

GLAXOSMITHKLINE PLC

Form 6-K

July 02, 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 July 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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Issued: Monday 2 July 2012, London UK & Philadelphia, US

GlaxoSmithKline concludes previously announced agreement in principle to resolve multiple investigations with US Government and numerous states

- Final settlement of \$3bn covered by existing legal provisions announced in November 2011
- Fundamental changes to US compliance, marketing and selling procedures implemented in recent years

GlaxoSmithKline plc (GSK) today announced that it has reached an agreement with the US Government, multiple states and the District of Columbia to conclude the Company's most significant ongoing Federal government investigations. The final settlement is a result of negotiations which reached agreement in principle in November 2011. GSK will make payments totalling \$3bn which are covered by existing provisions and will be funded through existing cash resources.

The agreement resolves criminal and civil liabilities related to: an investigation begun by the US Attorney's office of Colorado in 2004 and later taken over by the US Attorney's Office of Massachusetts into GSK's sales and marketing practices for nine products; the U.S. Department of Justice's investigation of possible inappropriate use of the nominal price exception under the Medicaid Rebate Program; and the Department of Justice's investigation of the marketing and regulatory submissions of Avandia.

As part of the agreement, GSK has entered into a corporate integrity agreement (CIA) with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. The CIA will also cover a portion of GSK's manufacturing operations, related to the company's settlement in 2010 on events in the early 2000s at GSK's former manufacturing facility in Cidra, Puerto Rico. In both areas, the CIA will build on the company's existing comprehensive compliance programmes.

Commenting on the agreement, GlaxoSmithKline CEO Sir Andrew Witty said: "Today brings to resolution difficult, long-standing matters for GSK. Whilst these originate in a different era for the company, they cannot and will not be ignored. On behalf of GSK, I want to express our regret and reiterate that we have learnt from the mistakes that were made.

"We are deeply committed to doing everything we can to live up to and exceed the expectations of those we work with and serve. Since I became CEO, we have had a clear priority to ingrain a culture of putting patients first, acting transparently, respecting people inside and outside the organisation and displaying integrity in everything we do.

"In the US, we have taken action at all levels in the company. We have fundamentally changed our procedures for compliance, marketing and selling. When necessary, we have removed employees who have engaged in misconduct. In the last two years, we have reformed the basis on which we pay our sales representatives and we have

enhanced our ability to 'claw back' remuneration of our senior management.

"We have a vital role to play in bringing innovative medicines to patients and we understand how important it is that our medicines are appropriately promoted to healthcare professionals and that we adhere to the standards rightly expected by the US Government."

Under the terms of the settlement, GSK will plead guilty to misdemeanor violations of the Federal Food, Drug, and Cosmetic Act related to certain aspects of the marketing of Paxil for paediatric use and of Wellbutrin for certain uses, and for failure to include information about the initiation or status of certain Avandia studies in Periodic and Annual Reports submitted to FDA.

The civil settlement reached with the Government does not constitute an admission of any liability or wrongdoing in the selling and marketing of Lamictal, Zofran, Imitrex, Lotronex, Flovent, Valtrex, Avandia or Advair products, nor in its nominal pricing practices.

GSK has made fundamental changes to its procedures for compliance, marketing and selling in the US over the last few years. The company has adopted new policies, enhanced others, and implemented measures to strengthen training and compliance programs, including adding compliance staff. Since January 2011, the company has put in place a new incentive compensation system for GSK professional sales representatives who work directly with health care professionals. The new system eliminates individual sales targets as a basis for bonuses, and instead bases incentive compensation on the quality of the service these representatives deliver to customers to support improved patient health.

These changes ensure that the company's programs and activities are well-controlled and aligned with the evolving expectation of its stakeholders. Most importantly, the changes are in keeping with the company's core values, ensuring that its activities and relationships are transparent, based on integrity and respect, and focused on the best interests of patients. The Company's US Commercial Practices Policies now meet or exceed the US PhRMA Code governing interactions with healthcare professionals.

The finalisation of the terms of the settlement mean that this matter can be resolved within the existing pre-tax provision. The after tax cost will be approximately \$150m lower than provided. As a result a credit will be recorded to the non-core tax charge for the second quarter 2012.

However, due to the evolving state litigation environment, GSK expects to utilise the tax benefit arising in recording an offsetting additional pre-tax provision of approximately \$180m (equating to an after tax cost of \$150m) related to these matters. This will be recorded as a non-core charge in SG&A in Q212.

The net effect of these movements on total earnings is expected to be neutral. The overall legal provision held for all matters across the Group will be reviewed as part of the company's standard quarterly close process.

V A Whyte  
Company Secretary

2 July 2012

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit [www.gsk.com](http://www.gsk.com).

## GlaxoSmithKline

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## 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 GSK's operations are described under 'Risk factors' in the 'Financial review & risk' section in the company's Annual Report 2011 included as exhibit 15.2 to the company's Annual Report on Form 20-F for 2011.

Registered in England & Wales:  
No. 3888792

Registered Office:  
980 Great West Road  
Brentford, Middlesex  
TW8 9GS

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: July 2, 2012

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