

GLAXOSMITHKLINE PLC
Form 6-K
February 25, 2010

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 February 2010

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 x 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

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Securities Exchange Act of 1934.

Yes No x

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Publication of GlaxoSmithKline plc's

Annual Report 2009

Today, 25 February 2010, GlaxoSmithKline plc published on the Company's website, www.gsk.com/annualreport, its Annual Report in respect of the year ended 31 December 2009.

A hard copy version of the Annual Report 2009 together with the Notice of Annual General Meeting will be sent to those shareholders who have elected to continue to receive paper communications and will be submitted to the UK Listing Authority on or about 16 March 2010. Shareholders who have not elected to continue to receive paper communications will be sent a 2009 Summary notifying them of the availability of these documents on the Company's website.

In accordance with the requirements of Rule 4.1 of the Disclosure and Transparency Rules of the UK Financial Services Authority which applies in respect of accounting periods commencing after 20 January 2007, 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 2009 were announced on 4 February 2010.

S M Bicknell

Company Secretary

25 February 2010

Cautionary statement regarding forward-looking statements

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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

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 thinks, based on the CET's most recent annual workshop to identify the most significant risks facing the Group, could cause its actual results to differ materially from expected and historical results. There are other risks and uncertainties not currently known to the Group or which are deemed immaterial.

For each of the risks described below, the Group has implemented a system of internal control that involves 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. 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 major risks that might affect GSK's business are:

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

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 products is a costly, lengthy and uncertain process.

A new product candidate can fail at any stage of the 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, fail to reach the market or 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 terms 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 FDA, the European Medicines Agency and the Japan Pharmaceuticals and Medicines Device Agency have increased their focus on safety when assessing the benefit/risk balance of drugs, which has made it more difficult for pharmaceutical products to gain regulatory approval.

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

RISK OF UNPLANNED LOSS OF PATENTS

Patent infringement litigation

The Group's patents, in common with all patents, can be challenged at any time. Efforts by generic manufacturers 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 GSK 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 where the Group has its highest turnover and margins, the Group's financial results may be materially and adversely affected.

Generic drug manufacturers are seeking to market generic versions of many of the Group's most important products, prior to the expiration of the Group's patents, and have exhibited a readiness to do so for other products in the future. The US launch of generic products competing with Lamictal, Imitrex, Paxil CR, Requip, Wellbutrin XL and Valtrex had a significant impact on the Group's overall turnover and earnings for 2009.

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 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.

Weakness of intellectual property protection in certain countries

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, could materially and adversely affect the Group's financial results in those national markets but is not expected to be material to the Group overall. Absence of adequate patent protection could limit the opportunity to look to such markets for future sales growth.

Risk of substantial adverse outcome of litigation and government investigations

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 material provisions in 2009 and prior years related to legal proceedings and investigations which reduced its earnings.

The Group may also make additional significant provisions related to legal proceedings and investigations in the future, which would reduce its earnings. In many cases the practice of the plaintiff bar is to claim damages in amounts that bear no relationship to the underlying harm.

Recent insurance loss experience, including pharmaceutical product liability exposures, has increased the cost of, and narrowed the coverage afforded by, insurance 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 un-insured exposure. In addition, where claims are made under insurance policies, insurers may reserve the right to deny coverage on various grounds. If denial of coverage is

ultimately upheld on these claims, this could result in additional charges that may materially and adversely affect the Group's financial results.

Product liability litigation

Pre-clinical and clinical trials are conducted during the development of potential products to determine the safety and efficacy of products for use by humans following approval by regulatory bodies. Notwithstanding these efforts, when drugs and vaccines are introduced into the marketplace, unanticipated side effects may become evident.

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 products which may be publicised by the media and may result in product liability claims. The Group is currently a defendant in a number of product liability lawsuits, including class actions, that involve substantial claims for damages related to the Group's pharmaceutical products. Litigation, particularly in the USA, is inherently unpredictable and excessive verdicts that are not justified by the evidence can occur. 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 initial 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. Damages in adverse anti-trust verdicts are subject to automatic trebling in the USA. Similarly, anti-trust claims may be brought following settlement of patent litigation, alleging that such settlements are anti-competitive and in violation of anti-trust laws. A successful anti-trust claim against the Group could materially and adversely affect the Group's financial results.

