

GLAXOSMITHKLINE PLC  
Form 6-K  
March 04, 2009

**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 2009

**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

Securities Exchange Act of 1934.

Yes No x

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**Publication of GlaxoSmithKline plc's  
Annual Report 2008**

Today,

4 March 2009

, GlaxoSmithKline plc published on the Company's website, [www.gsk.com](http://www.gsk.com), its Annual Report in respect of the year ended

31 December 2008

A hard copy version of the Annual Report 2008 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

24 March 2009

. Shareholders who have not elected to continue to receive paper communications will be sent a 2008 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 Rules 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 2008

, which were announced on

5 February 2009

, were prepared in accordance with IAS 34.

Appendix B to this announcement contains the consolidated Cash Flow Statement for the year ended 31 December 2008 and an explanatory note regarding a number of reclassifications and other minor amendments to the consolidated Cash Flow Statement included in the unaudited Preliminary Results.

**S M Bicknell**

**Company Secretary**

4 March 2009

**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**

There are risks and uncertainties relevant to the Group's business, financial condition and results of operations that may affect future performance. These include R&D, anticipated sales growth and expected earnings. The factors below are among those that the Group thinks 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. The major risks that might affect GSK's business are:

#### **Risk that r&d will not deli**

**ver**

#### **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, inability to obtain necessary regulatory approvals, difficulty or excessive costs to manufacture, erosion of patent term as a result of a lengthy development period, infringement of patents or other intellectual property rights of others or inability to differentiate the product adequately from those with which it competes.

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. Payers are also becoming increasingly more demanding with regard to the incremental benefit required to gain reimbursement and secure appropriate pricing.

### **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 turnover and margins would be 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*  
and  
*Wellbutrin XL*

had a significant impact on the Group's overall turnover and earnings for 2008.

**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 affecting the exclusivity period for the Group's products, including biological products. Should such proposals be enacted they could have an adverse impact on the Group's future sales and results of operations.

**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. In an effort to control public health crises, some developing countries, such as  
South Africa

,  
Thailand  
and  
Brazil

, have considered plans for substantial reductions in the scope of patent protection for pharmaceutical products. In particular, these countries could facilitate competition within their markets from generic manufacturers who would otherwise be unable to introduce competing products for a number of years.

Any loss of patent protection, including abrogation of patent rights or compulsory licensing, is likely to affect adversely the Group's operating 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 AD**

**VER**

**SE OUTCOME OF LITIGATION**

**AND**

**GO**

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**NMENT**

## **INVESTIGATIONS**

Unfavourable resolution of proceedings and governmental

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investigations, involving matters which if proven could give rise to civil and/or criminal liabilities, in which the Group is currently involved 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 2006, 2007 and 2008 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 material additional charges.

### **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 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.

### **Anti-trust litigation**

In the

USA

it has become increasingly common that following publicity around government investigations or an adverse outcome in prosecution of patent infringement actions, the defendants and direct and indirect purchasers and other payers initiate anti-trust actions as well. 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.

### **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.

## **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 could adversely affect the Group's operating 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 could adversely affect the Group's competitive position, while continued consolidation among the Group's customers may increase pricing pressures.

The Group had eight products with over £500 million in annual global sales in 2008. Among these products are

*Augmentin IR*

,

*Imitrex*

and

*Lamictal*

for which there is generic competition, and

*Avandia*

and

*Valtrex*

, with respect to which the Group's intellectual property rights in the

USA

are currently the subject of litigation or settlement agreements related to such litigation.

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 adverse impact on the Group's revenues and operating results could be significant. 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 predict whether existing controls, pressures or restrictions will increase or new controls, pressures or restrictions will be introduced that will reduce the Group's margins or affect adversely its ability to introduce new products profitably.

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 develops under the outpatient pharmaceutical programme covering Medicare beneficiaries that began in 2006. The private insurers through which coverage is offered, through their enormous purchasing power under the programme, could demand discounts that may implicitly create price controls on prescription drugs.

Changes to the enabling legislation could afford the

US

government a direct role in negotiating prices under the Medicare programme. Additionally, a number of states have proposed or implemented various schemes to control prices for their own senior citizens' programmes, including 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. These trends may adversely affect the Group's revenues and margins from sales in the

USA

## **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, declines in sales of

*Avandia*

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 have a major impact on the marketing and sale of the product.

## **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 fines or disgorgement remedy 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 84% of the Group's

US

pharmaceutical sales. At

31st December 2008

the Group had trade receivables due from these three wholesalers totalling £1,067 million (

31st December 2007

- £915 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.

#### **RELIANCE ON INFORMATION TECHNOLOGY**

The Group is increasingly dependent on information technology systems, including Internet-based systems, for internal communication as well as communication with customers and suppliers. Any significant disruption of these systems, whether due to computer viruses or other outside incursions, could materially and adversely affect the Group's operations.

#### **GLOBAL POLITICAL**

**AND**

#### **ECONOMIC CONDITIONS**

Many of the world's largest economies, including the major markets in which the Group operates, and financial institutions currently face extreme financial difficulty, including a decline in asset prices, liquidity problems and limited availability of credit. It is uncertain how long this crisis will last, but many countries are concerned that their economies may enter a deep and prolonged recession.

Such a decline in economic activity 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, the financial crisis 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 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**

The effective tax rate on the Group's earnings benefits from the fact that a portion of its earnings is taxed at more favourable rates in some jurisdictions outside the

UK

. Changes in tax laws or in their application with respect to matters such as transfer pricing, foreign dividends, controlled companies or a restriction in tax relief allowed on the interest on intra-Group debt, could increase the Group's effective tax rate and adversely affect its financial results. The Group has open issues with the revenue authorities in the

USA

,  
Japan

and

Canada

#### **DISRUPTION FROM PANDEMIC INFLUENZA**

In the event of pandemic influenza, the Group could be subject to disruption from a range of factors. National governments may be more willing to abrogate intellectual property rights for medicines that might otherwise be in short supply.

In a country afflicted by pandemic 'flu, there would be a risk that employees and their families will be affected with the consequence that sales and distribution and manufacturing activities could be shut down and supply continuity - for active ingredients and finished goods - affected.

#### **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 could materially and adversely affect the Group's operations.

#### **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 adversely impact the Group's reported 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.

#### **HUMAN RESOURCES**

The Group has  
approximately 99

,000 employees globally and is subject to laws and regulations concerning its employees - ranging from discrimination and harassment to personal privacy to labour relations - that vary significantly from jurisdiction to jurisdiction. The Group faces intense competition for qualified individuals from other

pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. Failure to continue to recruit and retain the right people and maintain a culture of compliance may have a significant adverse effect.

**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 health 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 fulfill its contractual obligations in a timely manner may result in delays or service interruptions which could constrain the sales of the Group's products.

**(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.

<b>Name</b>	<b>Function</b>
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 Lawrence Culp	Non-Executive Director
Sir Crispin Davis	Non-Executive Director

Sir Deryck Maughan	Non-Executive Director
Dr Daniel Podolsky	Non-Executive Director
Sir Ian Prosser	Senior Independent Non-Executive Director
Dr Ronaldo Schmitz	Non-Executive Director
Mr Tom de Swaan	Non-Executive Director
Sir Robert Wilson	Non-Executive Director

## APPENDIX B

### Cash Flow Statement Year ended 31<sup>st</sup> December 2008

	2008	2007
	£m	£m
	----	----
	<b>4,712</b>	5,310
<b>Profit after tax</b>	<b>1,947</b>	2,142
Tax on profits		
Share of after tax profits of associates and joint ventures	<b>(48)</b>	(50)
	<b>530</b>	191
Net finance expense		
Depreciation and other non-cash items	<b>1,437</b>	1,333
Decrease/(i ncrease ) in working capital	<b>69</b>	(538)
Increase/(decrease) in other net liabilities	<b>408</b>	(308)
	----	----
<b>Cash generated from operations</b>	<b>9,055</b>	8,080
Taxation paid	<b>(1,850)</b>	(1,919)
	----	----
<b>Net cash inflow from operating activities</b>	<b>7,205</b>	6,161
	----	----

**Cash flow from investing activities**

Purchase of property, plant and equipment	(1,437)	(1,516)
Proceeds from sale of property, plant and equipment	20	35
Purchase of intangible assets	(632)	(627)
Proceeds from sale of intangible assets	171	9
Purchase of equity investments	(87)	(186)
Proceeds from sale of equity investments	42	45
Purchase of businesses, net of cash acquired	(454)	(1,027)
Investment in associates and joint ventures	(9)	(1)
Decrease/(increase) in liquid investments	905	(39)
	320	247
Interest received		
Dividends from associates and joint ventures	12	12
	----	----

**Net cash outflow from investing activities**

	(3,048)	
	(1,149)	
	----	----

**Cash flow from financing activities**

Proceeds from own shares for employee share options	9	116
Shares acquired by ESOP Trusts	(19)	(26)
	62	417
Issue of share capital		
Purchase of own shares for cancellation	(3,706)	(213)
	-	
Purchase of Treasury shares	(3,538)	
	5,523	3,483
Increase in long-term loans		
Repayment of long-term loans	-	(207)
Net (repayment of)/increase in short-term loans	(3,059)	1,632
	(48)	(39)

Net repayment of obligations under finance leases		
Interest paid	(730)	(378)
Dividends paid to shareholders	(2,929)	(2,793)
Dividends paid to minority interests	(79)	(77)
	68	
Other financing cash flows		(79)
	----	----
<b>Net cash outflow from financing activities</b>	<b>(4,908)</b>	<b>(1,702)</b>
	----	----
<b>Increase in cash and bank overdrafts in the year</b>	<b>1,148</b>	<b>1,411</b>
	<b>1,103</b>	<b>48</b>
Exchange adjustments		
Cash and bank overdrafts at beginning of year	3,221	1,762
	----	----
<b>Cash and bank overdrafts at end of year</b>	<b>5,472</b>	<b>3,221</b>
	----	----
Cash and bank overdrafts at end of year comprise:		
	<b>5,623</b>	<b>3,379</b>
Cash and cash equivalents		
Overdrafts	(151)	(158)
	----	----
	<b>5,472</b>	<b>3,221</b>

During the finalisation of the Annual Report, a number of reclassifications and other minor amendments have been made to items in the consolidated

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low  
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tatement. These have the effect of reducing cash generated from operations for 2008 from the £9,161 million reported in the unaudited Preliminary Results to £9,055 million. One of these reclassifications changes the total net cash outflow from investing activities and the total net cash outflow from financing activities, but the increase in cash and bank overdrafts remains £1,148 million, as reported in the unaudited Preliminary Results . Comparative figures have also been reclassified where appropriate.

This latter reclassification would also apply to cash flow statements reported in previous quarterly announcements issued in 2008.

#### **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 04 2009

By: VICTORIA WHYTE

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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc