-bearing loans         164           Inventories         148, 163           Ironwood         31,57           Key performance indicators         26           Leases         148, 190           Liftocycle of a medicine         14           Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         Governance Committee         117           Oncology         65           Operational overview         4           Other investments         148, 163           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Priocipal risks and uncertainties         75           Product revenue information         150           Provisions for liabilities a		
Interest-bearing loans and borrowings 164 Inventories 148, 163 Ironwood 31, 57 Key performance indicators 26 Leases 148, 190 Lifecycle of a medicine 14 Litigation 102, 149, 184 Market definitions 209 Medicines 2, 14, 30, 50 Neuroscience 61 Nomination and Governance Committee 117 Oncology 65 Operating profit 2, 4, 89, 150 Operational overview 4, 4 Other investments 148, 163 Patents see Intellectual Property Patient safety 34 People 5, 24, 28, 43, 179 Pharmaceutical industry 16 Pipelline 4, 24, 26, 30, 51, 199 Political donations 120 Portfolio Investment Board 119 Post-retirement benefits 102, 131, 167 Pricing 18, 38 Principal risks and uncertainties 75 Product revenue information 150 Property, plant and equipment 148, 157 Provisions for liabilities and charges 167 Regulatory requirements 190, 205 Relations with shareholders 117 Research and Development 30, 147, 151 Reserves 171 Respiratory & Inflammation 67 Responsible Business 28, 48 Restructuring 21, 151 Results of operations 2012 89 Revised Core financial measures 97 Safety, health and wellbeing 46 Sales and Marketing 37 Sales by geographical area 50 Science Committee 118 Segment information 150 Science Committee 118 Science Committee 119 Science Committee 11	Intangible assets	92, 97, 101, 159
and borrowings         164           Inventories         148, 163           Ironwood         31, 57           Key performance indicators         26           Leases         148, 190           Lifecycle of a medicine         14           Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         30           Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patients         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portrolial investment Board         1919           Portrolial investment Board         1919           Pricing         18, 38           Pricing         18, 38           Pricing         18, 38 <td>Intellectual Property</td> <td>35</td>	Intellectual Property	35
Inventories	Interest-bearing loans	
Ironwood   31, 57     Key performance indicators   26     Leases   148, 190     Lifecycle of a medicine   14     Litigation   102, 149, 184     Market definitions   209     Medicines   2, 14, 30, 50     Neuroscience   61     Nomination and     Governance Committee   117     Oncology   65     Operating profit   2, 4, 89, 151     Operating profit   2, 4, 89, 151     Operational overview   4     Other investments   148, 163     Patents   see Intellectual Property     Patient safety   34     People   5, 24, 28, 43, 179     Pharmaceutical industry   16     Pipelline   4, 24, 26, 30, 51, 199     Political donations   120     Portfolio Investment Board   119     Post-retirement benefits   102, 131, 167     Pricing   18, 38     Principal risks and uncertainties   75     Product revenue information   150     Property, plant and equipment   148, 157     Provisions for liabilities and charges   167     Regulatory requirements   17     Related party transactions   190, 205     Relations with shareholders   114     Remuneration Committee   117     Research and Development   30, 147, 151     Respiratory & Inflammation   67     Respiratory & Inflammation   150     Safety, health and wellbeing   36     Sales by Goperations 2012   89     Revised Core financial measures   97     Sales by Therapy Area   50     Science Committee   118     Segment information   190     Strategy   20     Subsidiaries   191     Supply and Manufacturing   40     Taxation and other poevables   148, 164     Trade and other receivables   148, 164     Trade and other	and borrowings	164
Key performance indicators         26           Leases         148, 190           Lifecycle of a medicine         14           Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulated party transactions         190, 205 <tr< td=""><td>Inventories</td><td>148, 163</td></tr<>	Inventories	148, 163
Leases         148, 190           Lifecycle of a medicine         14           Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipelline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulated party transactions         190, 205           Relations with shareholders         114	Ironwood	31, 57
Leases         148, 190           Lifecycle of a medicine         14           Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipelline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulated party transactions         190, 205           Relations with shareholders         114	Key performance indicators	
Lifecycle of a medicine         14           Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         Governance Committee           Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Portfolio Investment Board         119           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Property, plant and equipments         16           Regulatory requirements         17           Related party transact	-	
Litigation         102, 149, 184           Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patients afety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Property, plant and equipments         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114		
Market definitions         209           Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         117           Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Resear		
Medicines         2, 14, 30, 50           Neuroscience         61           Nomination and         61           Oocorrance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Porticing         18, 38           Pricingal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Re		
Neuroscience         61           Nomination and         Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Property, plant and equipment         148, 157           Property, plant and equipment         148, 157           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development		
Nomination and Governance Committee	Medicines	2, 14, 30, 50
Governance Committee         117           Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48	Neuroscience	61
Oncology         65           Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Property, plant and equipment         148, 157           Property, plant and equipments         167           Regulatory requirrements         17           Related party transactions         190, 205           Regulatory requirrements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         3	Nomination and	
Operating profit         2, 4, 89, 151           Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Property, plant and equipment         148, 157           Property, plant and equipments         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151 <td>Governance Committee</td> <td>117</td>	Governance Committee	117
Operational overview         4           Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Regulatory requirements         17           Regulatory with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Revised Core financial measures         97	Oncology	65
Other investments         148, 163           Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Related party transactions         190, 205 <td>Operating profit</td> <td>2, 4, 89, 151</td>	Operating profit	2, 4, 89, 151
Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing	Operational overview	4
Patents         see Intellectual Property           Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing	Other investments	148, 163
Patient safety         34           People         5, 24, 28, 43, 179           Pharmaceutical industry         16           Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area		
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Pipeline         4, 24, 26, 30, 51, 199           Political donations         120           Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Share repurchase <t< td=""><td></td><td></td></t<>		
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Portfolio Investment Board         119           Post-retirement benefits         102, 131, 167           Pricing         18, 38           Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share repurchase <td< td=""><td></td><td></td></td<>		
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Principal risks and uncertainties         75           Product revenue information         150           Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Responsible Business         28, 48           Restructuring         21, 151           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155 <t< td=""><td>Post-retirement benefits</td><td>102, 131, 167</td></t<>	Post-retirement benefits	102, 131, 167
Product revenue information 150 Property, plant and equipment 148, 157 Provisions for liabilities and charges 167 Regulatory requirements 17 Related party transactions 190, 205 Relations with shareholders 114 Remuneration Committee 117 Research and Development 30, 147, 151 Reserves 171 Respiratory & Inflammation 67 Responsible Business 28, 48 Restructuring 21, 151 Results of operations 2011 95 Results of operations 2012 89 Revised Core financial measures 97 Safety, health and wellbeing 46 Sales and Marketing 37 Sales by geographical area 50 Science Committee 118 Segment information 155 Senior Executive Team 108, 118 Share capital 172, 196, 203 Share repurchase 7, 94, 173, 196 Statutory and other information 190 Strategy 20 Subsidiaries 191 Taxation 194, 166 Trade and other payables 148, 166 Trade and other receivables 148, 164 Trade marks 211 Transactions with directors 133	Pricing	18, 38
Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation information for shareholders         206 <td>Principal risks and uncertainties</td> <td>75</td>	Principal risks and uncertainties	75
Property, plant and equipment         148, 157           Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation information for shareholders         206 <td>Product revenue information</td> <td>150</td>	Product revenue information	150
Provisions for liabilities and charges         167           Regulatory requirements         17           Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Research search and Development         30, 147, 151           Research and Development         30, 147, 151           Responsible Business         28, 48           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Results of operations 2011         97           Results of operations 2012         89           Results of operations 2011         95           Results of operations 2011         93           Results of operations 2012         89           Results of operations 2012         89           Results of operations 2011         95           Sales by geographical area         70		
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Related party transactions         190, 205           Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Respiratory & Inflammation         67           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166     <		
Relations with shareholders         114           Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Respiratory & Inflammation         67           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166      <		
Remuneration Committee         117           Research and Development         30, 147, 151           Reserves         171           Respiratory & Inflammation         67           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164 <td></td> <td></td>		
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Respiratory & Inflammation         67           Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Research and Development	30, 147, 151
Responsible Business         28, 48           Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Reserves	171
Restructuring         21, 151           Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Respiratory & Inflammation	67
Results of operations 2011         95           Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Responsible Business	28, 48
Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Restructuring	21, 151
Results of operations 2012         89           Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Results of operations 2011	95
Revised Core financial measures         97           Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
Safety, health and wellbeing         46           Sales and Marketing         37           Sales by geographical area         70           Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
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Sales by Therapy Area         50           Science Committee         118           Segment information         155           Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
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Senior Executive Team         108, 118           Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Science Committee	118
Share capital         172, 196, 203           Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Segment information	155
Share repurchase         7, 94, 173, 196           Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Senior Executive Team	108, 118
Statutory and other information         190           Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Share capital	172, 196, 203
Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133	Share repurchase	7, 94, 173, 196
Strategy         20           Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
Subsidiaries         191           Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
Supply and Manufacturing         40           Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
Taxation         99, 103, 147, 152, 189, 194           Taxation information for shareholders         206           Trade and other payables         148, 166           Trade and other receivables         148, 164           Trade marks         211           Transactions with directors         133		
Taxation information for shareholders     206       Trade and other payables     148, 166       Trade and other receivables     148, 164       Trade marks     211       Transactions with directors     133		
Trade and other payables148, 166Trade and other receivables148, 164Trade marks211Transactions with directors133		
Trade and other receivables     148, 164       Trade marks     211       Transactions with directors     133		
Trade marks     211       Transactions with directors     133	Trade and other payables	148, 166
Transactions with directors 133	Trade and other receivables	148, 164
	Trade marks	211
World pharmaceutical markets	Transactions with directors	133
vvona priarriaceatical markets 16	World pharmaceutical markets	16

#### 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 advisers 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 75 of this Annual Report. Nothing in this Annual Report should be construed as a profit forecast.

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

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 2012 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 2012; such data is not adjusted for Medicaid and similar 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 54 countries contained in the IMS Health MIDAS Quantum database, which amounted to approximately 92% (in value) of the countries audited by IMS Health.

#### AstraZeneca websites

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

#### External/third party websites

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

#### **Figures**

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



This Annual 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 the 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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