Sales, marketing and 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. As those rules and regulations change or as governmental interpretation of those rules and regulations evolve, prior conduct may be called into question.

In the USA, for example, the Group is responding to federal and state governmental investigations into pricing, marketing and reimbursement of its prescription drug products. These investigations could result in related restitution or civil false claims act litigation on behalf of the federal or state governments, as well as 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. Criminal proceedings may also be initiated against the Group. Any of these consequences could materially and adversely affect the Group's financial results.

RISKS OF COMPETITION, PRICE CONTROLS AND LIMITATIONS ON SALES

Third party competition

The Group operates in highly competitive markets. In the pharmaceuticals business, it faces competition both from proprietary products of large international manufacturers and producers of generic pharmaceuticals. Significant product innovations, technical advances or the intensification of price competition by competitors may materially and adversely affect the Group's financial results. The Group cannot predict the timing or impact of competitive products or their potential impact on sales of the Group's products. Continued consolidation in the pharmaceutical industry may adversely affect the Group's competitive position, while continued consolidation among the Group's customers may increase pricing pressures.

The Group had nine pharmaceutical products with over £500 million in annual global sales in 2009. Among these products are Augmentin IR and ES, Lamictal IR, Paxil and Valtrex for which there is generic competition in the USA.

If any of the Group's major products were to become subject to a problem such as unplanned loss of patent protection, unexpected side effects, regulatory proceedings, publicity affecting doctor or patient confidence or pressure from competitive products, or if a new, more effective treatment should be introduced, the Group's financial results may be materially and adversely affected.

In particular, the Group faces intense competition from manufacturers of generic pharmaceutical products in all of its major markets. Generic products often enter the market upon expiration of patents or data exclusivity periods for the Group's products. Introduction of generic products typically leads to a dramatic loss of sales and reduces the Group's revenues and margins for its proprietary products.

Governmental and payer controls

Pharmaceutical products are subject to price controls or pressures and other restrictions in many markets, including Japan, Germany, Spain, France and Italy. Some governments intervene directly in setting prices.

In addition, in some markets major purchasers of pharmaceutical 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.

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, pricing pressures could significantly increase as experience continues to develop under the outpatient pharmaceutical programme covering Medicare beneficiaries that began in 2006. Also, changes to the related enabling legislation could afford the US government a direct role in negotiating prices under the Medicare programme.

In addition, the US Congress is considering comprehensive health care reform legislation that could significantly expand the scope of government health care programs that include specific price control mechanisms or that could increase the Group's rebate liability with respect to those programs.

Additionally, a number of states have proposed or implemented various schemes to control prices for their low-income and senior citizens' programmes, including increasing the rebate liability of pharmaceutical companies, importation from other countries and bulk purchases of drugs. The growth in the number of patients covered through large managed care institutions in the USA, which has increased with implementation of the Medicare benefit, also increases pricing pressures on the Group's products. 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 testing, approval, manufacturing and marketing of many of its pharmaceutical and consumer healthcare products, particularly in the USA and countries of the European Union, 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. Health authorities have increased their focus on safety when assessing the benefit risk/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 can 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 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 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 suppliers of key services and materials or the Group's own manufacturing facilities could lead to product recalls and seizures, interruption of production and delays in the approvals of new products pending resolution of manufacturing issues. Non-compliance can also result in fines and disgorgement of profits. Any interruption of supply or the incurrance of fines or disgorgement could materially and adversely affect the Group's financial results.

Although the Group undertakes business continuity planning, single sourcing for certain components, bulk active materials and finished products creates a risk of failure of supply in the event of regulatory non-compliance or physical disruption at the manufacturing sites.

Risk from concentration of sales to wholesalers

In the USA, in line with other pharmaceutical 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 85% of the Group's US pharmaceutical sales in 2009. At 31st December 2009 the Group had trade receivables due from these three wholesalers totalling £867 million (31st December 2008 - £1,067 million). The Group is exposed to a concentration of credit risk in respect of these wholesalers such that, if one or more of them is affected by financial difficulty, it could materially and adversely affect the Group's financial results.

Global political and economic conditions

Many of the world's largest economies, including the major markets in which the Group operates, and financial institutions have recently faced extreme financial difficulty, including a decline in asset prices,

liquidity problems and limited availability of credit. Many of these economies have experienced sharp recessions. While some economies have shown signs of recovery, the rate of recovery may be slow.

Continued economic weakness may have a material adverse effect on the Group's sales, results of operations, financial condition and ability to raise capital. Some of the Group's businesses, including Consumer Healthcare, may be particularly sensitive to declines in consumer 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. 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.

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. The Group is currently appealing a court decision in respect of transfer pricing with the Canadian Tax Authorities as discussed in Note 14 to the financial statements in the Annual Report 2009, 'Taxation'.

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.

Pandemic Influenza

The market for pandemic influenza vaccines is experiencing significant volatility given changes in risk perception, developing epidemiology and the relative mild nature of the virus, which was not anticipated by governments or the medical community. Some governments that have placed orders for the pandemic vaccine or that have announced changes in their planned immunisation programmes have renegotiated their contracts, and other governments are seeking, or may in the future seek, to renegotiate their contracts. While deliveries of pandemic vaccines provided significant contributions to the Group's results in

2008 (H5N1 vaccines) and 2009 (H1N1 vaccines), and the Group expects the level of sales in 2010 (H1N1, possibly stockpile agreements) to be roughly the same as in 2009, there can be no assurance that sales of influenza vaccines will meet these estimates or contribute significantly to the Group's results in 2011 or beyond.

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.

Accounting standards

New or revised accounting standards, rules and interpretations circulated from time to time by an international standard setting board could result in changes to the recognition of income and expense that may materially and adversely affect the Group's financial results.

International standard changes in the market valuation of certain financial instruments are reflected in the Group's reported results before those gains or losses are actually realised and 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 ownership of 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, which may materially and adversely affect the Group's financial results.

Failure of third party providers

Unaffiliated third-party suppliers provide a number of goods and services to the Group's operations. Many of these services, for example services provided by clinical research organizations to support development of key products, are very important to the operations of the Group's businesses. Materials provided by third-party suppliers are necessary for the commercial production of our products, including speciality chemicals, commodities and components necessary for the manufacture, fill-finish and packaging of many of the Group's pharmaceutical and Consumer Healthcare products. While the Group does not believe that any of these third-party relationships are individually significant in the context of the overall Group, the failure of any third-party supplier to fulfil its contractual obligations in a timely manner may result in delays or service interruptions, which may 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 personally identifiable information, trade secrets, intellectual property and corporate strategic plans. The security of such data is exposed to increasing

threats. The Group is also subject to various standards for the protection of personally identifiable information. 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 affect the Group's operations.

Alliances and acquisitions

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 to meet its objectives. The Group faces intense competition for qualified individuals, as the supply of people with specific skills or in specific geographic regions may be limited, particularly given the Group's plans to expand its operations in emerging markets, Biologicals and Consumer Healthcare.

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 financial results.

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. There can be no assurance that the Group will be able to implement its strategic priorities fully or that the strategic priorities will deliver the expected benefits.

(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 Business review section contained in the Annual Report includes a fair view 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 |
| Mr Andrew Witty | Chief Executive Officer |
| Mr Julian Heslop | 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 |
| Mr Larry Culp | Non-Executive Director |
| Sir Crispin Davis | Non-Executive Director |
| Sir Deryck Maughan | Non-Executive Director |
| Mr James Murdoch | Non-Executive Director |
| Dr Daniel Podolsky | Non-Executive Director |
| Mr Tom de Swaan | Non-Executive Director |
| Sir Robert Wilson | Senior Independent Non-Executive Director |

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: February 25 2010

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc