

GLAXOSMITHKLINE PLC

Form 6-K

March 12, 2012

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 period ending March 2012

GlaxoSmithKline plc  
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS  
(Address of principal executive offices)

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

Form 20-F  Form 40-F

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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

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GlaxoSmithKline plc  
Publication of Annual Report 2011

Today, 12 March 2012, GlaxoSmithKline plc published on the Company's website, [www.gsk.com/corporatereporting](http://www.gsk.com/corporatereporting), its Annual Report for the year ended 31 December 2011.

A hard copy version of the Annual Report 2011, together with the Notice of Annual General Meeting, will be sent to those shareholders, who have elected to continue to receive paper communications, on or about 26 March 2012. Shareholders who have not elected to continue to receive paper communications, will be sent a Summary 2011 notifying them of the availability of these documents on the Company's website. The Annual Report 2011, Summary 2011 and Notice of Annual General Meeting will be submitted to the UK Listing Authority.

In accordance with the requirements of Rule 4.1 of the Disclosure and Transparency Rules of the UK Financial Services Authority, Appendix A to this announcement contains a description of the principal risks and uncertainties affecting the Group and a responsibility statement.

The unaudited Preliminary Results for the year ended 31 December 2011 were announced on 7 February 2012.

V A Whyte  
Company Secretary  
12 March 2012

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under 'Risk Factors' in Appendix A of this announcement.

Brand names

Brand names appearing in italics throughout this announcement are trademarks either owned by and/or licensed to GlaxoSmithKline or associated companies.

APPENDIX A

(i) Principal risks and uncertainties

Risk factors

There are risks and uncertainties relevant to the Group's business, financial condition and results of operations that may affect the Group's performance and ability to achieve its objectives. The factors below are among those that the Group believes could cause its actual results to differ materially from expected and historical results. There are other risks and uncertainties that may affect the Group's performance and ability to achieve its objectives that are not currently known to the Group, or which are deemed immaterial.

The Group reviews and assesses significant risks on a regular basis and has implemented an oversight programme to help ensure that there is a system of internal control in place. This system includes policies and procedures, communication and training programmes, supervision and monitoring and processes for escalating issues to the appropriate level of senior management. Such a system helps facilitate the Group's ability to respond appropriately to risks and to achieve Group objectives and helps ensure compliance with applicable laws, regulations and internal policies. The Group's management of risks is further discussed on pages 91 to 94 'Corporate Governance' section of the Annual Report 2011.

It is not possible, however, for the Group to implement controls to respond to all the risks that it may face, and there can be no assurance that the steps the Group has taken to address certain risks will manage these risks effectively or at all. The six principal risks and uncertainties that might affect GSK's business are broken down in the following areas:

**Risk that R&D will not deliver commercially successful new products**

The Group operates in highly competitive markets. In the Pharmaceuticals and Vaccines businesses, it faces competition from proprietary products of large, international manufacturers and from producers of generic pharmaceuticals. The Pharmaceuticals and Vaccines businesses also face increasing competition from manufacturers in emerging markets, with a lower cost manufacturing base than that of the Group. In the Consumer Healthcare business, the Group likewise faces competition from large, international consumer healthcare companies as well as local consumer healthcare companies. Significant product innovations, technical advances or the intensification of price competition by competitors may materially and adversely affect the Group's financial results in the three businesses. The Group cannot always predict the timing or impact of competitive products or their potential impact on sales of the Group's products. In light of the competitive environment in which the Group operates, continued development of commercially viable new products as well as the development of additional uses for existing products is critical to the Group's ability to replace sales of older products that decline upon expiration of exclusive rights, and to increase overall sales.

Developing new pharmaceutical and vaccine products is a costly, lengthy and uncertain process. A new product candidate can fail at any stage of the development process, and one or more late stage product candidates could fail to receive regulatory approval.

New product candidates may appear promising in development but, after significant investment of Group economic and human resources, may fail to reach the market or may have only limited commercial success. This, for example, could be as a result of efficacy or safety concerns, an inability to obtain necessary regulatory approvals, difficulty manufacturing or excessive manufacturing costs, erosion of patent coverage as a result of a lengthy development period, infringement of patents or other intellectual property rights of others or an inability to differentiate the product adequately from those with which it competes. Furthermore, health authorities such as the US Food and Drug Administration, the European Medicines Agency and the Japan Pharmaceuticals and Medicines Device Agency have increased their focus on safety and product differentiation when assessing the benefit/risk balance of drugs, which has made it more difficult for pharmaceutical and vaccine products to gain regulatory approval.

There is also increasing pressure on healthcare budgets as a result of the financial crisis, the increase in the average age of the population in developed markets, and the increase in the absolute population in developing markets. Payers therefore, increasingly have demanded greater incremental benefit from pharmaceutical and vaccine products before agreeing to reimburse drug manufacturers at prices manufacturers consider appropriate. A failure to develop commercially successful products or to develop additional uses for existing products for any of these reasons could materially and adversely affect the Group's financial results.

**Intellectual property protection**

Failure to obtain effective intellectual property protection for our products

As an innovator pharmaceutical, vaccine and consumer healthcare company, the Group seeks to obtain appropriate intellectual property protection for our products. Our ability to obtain and enforce patents and other proprietary rights with regard to our products is critical to the Group's business strategy and success. In a number of markets in which the Group operates, the intellectual property laws and patent offices are still developing, and some markets may be unwilling to extend intellectual property protection to innovative products in a fashion similar to markets in more developed regions such as the European Union, Japan and the USA or to enforce previously granted intellectual property rights. The Group's inability to obtain and enforce effective intellectual property protection for our products in certain markets could have a material adverse result on the Group's financial results.

In some of the countries in which the Group operates, patent protection may be significantly weaker than in the USA or the European Union. Some developing countries have reduced, or threatened to reduce, effective patent protection for pharmaceutical products generally, or in particular therapeutic areas, to facilitate early competition within their markets from generic manufacturers. Any loss of patent protection, including reducing the scope of patent rights or compulsory licensing (in which a government forces a manufacturer to license its intellectual property to a competitor), could materially and adversely affect the Group's financial results in those markets. Absence of adequate patent protection could limit the opportunity to rely on such markets for future sales growth for the Group's products.

Expiry of intellectual property rights protection on the Group's products and on competitive products; Competition from generic manufacturers

Pharmaceutical and vaccine products are usually only protected from being copied by generic manufacturers during the period of exclusivity provided by an issued patent or related intellectual property rights such as Regulatory Data Protection or Orphan Drug status. Following expiry of intellectual property rights protection, a generic manufacturer may produce a generic version of the product.

The Group faces intense competition from manufacturers of generic pharmaceutical products in all of its major markets. Introduction of generic products, particularly in the USA where the Group has its highest turnover and margins, typically leads to a dramatic loss of sales and reduces the Group's revenues and margins for its proprietary products. The Group had eleven pharmaceutical and vaccine products with over £500 million in annual global sales in 2011. For certain of these products there is generic competition in the USA and some markets in Europe.

In addition, the timing and impact of entry for a 'follow-on' product to Seretide/Advair that contains the same active ingredients is uncertain.

The US patent for compositions containing the combination of active substances in Seretide/Advair expired during 2010. The outlook for the timing and impact of entry of 'follow-on' competition is uncertain. GSK has not been notified of any acceptance by the US FDA of an application for a 'follow-on' product that refers to Seretide/Advair and contains the same active ingredients (as would be expected to precede the introduction of such a product), and is not able to predict when this may occur or when any such 'follow-on' product may enter the US market.

Generic drug manufacturers have also exhibited a readiness to market generic versions of many of the Group's most important products prior to the expiration of the Group's patents. Efforts may involve challenges to the validity or enforceability of a patent or assertions that their generic product does not infringe the Group's patents. If the Group is not successful in defending an attack on its patents and maintaining exclusive rights to market one or more of its major products, particularly in the USA and Europe, the Group's financial results would be adversely affected. The expiration dates for patents for the Group's major products and a description of litigation settlements which may affect the dates on which generic versions of the Group's products may be introduced are set out on page 239 of the Annual Report 2011. Legal proceedings involving patent challenges are set out in Note 44 to the financial statements, 'Legal proceedings' in the Annual Report 2011.

The Group may also experience an impact on sales of one of its products due to the expiry or loss of patent protection for a product marketed by a competitor in a similar product class or for treatment of a similar disease condition. The availability of generic products in the same or similar product class in which one of the Group's products competes could have a material adverse impact on sales of the Group's products.

#### Potential changes in intellectual property laws and regulations

Proposals to change existing patent and data exclusivity laws and regulations in major markets in which the Group sells its products are a continuing feature of the political process in those countries. These include proposals that could have the effect of making prosecution of patents for new products more difficult and time consuming or that could adversely affect the exclusivity period for the Group's products, including biological products. Should such proposals be enacted, they may materially and adversely affect the Group's financial results. For example, in 2010, as part of the comprehensive healthcare reform in the USA, the Biologics Price Competition and Innovation Act was enacted which introduced new regulations for 'follow-on' biologics that allow a sufficiently similar biologic to be able to rely on an innovator's approval following a 12-year data exclusivity period. Regulations outlining the requirements for establishing biosimilars and interchangeable products, as well as the operation of complicated patent litigation provisions, have not yet been proposed by the FDA. In Europe, the EMA has finalised guidelines for similar biological medicinal products containing MAb (Monoclonal antibodies).

The loss of patent protection for some or all of the Group's products could have a material adverse impact on sales of the Group's products.

#### Risk of substantial adverse outcome of litigation and government investigations

Note 44 to the financial statements, 'Legal proceedings' in the Annual Report 2011, contains a discussion of material proceedings and governmental investigations currently involving the Group which, if proven, could give rise to civil and/or criminal liabilities. Unfavourable resolution of these and similar future proceedings or investigations may have a material adverse effect on the Group's financial condition and results of operations. The Group has made provisions in 2011 and prior years related to such legal proceedings and investigations, which reduced its earnings.

In the future, the Group may also make additional significant provisions related to legal proceedings and investigations which would reduce its earnings. In many cases, the Group believes that it is the practice of the plaintiff bar to claim damages in amounts that bear no reasonable relationship to the underlying harm allegedly caused by the Group's products or its actions. Accordingly, it may be potentially misleading for the Group to quantify, based on the amount of damages claimed, its potential exposure to claims, proceedings and investigations of the type described in Note 44 to the financial statements, 'Legal proceedings' in the Annual Report 2011.

Recent insurance loss experience, including pharmaceutical product liability exposures, has increased the cost, and reduced the capacity, of insurers to provide coverage for pharmaceutical companies generally, including the Group.

In order to contain insurance costs in recent years, the Group has continued to adjust its coverage profile, accepting a greater degree of uninsured exposure in some areas, and a lesser degree in others, in order to optimise the value of insurance markets. In addition, where claims are made under insurance policies, insurers regularly reserve the right to deny cover on various grounds.

#### Product liability litigation

Pre-clinical and clinical trials are conducted during the development of potential pharmaceutical, vaccine and consumer healthcare products to determine the safety and efficacy of the products for use by humans following approval by regulatory authorities. Notwithstanding the efforts the Group makes to determine the safety of its products through regulated clinical trials, unanticipated side effects may become evident only when drugs and vaccines are widely introduced into the marketplace.

In other instances, third parties may perform analyses of published clinical trial results which, although not necessarily accurate or meaningful, may raise questions regarding the safety of pharmaceutical, vaccine or consumer healthcare products which may be publicised by the media and may result in product liability claims. The Group is currently a defendant in a substantial number of product liability lawsuits, including class actions, that involve significant claims for damages related to the Group's pharmaceutical and consumer healthcare products. Litigation, particularly in the USA, is inherently unpredictable. Class actions that sweep together all persons who were prescribed the Group's products can inflate the potential liability by the force of numbers. Claims for pain and suffering and punitive damages are frequently asserted in product liability actions and, if allowed, can represent potentially open ended exposure and thus could materially and adversely affect the Group's financial results.

#### Anti-trust litigation

In the USA, it has become increasingly common for patent infringement actions to prompt claims that anti-trust laws have been violated during the prosecution of the patent or during litigation involving the defence of that patent. Such claims by direct and indirect purchasers and other payers are typically filed as class actions. The relief sought may include treble damages and restitution claims. Similarly, anti-trust claims may be brought by government entities or private parties following settlement of patent litigation, alleging that such settlements are anti-competitive and in violation of anti-trust laws. The Group may also be subject to other anti-trust litigation involving competition claims unrelated to patent infringement and prosecution. A successful anti-trust claim by a private party or government entity against the Group could materially and adversely affect the Group's financial results.

#### Sales and marketing regulation

The Group operates globally in complex legal and regulatory environments that often vary among jurisdictions. The failure to comply with applicable laws, rules and regulations in these jurisdictions may result in civil and criminal legal proceedings brought against the Group by governmental entities at the federal and state levels and by private plaintiffs. As those rules and regulations change or as governmental interpretation of those rules and regulations evolve, conduct of the Group may be called into question.

In the USA, for example, while the Group has reached agreement in principle to resolve certain federal governmental investigations into the pricing, marketing and reimbursement of its prescription drug products, as detailed in Note 44 to the financial statements, "Legal proceedings" in the Annual Report 2011, related state investigations that have been initiated on the basis of the same factual claims could result in restitution or civil litigation on behalf of state governments, and could also result in related proceedings initiated against the Group by or on behalf of consumers and private payers. Such proceedings may result in trebling of damages awarded or fines in respect of each violation of law. The conduct of the Group could result in additional investigations in the future by the US federal and state governments and similar civil litigation. Any of these consequences could materially and adversely affect the Group's financial results.

#### Governmental, payer and regulatory controls

##### Pricing

Pharmaceutical and vaccine products are subject to price controls or pressures and other restrictions in many markets, including but not limited to France, Germany, Italy, Japan and Spain. Some governments intervene directly in setting prices. In addition, in some markets, major purchasers of pharmaceutical or vaccine products (whether governmental agencies or private health care providers) have the economic power to exert substantial pressure on prices or the terms of access to formularies. Difficult economic conditions, particularly in the major markets in Europe, could increase the pricing pressures on the Group's pharmaceutical and vaccine products. The Group cannot accurately predict whether existing controls, pressures or restrictions will increase or whether new controls, pressures or restrictions will be introduced. Such measures may materially and adversely affect the Group's ability to introduce new products profitably and its financial results.

For example, in the USA, where the Group has its highest margins and the most sales for any country, there are no direct government price controls over private sector purchases, but federal law requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to be eligible for reimbursement under several state and federal healthcare programmes, primarily Medicare and Medicaid. Pricing pressures are likely to increase as the US government's share of national health spending continues to increase. Additionally, due to passage of comprehensive health care reform in 2010, the US government's role in providing or subsidising health insurance is expected to significantly expand in 2014, which indicates the growing role and leverage the government will bring to bear on the Group's rebate liability with respect to US federal programs.

In recent years, a number of states have also proposed or implemented various schemes to control the pharmacy budget for drugs used by their low-income and senior citizens' programmes, including increasing the rebate liability of pharmaceutical companies, importation from other countries and bulk purchases of drugs. Given the new state mandates contained in the US health care reform law, which will increase the number of Medicaid eligible participants, and the economic pressures on state government budgets, pricing pressures on the Group's pharmaceutical and vaccine products are likely to increase. Any of these trends may materially and adversely affect the Group's financial results.

#### Regulatory controls

The Group must comply with a broad range of regulatory controls on the manufacturing, testing, approval, distribution and marketing of many of its pharmaceutical, vaccine and consumer healthcare products that affect not only the cost of product development but also the time required to reach the market and the uncertainty of successfully doing so. Historically, there have been more stringent regulatory requirements in developed markets. However, in recent years, emerging markets have been increasing their regulatory expectations based on their own national interpretations of US and EU standards. As detailed on page 15 of the Annual Report 2011, health authorities in developed markets have increased their focus on safety when assessing the risk/benefit balance of drugs in the context of not only initial product approval but also in the context of approval of additional indications and review of information regarding marketed products. Stricter regulatory controls also heighten the risk of changes in product profile or withdrawal by regulators on the basis of post-approval concerns over product safety, which could reduce revenues and result in product recalls and product liability lawsuits. There is also greater regulatory scrutiny, especially in the USA, on advertising and promotion and in particular on direct-to-consumer advertising.

In addition, in some cases, the Group may voluntarily cease marketing a product or face declining sales based on concerns about efficacy or safety (for example, the decline in sales of the Group's product Avandia beginning in 2007 following publicity around questions regarding risks associated with the product), whether or not scientifically justified, even in the absence of regulatory action. The development of the post-approval adverse event profile for a product or the product class may materially and adversely affect the Group's financial results.

#### Risk of interruption of product supply

The manufacture of pharmaceutical and vaccine products and their constituent materials requires compliance with good manufacturing practice regulations. The Group's manufacturing sites are subject to review and approval by the FDA and other regulatory agencies. Compliance failure by the Group's manufacturing facilities or by suppliers of key services and materials could lead to product recalls and seizures, interruption of production, delays in the approval of new products, and revoking of license to operate pending resolution of manufacturing issues. For example, non-compliance with current Good Manufacturing Practice (cGMP) requirements for US supply could ultimately result, in the most severe circumstances, in fines and disgorgement of profits. Any interruption of supply or the incurring of fines or disgorgement impacting significant products or markets could materially and adversely affect the Group's financial results.

Materials and services provided by third-party suppliers are necessary for the commercial production of our products, including speciality chemicals, commodities and components necessary for the manufacture and packaging of many of the Group's Pharmaceutical, Vaccine and Consumer Healthcare products. Some of the third-party services procured,



for example, services provided by clinical research organisations to support development of key products, are very important to the operation of the Group's businesses. Although the Group undertakes business continuity planning, single sourcing for certain components, bulk active materials, finished products, and services creates a risk of failure of supply in the event of regulatory non-compliance or physical disruption at the manufacturing sites. The failure of a small number of single-source, third-party suppliers or service providers to fulfil their contractual obligations in a timely manner or as a result of regulatory non-compliance or physical disruption at the manufacturing sites may result in delays or service interruptions, which may materially and adversely affect the Group's financial results.

#### Taxation and Treasury

The Group's effective tax rate is driven by rates of tax in jurisdictions that are both higher and lower than that applied in the UK. In addition, many jurisdictions such as the UK, Belgium and the USA currently offer regimes that encourage innovation and new scientific endeavours by providing tax incentives, for example R&D tax credits. Furthermore, given the scale and international nature of the Group's business, intra-group transfer pricing is an inherent tax risk as it is for other international businesses. Changes in tax laws or in their application with respect to matters such as transfer pricing, foreign dividends, controlled companies, R&D tax credits or a restriction in tax relief allowed on the interest on intra-group debt, could increase the Group's effective tax rate and materially and adversely affect its financial results.

The tax charge included in the financial statements is the Group's best estimate of its tax liability but, until such time as audits by tax authorities are concluded, there is a degree of uncertainty regarding the final tax liability for the period. The Group's policy is to submit tax returns within the statutory time limits and engage tax authorities to ensure that the Group's tax affairs are as current as possible, and that any differences in the interpretation of tax legislation and regulation are resolved as quickly as possible. In exceptional cases where matters cannot be settled by agreement with tax authorities, GSK may have to resolve disputes through formal appeals or other proceedings. For example, in January 2012, the Supreme Court of Canada heard an appeal in respect of the Groups transfer pricing, as discussed in Note 14 to the financial statements, 'Taxation' in the Annual Report 2011.

The Group deals in high value transactions on a frequent basis which may result in an increased risk of financial loss due to the mismanagement of cash or entering into high risk positions on hedge transactions, any of which could materially and adversely affect the Group's financial results.

There are a number of further risks, which could affect the financial condition or results of the Group, as follows:

#### Implementing the Group's strategic priorities

The Group has established three strategic priorities: to grow a diversified business, deliver more products of value, and simplify its operating model. The Group may not be able to implement its strategic priorities fully. Even if the Group is able to implement them, the strategic priorities may not deliver the expected benefits.

For example, the strategic priority to grow a diversified business involves expanding the Group's business into Emerging Markets. The Group's pharmaceutical sales in Emerging Markets grew 6% in 2011 to nearly £3.7 billion, and represented 17% of the Group's 2011 pharmaceutical turnover. There is no guarantee that the Group's sales in Emerging Markets will continue to grow or that these markets will continue to experience relatively high growth rates. Some emerging markets may be especially vulnerable to the ongoing global financial crisis, or may have very limited resources to spend on healthcare. Competition in these markets for staff with the skills and training suitable for employment at an enterprise such as the Group's may be intense. In some emerging markets, the Group may be required to rely on third party agents, which may put the Group at risk of liability, and some emerging markets lack sufficient protection against crimes such as counterfeiting. A failure to continue to expand its business in emerging growth markets could materially and adversely affect the Group's financial results.

In addition, the Group is undertaking a restructuring programme that has an estimated cost of approximately £4.85 billion and is expected to deliver annual pre-tax savings of approximately £2.8 billion by the time it is substantially complete in 2014. The Group may not be able to execute fully this transformation of its business. Furthermore, changes in the Group's structure, operations, revenues, costs or efficiency resulting from these restructuring activities or other strategic initiatives could result in higher than expected costs or other difficulties. Failure to realise the expected cost savings by the end of the restructuring programme or to achieve and maintain a competitive cost base could materially and adversely affect the Group's financial results.

#### Anti-bribery and corruption

The Group's extensive and increasing international operations may give rise to possible claims of bribery and corruption. Failure to comply with applicable legislation such as the US Foreign Corrupt Practices Act and the UK Bribery Act, or similar legislation in other countries, could expose the Group and senior officers to civil and criminal sanction, including fines, prosecution, potential debarment from public procurement and reputational damage, all of which could materially and adversely affect the Group's financial results. The compliance mechanisms and monitoring programmes that the Group has in place may not adequately prevent or detect possible violations under applicable anti-bribery and corruption legislation.

#### Risk from concentration of sales to wholesalers

In the USA, similar to other pharmaceutical and vaccine companies, the Group sells its products through a small number of wholesalers in addition to hospitals, pharmacies, physicians and other groups. Sales to the three largest wholesalers amounted to approximately 77% of the Group's US Pharmaceuticals and Vaccines turnover in 2011.

At 31 December 2011, the Group had trade receivables due from these three wholesalers totalling £934 million (31 December 2010 - £890 million). The Group is exposed to a concentration of credit risk in respect of these wholesalers such that, if one or more are affected by financial difficulty, it could materially and adversely affect the Group's financial results.

#### Global political and economic conditions

As described on page 13 of the Annual Report 2011, many of the world's largest economies, including the major markets in which the Group operates, and financial institutions have in the recent past faced extreme financial difficulty, including a decline in asset prices, liquidity problems and limited availability of credit. The economic uncertainty continued in 2011, with multiple downgrades of sovereign credit ratings, particularly in the Eurozone. High levels of sovereign debt are negatively impacting growth in the global economy. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. The ongoing debt crisis in certain countries in Europe has increased pressures on the payers in those countries to force healthcare companies such as the Group to decrease the price of its products. The debt crisis has also given rise to concerns that some countries may not be able to pay for our products. Current economic conditions may also adversely affect the ability of our distributors, customers, suppliers and service providers to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us, which could disrupt our operations, and negatively impact our business and cash flow. Some of our distributors, customers, suppliers and service providers may be unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to risk from business interactions directly with fiscally-challenged government payers.

Such continued economic weakness and uncertainty could materially and adversely affect the Group's revenues, results of operations and financial condition. The Group's businesses, including Pharmaceuticals, Vaccines and Consumer Healthcare, may be particularly sensitive to declines in consumer or government spending. In addition, further or renewed declines in asset prices may result in a lower return on the Group's financial investments and may

cause the value of the Group's investments in its pension plans to decrease, requiring the Group to increase its funding of those pension plans.

The Group conducts a substantial portion of its operations outside the UK. The Group's management of foreign exchange rates is discussed in Business review, 'Foreign exchange management' (see page 66 of the Annual Report 2011). Fluctuations in exchange rates between Sterling and other currencies, especially the US dollar, the Euro and the Japanese Yen, could materially and adversely affect the Group's financial results.

The Group has no control over changes in inflation and interest rates, foreign currency exchange rates and controls or other economic factors affecting its businesses or the possibility of political unrest, legal and regulatory changes or nationalisation in jurisdictions in which the Group operates.

The Group operates in a number of markets that are experiencing political and social unrest. These events may lead to business disruption and liquidity problems that could adversely impact the Group's results.

#### Environmental liabilities

The environmental laws of various jurisdictions impose actual and potential obligations on the Group to remediate contaminated sites. The Group has also been identified as a potentially responsible party under the US Comprehensive Environmental Response Compensation and Liability Act at a number of sites for remediation costs relating to the Group's use or ownership of such sites. Failure to manage properly the environmental risks could result in additional remedial costs that may materially and adversely affect the Group's financial results. See Note 44 to the financial statements, 'Legal proceedings' in the Annual Report 2011, for a discussion of environmental related proceedings in which the Group is involved. The Group routinely accrues amounts related to its liabilities for such matters.

#### Accounting standards

New or revised accounting standards, rules and interpretations issued from time to time by the International Accounting Standards Board could result in changes to the recognition of income and expense that may materially and adversely affect the Group's financial results.

Under International Financial Reporting Standards, changes in the market valuation of certain financial instruments are required to be reflected in the Group's reported results before those gains or losses are actually realised. This could have a significant impact on the income statement in any given period. Accounting for deferred taxation on inter-company inventory may give rise to volatility depending upon the Group entity that owns the inventory.

Regulators regularly review the financial statements of listed companies for compliance with accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning its financial statements and disclosures. However, other companies have experienced investigations into potential non-compliance with accounting and disclosure requirements that have resulted in restatements of previously reported results and sometimes significant penalties. Any such investigation and required restatement could materially and adversely affect the Group's financial results.

#### Protection of electronic information and assets

The Group relies on critical and sensitive data, such as corporate strategic plans, personally identifiable information, trade secrets and intellectual property, to drive planning and operations. Security of this type of data is exposed to escalating external threats that are increasing in sophistication and changing from a goal of disruption to being financially or politically motivated. The Group is also subject to various standards for the protection of personally identifiable information and this year submitted an application for Binding Corporate Rules status, which is under review by UK Information Commissioner's Office.

Failure to implement appropriate safeguards to adequately protect against any unauthorised or unintentional access, acquisition, use, modification, loss or disclosure of this critical or sensitive data may adversely impact the Group's

ability to maintain patent rights and competitive advantages or may result in regulatory non-compliance resulting in fines and penalties or inability to sell product in a particular market.

#### Alliances and acquisition

As part of the Group's strategy to diversify into new product areas and markets, the Group has grown, and expects to continue to grow, in part through acquisitions and business alliances. There is intense competition for alliance and acquisition candidates in the pharmaceutical industry, and, as such, the Group may be unable to make these deals on acceptable terms or at all. In acquiring or forming alliances with companies, the Group may assume significant debt, become subject to unknown or contingent liabilities or fail to realise the benefits expected from these transactions. For example, most pharmaceutical companies, including those that the Group may consider acquiring, are involved in patent disputes, product liability litigation, government investigations and other legal proceedings whose outcome is subject to considerable uncertainty. The assumption of debt or unknown or contingent liabilities or the failure to realise the expected benefits may materially and adversely affect the Group's financial results.

The process of integrating companies the Group may acquire may result in disruption to the ongoing business as the effort of integrating organisations in different locations and with, among other things, differing systems and corporate cultures may divert attention and resources, result in the loss of key employees or have other adverse consequences, any of which may materially and adversely affect the Group's financial results.

#### Attraction and retention

The Group relies heavily on recruiting and retaining talented employees with a range of skills and capabilities to meet its objectives. The Group faces 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, particularly given the Group's plans to expand its operations in Emerging Markets and Vaccines.

The inability to attract staff with specific technical and leadership skills, retain key employees or ensure effective succession planning for critical positions may materially and adversely affect the Group's ability to implement key strategic objectives and ultimately impact financial results.

#### (ii) Directors' responsibility statement

Each of the current Directors, whose names and functions are listed below, confirms that, to the best of his or her knowledge:

- 1) the Group financial statements, which have been prepared in accordance with IFRS as adopted by the EU and IFRS as issued by IASB, give a true and fair view of the assets, liabilities, financial position and profit of the Group; and
- 2) the Overview, Strategic review and Financial review and risk sections contained in the Annual Report include a fair review of the development and performance of the business and the position of the Group, together with a description of the principal risks and uncertainties that it faces.

Name	Function
Sir Christopher Gent	Chairman
Sir Andrew Witty	Chief Executive Officer
Simon Dingemans	Chief Financial Officer
Dr Moncef Slaoui	Executive Director and Chairman, Research & Development
Professor Sir Roy Anderson	Non-Executive Director
Dr Stephanie Burns	Non-Executive Director

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Stacey Cartwright	Non-Executive Director
Larry Culp	Non-Executive Director
Sir Crispin Davis	Non-Executive Director
Judy Lewent	Non-Executive Director
Sir Deryck Maughan	Non-Executive Director
James Murdoch	Non-Executive Director
Dr Daniel Podolsky	Non-Executive Director
Tom de Swaan	Non-Executive Director
Sir Robert Wilson	Senior Independent Non-Executive Director

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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 authorised.

GlaxoSmithKline plc  
(Registrant)

Date: March 12, 2012

By: VICTORIA WHYTE  
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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc