

RISK

As a research-based pharmaceutical company doing business globally, we are subject to a variety of risks. Set out below is a summary of the principal risks that may affect our business. They are grouped under the headings Industry/Economic Environment Risks; Legal/Regulatory Risks; Business Execution Risks; and Reputation. Any of these risks (together with other risks and uncertainties discussed throughout this report or which are not presently known to us or currently considered material) could have a significant effect on our financial condition, results of operations and/or reputation. These risks have not been listed in any assumed order of priority and should be read in conjunction with the cautionary statements regarding forward-looking statements set out on the inside front cover of this report and below. The Managing Risk section on page 47 contains general information about how we manage risks and summary information about our approach to managing certain specific risks.

RISKS ASSOCIATED WITH FORWARD-LOOKING STATEMENTS

This report contains certain forward-looking statements about AstraZeneca. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. Forward-looking statements are identified in this report by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions. These forward-looking statements are subject to numerous risks and uncertainties. Important factors that could cause actual results to differ materially from those in forward-looking statements, certain of which are beyond our control, include, among other things, the risks detailed below:

INDUSTRY/ECONOMIC ENVIRONMENT RISKS

Risk of expiration of patents or marketing exclusivity

Scientific development and technological innovation are crucial if we are to deliver long-term market success. Patent protection and other types of marketing exclusivity are important ways in which we create value from such development and innovation, but all patents and marketing exclusivity will eventually expire. In the pharmaceutical market, a drug or diagnostic or medical device is normally only protected from competition from alternative products, for the same use, during the period of patent protection or marketing exclusivity. Once patent protection or marketing exclusivity has expired, the product is generally open to competition from generic copy products.

Products under patent protection or having marketing exclusivity usually generate significantly higher revenues than those not protected by patents or marketing exclusivity. For example, we anticipate the expiry of certain patents and/or marketing exclusivity relating to *Arimidex* in a number of major markets within the next few years. *Arimidex*, for the treatment of breast cancer, had global sales of \$1,730m in 2007.

Risk of patent litigation and early loss of patents, marketing exclusivity or trademarks

We believe that we have robust patent protection for our products. However, over the last few years there has been a marked increase in intellectual property litigation in the pharmaceutical industry. Increasingly, manufacturers of generic pharmaceutical products, whether based in developing countries, such as those in Asia, or elsewhere in the world, seek to challenge our patents or other types of marketing exclusivity and/or assert that their products do not infringe our patents in order to gain access to the market for their own generic products. Generic drug manufacturers are seeking to market generic versions of many of our more important products, prior to the expiration of our patents and marketing exclusivity periods. For example, we are currently facing challenges from multiple generic manufacturers to certain of our patents for *Nexium*, *Seroquel* and *Crestor*, some of our best-selling products in the US, our largest market. If such challenges are successful and result in the launch of generic products, or if otherwise generic products are launched 'at risk' on the expectation that challenges will be successful, this may have a materially adverse effect on our financial condition and results of operations. US sales for *Nexium* in 2007 were \$3,383m, for *Seroquel* were \$2,863m and for *Crestor* were \$1,424m. As a result of challenges by generic manufacturers, certain of our US patents covering *Toprol-XL* were held to be invalid during 2007 and generic versions of the product are now being sold in the US. Sales of *Toprol-XL* in the US, which were \$1,382m in 2006, were down 30% in 2007 to \$969m. The more significant patent litigation relating to our products is described in Note 27 to the Financial Statements.

In addition to generic manufacturers, the research-based pharmaceutical industry has become more aggressive in recent years in using intellectual property rights offensively as an additional basis for commercial competition between patented products. This has included the use of patent litigation directed at relatively

young products. In the case of litigation both by generic manufacturers and other research-based companies, we expect that the greatest challenges will be focused on the most valuable products.

Parts of our technology, techniques and proprietary compounds and potential new drugs, including those that are in-licensed, may be found to infringe patents owned by or granted to others. This risk may increase as our focus on biologics and vaccines increases, because intellectual property issues related to biological medicines can be extremely complex. If we cannot resolve any intellectual property disputes, we may be liable for damages, be required to obtain costly licences or be stopped from manufacturing, using or selling our products. During the course of our activities, we may become aware of broad patents owned by others relating to some of our intellectual property, and in some instances we may receive notices from the owners of patents claiming that their patents may be infringed by the development, manufacture or sale of some of our products and potential new drugs. In response, we may obtain licences, determine that our products do not infringe the patents or that the patents are not valid, or we may make various modifications that we believe should not infringe the patents and that should permit commercialisation of our products. Defending such claims can be costly, even if we are successful.

We vigorously defend our intellectual property rights, including taking appropriate infringement action in various courts throughout the world. However, there can be no assurance that any of our currently patented products will not be the subject of intellectual property litigation or other disputes involving patent offices, anti-trust authorities or other government or law enforcement agencies in the future, despite our efforts to establish and defend the most robust patent protection. We may not prevail in a patent infringement action; be able to obtain a licence to any third party patent on commercially reasonable terms; successfully develop non-infringing alternatives on a timely basis; or be able to license alternative non-infringing technology, if any exists, on commercially reasonable terms; and patent protection may not be available at all. If we were not successful during the patent protection or data exclusivity periods in maintaining exclusive rights to market one or more of our major products, particularly in the US where we have our highest revenue and margins, our revenue and margins would be significantly adversely affected.

RISK CONTINUED

In addition to challenges to our patented products from manufacturers of generic or other patented pharmaceutical products, there is a risk that some countries, particularly those in the developing world, may seek to impose limitations on the availability of patent protection for pharmaceutical products, or on the extent to which such protection may be obtained, within their jurisdictions. As a result, generic manufacturers in these countries may be increasingly and more easily able to introduce competing products to the market earlier than they would have been able to, had the patent protection been available.

Trade mark protection for our products is also an important element of our overall product marketing programmes. Combined with patent protection and other types of marketing exclusivity, products protected by a valid trade mark usually generate higher revenues than those not protected by a trade mark. We believe that we have robust trade mark protection for our products. However, trade mark protection may be challenged by third parties.

Risk of expiration or earlier loss of patents covering competing products

The expiration or earlier loss of patents belonging to other pharmaceutical manufacturers that cover branded products, which either compete directly against one of our products or compete in the same therapy area or product class as one of our products, could have a materially adverse effect on our financial condition and results of operations, by allowing competing generic products to enter the market.

Failure to obtain patent protection

It is our policy to apply for intellectual property protection for all inventions and innovations created as a result of the investments in R&D throughout the Group. Obtaining adequate protection for the intellectual property associated with our significant investment in R&D activities continues to be a key business imperative. The range of protection includes patents, trade marks, design registrations, copyright and domain name registrations. It is therefore important to our success that we are able to obtain and enforce patents and other proprietary rights in relation to our products.

We operate in a number of different countries in many of which the patent laws in the pharmaceutical field are continually evolving. As a result, we cannot be sure that, under the applicable legal regimes, new inventions will be patentable, that patents for which applications are now pending will be issued or reissued to us or that the scope of any

patent protection will be broad enough to protect our intellectual property to the extent to which we may receive protection under other, more developed regimes. Limitations on the availability of patent protection in certain developing countries could have an adverse effect on pricing and sales in respect of those products and, consequently, could adversely affect our revenues from those products in those countries, compared to countries where patent protection is available.

Impact of fluctuations in exchange rates

As a global business, currency fluctuations can significantly affect our results of operations, which are accounted for in US dollars. Approximately 49% of our 2007 sales were in North America (comprised of the US and Canada) with a significant proportion of that figure being in respect of US sales. The US is, and is expected to remain, our largest market. Sales in certain other countries are also in US dollars, or in currencies whose exchange rates are linked to the US dollar. Major components of our cost base are, however, located in Europe, where an aggregate of approximately 55% of our employees are based. Movements in the exchange rates used to translate foreign currencies into US dollars may therefore have a materially adverse effect on our financial condition and results of operations.

Certain of our subsidiaries import and export goods and services in currencies other than their own working currency. The results of such subsidiaries could, therefore, be affected by currency fluctuations arising between the transaction dates and the settlement dates for those transactions. We hedge these exposures through financial instruments. The fair value of financial instruments used to hedge these exposures, principally forward foreign exchange contracts and purchased currency options, at 31 December 2007 was \$30m. We have policies that seek to mitigate the effect of exchange rate fluctuations on the value of foreign currency cash flows and in turn their effects on the results of the various subsidiaries, but we do not seek to remove all such risks. Further information is contained on page 85 (Financial Review). In general, a unilateral strengthening of the US dollar adversely affects our reported results whereas a weakening of the US dollar is generally favourable. Exchange rate fluctuations may have a materially adverse effect on our financial condition and results of operations in the future.

Debt-funding arrangements

We incurred substantial debt in connection with the acquisition of MedImmune, Inc.. Our debt could affect our business flexibility and requires us to devote cash resources to service interest and principal payments. Our current debt level could limit our ability to engage in additional transactions or incur additional indebtedness and could potentially affect our investment grade credit rating.

The risks of owning and operating a biologics and vaccines business

The acquisition of MedImmune, Inc. in 2007, combined with the earlier acquisition of Cambridge Antibody Technology Group plc in 2006, accelerated our strategic aim of building a major presence in biologics and significantly increased the importance of biologics within the Group. As a result, the risks related to owning and operating a biologics and vaccines business are becoming more important to the Group. Some of the more significant of these risks are described below:

- > We may have limited access to and/or supply of biological materials, such as cells or animal products or by-products. In addition, government regulations in multiple jurisdictions, such as the US and countries within the EU, could result in restricted access to, or transport or use of, such materials. If we lose access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, we may not be able to conduct research activities as planned and may incur additional development costs.
- > The development, manufacturing and marketing of biological products are subject to regulation by the US Food and Drug Administration, the European Medicines Agency and other regulatory bodies. These regulations are often more complex and extensive than those applicable to other pharmaceutical products. As a result, the regulatory review and oversight process may affect production and release schedules for biological products to a greater extent than for other products. In addition, various legislative and regulatory authorities are considering whether an abbreviated approval process is appropriate for biosimilars or follow-on biological products (similar versions of existing biological products). It is uncertain as to when, or if, any such process may be adopted or how such a process would relate to intellectual property rights in connection with marketed or pipeline biological products, but any such process

could have a material effect on the future commercial prospects for patented biological products.

- > Manufacturing biological products, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Manufacturing biological products requires facilities specifically designed and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process may result in lot failure, product recalls or spoilage due to contamination or otherwise.
- > The methods of distributing and marketing biological products could have a material impact on the revenue we are able to generate from the sales of products such as *Synagis* and *FluMist*.

Competition, price controls and price reductions

The principal markets for our pharmaceutical products are the Americas, the countries of the EU, Asia Pacific, India, China and Japan. These markets are highly competitive. We compete in all of them, and elsewhere in the world, against major prescription pharmaceutical companies which, in many cases, are able to match or exceed the resources that we have available to us, particularly in the areas of R&D and marketing investment. Some of our most important products, such as *Crestor*, *Seroquel* and *Symbicort*, compete directly with similar products marketed by some of these companies. Industry consolidation has resulted in the formation of a small number of very large companies and continued consolidation could adversely affect our competitive position, whilst continued consolidation among our customers may increase price pressures. Increasingly, we also compete directly with biotechnology companies and companies that manufacture generic versions of our products following the expiry or loss of patent protection or other marketing exclusivity, which typically leads to a dramatic loss of sales and reduces our revenues and margins. Some of our patented products, including *Nexium*, *Crestor*, *Seroquel* and *Symbicort* are subject to price pressure from competition from generic products in the same product class.

In most of the principal markets in which we sell our products, there is continued economic, regulatory and political pressure to limit the

cost of pharmaceutical products. Certain groups have been involved in exerting price pressure on pharmaceutical companies with the aim of making medicines more affordable to those who need them. A summary of the principal aspects of price regulation in our most important markets, such as the US, the EU and Japan, is set out in the Sales and Marketing section on page 31. The Geographical Review section on page 69 also contains references to how price pressures are affecting our business.

In the US, as well as regulatory price pressure, realised prices are being depressed by pressure from managed care organisations and institutional purchasers, who use cost considerations to restrict the sale of preferred drugs that their physicians may prescribe, as well as other competitive activity. Such limited lists or formularies may force manufacturers either to reduce prices or be excluded from the list, thereby losing all the sales revenue from patients covered by that formulary. In addition, private health insurance companies and employers that self-insure have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products, among other reasons, to encourage beneficiaries to use generic products. The increased use of strict formularies by institutional customers in response to the current cost-containment environment and increasingly restrictive reimbursement policies could result in a materially adverse effect on our financial condition and results of operations.

In the EU, efforts by the European Commission to reduce inconsistencies and improve standards and best practice in the disparate national regulatory systems have met with little immediate success. The industry is, therefore, exposed to ad hoc national cost-containment measures on prices and the consequent cross-border movement of products from markets with prices depressed by governments into those where higher prices prevail.

The importation of pharmaceutical products from countries where prices are low due to government price controls or other market dynamics, to countries where prices for those products are higher, may increase. The accession of additional countries from Central and Eastern Europe to the EU may result in significant increases in the parallel trading of pharmaceutical products. Movements of pharmaceutical products into the US, in particular from Canada into the US, may increase despite the need to meet current or future safety requirements imposed by regulatory authorities. For example, the US

market has recently experienced efforts to introduce legislation such as the Pharmaceutical Market Access and Drug Safety Act of 2007, which would allow the commercial importation of drugs into the US from selected countries including some member states of the EU, Canada, Australia, New Zealand, Japan and Switzerland, by certain individual consumers, pharmacies and drug wholesalers. There may be further pressure for the adoption of such legislation, particularly given the forthcoming US presidential elections. The effects of any increase in the volume of this cross-border movement of products could result in a materially adverse effect on our financial condition and results of operations.

We expect that pressures on pricing will continue and may increase. Because of these pressures, there can be no certainty that we will be able to charge prices for a product that, in a particular country or in the aggregate, enable us to earn an adequate return on our investment in that product.

Taxation

The integrated nature of our worldwide operations can produce conflicting claims from revenue authorities as to the profits to be taxed in individual territories. The resolution of these disputes can result in a reallocation of profits between jurisdictions and an increase or decrease in related tax costs, and has the potential to affect our cash flows and earnings per share.

The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which enable us to ensure that our revenues and capital gains do not incur a double tax charge. If any of these double tax treaties should be withdrawn or amended, especially in a territory where a member of the Group is involved in a taxation dispute with a tax authority in relation to cross-border transactions, such withdrawal or amendment could have a materially adverse effect on our financial condition and results of operations. Similarly, a negative outcome of a tax dispute or failure of tax authorities to agree through competent authority proceedings could also have a materially adverse effect on our financial condition and results of operations.

Risk of substantial product liability claims

Given the widespread impact that prescription drugs may have on the health of large patient populations, pharmaceutical, biopharmaceutical and medical device companies have, historically, been subject to large product liability damages claims, settlements and awards for injuries allegedly caused by the use of their products.

RISK CONTINUED

Product liability claims, regardless of their merits or their outcome, are costly, divert management attention, and may adversely affect our reputation and demand for our products. Adverse publicity relating to the safety of a product or of other competing products may increase the risk of product liability claims. Litigation, particularly in the US, is inherently unpredictable and verdicts and/or unexpectedly high awards of damages can result. Substantial product liability claims that result in court decisions against us or in the settlement of proceedings could have a materially adverse effect on our financial condition and results of operations, particularly where such circumstances are not covered by insurance. We are currently subject to product liability litigation in relation to *Seroquel*, and further details about this and all material legal proceedings in which we are involved are set out in Note 27 to the Financial Statements. Information about our approach to patient safety is set out in the Medicines section on page 21.

Performance of new products

Although we carry out numerous and extensive clinical trials on all our products before they are launched, for a new product it can be difficult, for a period following its launch, to establish from available data a complete assessment of its eventual efficacy and/or safety in broader clinical use on the market. Due to the relatively short time that a product has been tested and the relatively small number of patients who have taken the product, the available data may be immature. Simple extrapolation of the data may not be accurate and could lead to a misleading interpretation of a new product's likely future commercial performance.

The successful launch of a new pharmaceutical product involves a substantial investment in sales and marketing costs, launch stocks and other items. The commercial success of our new medicines is of particular importance to us in order to replace sales lost as and when patent protection ceases in major markets for established marketed products. If a new product does not succeed as anticipated or its rate of sales growth is slower than anticipated, there is a risk that the costs incurred in launching it could have a materially adverse effect on our financial condition and results of operations. In addition, for launch of products that are seasonal in nature, delays for regulatory approval or manufacturing difficulties can have the effect of delaying launch to the next season and significantly reduce the value of costs spent in preparing for the launch for that season.

Environmental/occupational health and safety liabilities

We have environmental liabilities at some currently or formerly owned, leased and third party sites, as described in more detail in Note 27 to the Financial Statements. These liabilities are carefully managed by designated technical, legal and business personnel and there is no reason for us to believe that associated current and expected expenditure and/or risks are likely to have a materially adverse effect on our financial condition and results of operations as a general matter, although they could, to the extent that they exceed applicable provisions, have a materially adverse effect on our financial condition and results of operations for the relevant period. In addition, a change in circumstances (including a change in applicable laws or regulations) may result in such an effect.

Nonetheless, a significant non-compliance or incident for which we were responsible could result in us being liable to pay compensation, fines or remediation costs. In some circumstances, such liability could have a materially adverse effect on our financial condition, reputation and results of operations. In addition, our financial provisions for any obligations that we may have relating to environmental 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.

Developing our business in emerging markets

The development of our business in emerging markets may be a critical factor in determining our future ability to sustain or increase the level of our global product revenues. Challenges that arise in relation to the development of the business in emerging markets include, but are not limited to, competition from companies that are already present in the market, the need to correctly identify and leverage appropriate opportunities for sales and marketing, poor protection of intellectual property, inadequate protection against crime (including counterfeiting, corruption and fraud) (further details of which can be found below), inadvertent breaches of local law/regulation and not being able to recruit sufficient personnel with appropriate skills and experience. The failure to exploit potential opportunities appropriately in emerging markets may have a materially adverse effect on our financial condition and results of operations. Information on the risks associated with the failure to obtain patent protection can be found above.

Product counterfeiting

Counterfeit medicines are a danger to patients all over the world, as they may contain harmful substances, the wrong dose of the active pharmaceutical ingredient (API) or no API at all. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of the World Health Organization (WHO) estimates that approximately 10 to 30% of medicines in emerging economies are counterfeit, with parts of Latin America, Asia and Africa having a greater percentage than that range. By contrast, in developed countries with effective regulatory systems, counterfeits represent less than 1% of the market.

In addition, undue or misplaced concern about the issue might induce some patients to stop taking their medicines, with consequential risks to their health. Also, public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting could adversely affect our reputation and financial performance.

We use a range of measures against counterfeit medicines, and continue to develop such measures, including through the following:

- > We are introducing technologies that make it more difficult for counterfeiters to copy our products.
- > We conduct market surveillance and monitor the supply chain to identify potential counterfeiting operations.
- > We respond rapidly to any reports of counterfeit AstraZeneca medicines, working with regulators, healthcare professionals, distributors, law enforcement agencies and other organisations to protect patient interests.
- > We participate in a variety of anti-counterfeiting forums in the public and private sector, including the WHO's IMPACT working group and the Pharmaceutical Security Institute.

LEGAL/COMPLIANCE/REGULATORY RISKS

Risk of adverse outcome of litigation and/or government investigations and risk of insufficient insurance coverage

Note 27 to the Financial Statements includes information about legal proceedings in which we are currently involved. Unfavourable resolution of these and similar future proceedings, including government investigations, competition and anti-trust enquiries, investigations and litigation, product liability litigation and securities class action law suits, may have a materially