

ASTRAZENECA PLC  
Form 6-K  
March 25, 2013

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For the month of March 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b):  
82-\_\_\_\_\_

## ANNUAL FINANCIAL REPORT

AstraZeneca PLC (the Company) announced today the publication of its Annual Report and Form 20-F Information 2012 (Annual Report); Notice of Annual General Meeting 2013 and Shareholders' Circular, together with a covering letter from the Chairman, and 'AstraZeneca 2012 In Brief'.

Copies of the documents have been submitted to the National Storage Mechanism and will shortly be available for inspection at [www.morningstar.co.uk/uk/nsm](http://www.morningstar.co.uk/uk/nsm). The documents will be despatched to shareholders shortly. The documents are also available on the Company's website at [www.astrazeneca.com/annualreport2012](http://www.astrazeneca.com/annualreport2012), [www.astrazeneca.com/noticeofmeeting2013](http://www.astrazeneca.com/noticeofmeeting2013) and [www.astrazeneca.com/shareholderletter2012](http://www.astrazeneca.com/shareholderletter2012).

The meeting place for the Annual General Meeting (AGM) will be the Lancaster London Hotel, Lancaster Terrace, London, W2 2TY and the AGM will commence at 2.30 pm (BST) on 25 April 2013.

### EXPLANATORY NOTE AND WARNING

Solely for the purposes of complying with Disclosure Rules and Transparency Rules (DTR) 6.3.5R and the requirements it imposes on issuers as to how to make public annual financial reports, we set out below:

- in Appendix A, a management report;
- in Appendix B, the principal risks and uncertainties facing the Company;
- in Appendix C, the Directors' responsibility statement made in respect of the Financial Statements and Directors' Report contained in the Annual Report; and
- in Appendix D, a statement regarding related party transactions.

The appendices have been extracted from the Annual Report in unedited full text. This information should be read in conjunction with the Company's fourth quarter and full year results 2012 announcement, issued on 31 January 2013, which contained a condensed set of financial statements and which can be found at [astrazeneca.com/Investors/financial-information/Financial-results](http://astrazeneca.com/Investors/financial-information/Financial-results). Together, these constitute the material required by DTR 6.3.5R to be communicated to the media in unedited full text through a Regulatory Information Service.

Page numbers and section cross-references in the appendices refer to pages and sections in the Annual Report. Defined terms used in the appendices refer to terms as defined in the Annual Report.

This material is not a substitute for reading the full Annual Report.

A C N Kemp  
Company Secretary

25 March 2013

## APPENDIX A

### Chairman's statement

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.

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

#### CEO's review

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.

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  
Financial Review

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 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	2011	Percentage of sales
------	------	---------------------

Edgar Filing: ASTRAZENECA PLC - Form 6-K

2012 compared with  
2011

	Reported	CER	Growth due to exchange effects	Reported	Reported	Reported	CER	Reported
	\$m	growth	\$m	\$m	2012	2011	growth	growth
		\$m			%	%	%	%
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	2011	2012 compared with 2011
	Growth due to CER exchange Core growth		Total CER Core growth growth
	\$m	\$m	%
Gross profit	22,716	(4,355)	(16)
Gross margin %	81.2%		(18)
Distribution costs	(320)	16	(5)
Research and development	(4,452)	533	(8)
Selling, general and administrative costs	(8,541)	1,207	(11)
Other operating income and expense	1,027	200	(12)
Operating profit	10,430	(2,399)	(14)
Operating margin %	37.3%		(21)
Net finance expense	(430)		
Profit before tax	10,000		
Taxation	(1,885)		
Profit for the period	8,115		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Basic earnings per share (\$) 6.41 7.28

2012 Reconciliation of Reported results to Core results

	2012 Reported \$m	Restructuring costs \$m	Merck & MedImmune Amortisation \$m	Intangible impairments \$m	Legal 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.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

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	2011	2010
	\$m	\$m	\$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	-	1,772	-
Investments	(5,607)	577	(2,236)
Dividends	(3,665)	(3,764)	(3,361)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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	2011	2010
	\$m	\$m	\$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 (Italy), \$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. Amylin, 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 (pramlintide 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 \$	per share \$m	Shareholder distributions \$m

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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

1 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.

## APPENDIX B

### 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.

### 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.

#### 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.

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.

#### 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

#### 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.

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,

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.

#### 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

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.

#### 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.

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.

##### 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.

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.

#### 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.

#### 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

#### 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.

#### Impact

The failure to exploit potential opportunities appropriately in Emerging Markets may materially adversely affect our reputation, business or results of operations.

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.

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).

#### 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.

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

#### 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

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.

#### 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.

**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

significant cost and there is no guarantee that they will be successful.

#### 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.

#### 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

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.

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.

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.

#### 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 MAb 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.

#### 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

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, reimbursor 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.

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

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.

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.

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.

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.

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.

#### Supply chain and delivery risks

##### Manufacturing biologics

Manufacturing biologics, especially in large quantities, is complex and may require the use of innovative technologies to handle living micro-organisms and facilities specifically designed and validated for this purpose, with sophisticated quality assurance and control procedures.

##### Impact

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

##### 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.

##### 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%.

##### 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.

##### 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.

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

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

regulations in multiple jurisdictions could result in restricted access to, use or transport of such materials. on page 74.

#### 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.

##### 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.

##### Substantial product liability claims

Pharmaceutical companies have, historically, been subject to large product liability damages claims, settlements and awards for injuries allegedly caused by the use of their products. Adverse publicity relating to the safety of a product or of other competing products may increase the risk of product liability claims.

##### Impact

Substantial product liability claims that result in court decisions against us or in the settlement of proceedings could materially adversely affect our financial condition 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

##### Impact

Failure to comply with applicable laws, including ongoing control and regulation, could materially adversely

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.

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

Impact

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.

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.

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.

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.

#### 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

##### 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

unrest.

customers or ultimate payers to purchase our medicines. This could materially adversely affect our business or results of operations.

#### 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.

#### 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.

#### 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

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,

#### 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

which provide a framework for mitigating the incidence of double taxation on our revenues and capital gains.

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.

### APPENDIX C

This statement relates to and is extracted from the Annual Report. It is repeated here solely for the purpose of complying with DTR 6.3.5. It is not connected to the information presented in this announcement or in the Company's

fourth quarter and full year results 2012 announcement that was published on 31 January 2013.

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

## APPENDIX D

### 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).

### ADDITIONAL INFORMATION

#### 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	Meropen in the EU and rest of world (not in the US)
Naropin	Not in the US or the EU
Nexium	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Nolvadex	
Oxis	Not in the US or the EU
Turbuhaler	
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	Not in the US
SMART	
Symbicort	Not in the US or the EU
Turbuhaler	
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 names 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	
Symlyn	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

#### 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.

A C N Kemp  
Company Secretary  
25 March 2013

- ENDS -

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 25 March 2013

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary