

GLAXOSMITHKLINE PLC

Form 6-K

May 06, 2008

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K
Report of Foreign Issuer
Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the period ending 6 May 2008

GlaxoSmithKline plc

(Name of registrant)

980 Great West Road,

Brentford,

Middlesex, TW8 9GS

(Address of principal executive offices)

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

Form 20-Fx Form 40-Fo

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.

Yeso Nox

THIS REPORT ON FORM 6-K SHALL BE DEEMED TO BE INCORPORATED BY REFERENCE IN THE PROSPECTUS INCLUDED IN THE REGISTRATION STATEMENT ON FORM F-3 (FILE NO. 333-149531) OF GLAXOSMITHKLINE PLC, GLAXOSMITHKLINE CAPITAL INC. AND GLAXOSMITHKLINE CAPITAL PLC AND TO BE A PART THEREOF FROM THE DATE ON WHICH THIS REPORT IS FURNISHED, TO THE EXTENT NOT SUPERSEDED BY DOCUMENTS OR REPORTS SUBSEQUENTLY FILED OR FURNISHED.

GlaxoSmithKline plc
Results Announcement for the first quarter 2008

GlaxoSmithKline (GSK) together with its subsidiary undertakings, the Group - 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. GlaxoSmithKline's website www.gsk.com gives additional information on the Group. Information made available on the website does not constitute part of this current report on Form 6-K.

Exchange rates

The Group operates in many countries and earns revenues and incurs costs in many currencies. The results of the Group, as reported in Sterling, are affected by movements in exchange rates between Sterling and other currencies. Average exchange rates prevailing during the period are used to translate the results and cash flows of overseas subsidiaries, associates and joint ventures into Sterling. Period end rates are used to translate the net assets of those entities. The currencies which most influence these translations are the US dollar, the Euro and the Japanese Yen.

Business performance

Business performance, which is a supplemental measure, is the primary performance measure used by management and is presented after excluding restructuring charges relating to the new Operational Excellence programme, which commenced in October 2007, and significant acquisitions. Management believes that exclusion of these items provides a better reflection of the way in which the business is managed and gives a more useful indication of the underlying performance of the Group.

Constant exchange rate

In order to illustrate underlying performance, it is the Group's practice to discuss its results in terms of constant exchange rate (CER) growth. All commentaries are presented in terms of CER growth and compare 2008 business performance results with 2007 total results, unless otherwise stated. See Accounting Presentation and Policies on page 16.

Brand names

Brand names appearing in italics throughout this document are trademarks of GSK or associated companies with the exception of *Levitra*, a trademark of Bayer, *Bonviva/Boniva*, a trademark of Roche, and *Vesicare*, a trademark of Astellas Pharmaceuticals in many countries and of Yamanouchi Pharmaceuticals in certain countries, all of which are used under licence by the Group.

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this Results 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 on page 17.

PHARMACEUTICAL UPDATE

Total pharmaceutical turnover for the first quarter declined 4% to £4.8 billion, with growth from key products offset by significant generic competition to products in the USA and declines in *Avandia* sales in all regions. In the **United States**, turnover was £2,138 million, down 10%, in **Europe** turnover was £1,526 million, down 1%, and in **International** markets sales were £1,129 million, up 6%.

***Seretide/Advair* sales up 10% with strong performance in all regions**

Sales of *Seretide/Advair*, for asthma and COPD, rose 10% to £954 million, with sales in the USA also growing 10% to £499 million. In Europe, sales grew 9% to £351 million and in International sales grew by 16% to £104 million. GSK continues to see increased use of *Seretide/Advair* in the treatment of COPD and is in ongoing discussions with the FDA to expand further the indication for use in this patient group. GSK expects a decision from the FDA during the second quarter.

Vaccine sales of £436 million up 10% driven by strong US performance

US vaccine sales grew 34% for the quarter to £109 million, driven by continued strong performances of **hepatitis vaccines**, up 66% to £53 million, and *Infanrix/Pediarix*, up 21% to £51 million. In Europe, sales of vaccines were up 5% to £202 million. In International markets sales rose 2% to £125 million, adversely impacted in part by the timing of shipments. GSK expects stronger growth in this region in the rest of this year.

GSK expects to submit a response to the FDA's Complete Response letter regarding *Cervarix* in the second quarter and will continue discussions with the agency regarding the application. *Cervarix* has now been approved in more than 60 countries with discussions regarding reimbursement and tender orders on-going. Sales for *Cervarix* in the quarter were £12 million.

In April, GSK received FDA approval for *Rotarix*, a new two-dose vaccine to prevent rotavirus gastroenteritis, with launch expected in the second half of the year. Sales of *Rotarix* in markets outside of the USA grew 79% to £27 million.

In February, GSK received a positive opinion from the EMEA regarding *Prepandrix*, its pre-pandemic flu vaccine. *Prepandrix* will be the first vaccine approved for pre-pandemic use in Europe. In March a supply contract was signed by the Finnish Government for 5.2 million doses of *Prepandrix* for use in advance of a pandemic flu outbreak. Shipments will commence in the second half of 2008.

New growth drivers

Arixtra, for deep vein thrombosis and pulmonary embolism, delivered strong growth with sales up 70% to £35 million. Sales grew in Europe (up 33% to £14 million) following approval last year for the treatment of specific acute coronary syndromes (ACS). In the USA, GSK is in on-going discussions with the FDA regarding a potential ACS indication.

Avodart, for benign prostatic hyperplasia (enlarged prostate), continued to perform strongly with sales up 30% to £85 million for the quarter. GSK has filed for a co-prescription indication in the USA, Europe and International markets for use of *Avodart* in combination with the alpha-blocker, tamsulosin. In April, GSK received its first regulatory approval for this indication in Europe under the mutual recognition procedure. GSK expects a response from the FDA in June for this application.

GSK's co-promotion income for *Boniva/Bonviva*, the only once-monthly oral medicine for post-menopausal osteoporosis, was up 50% to £49 million.

Sales of GSK's newly acquired *Lovaza*, an omega-3-acid product for adult patients with very high levels of triglycerides, contributed £50 million (+72% on a proforma basis).

Tykerb/Tyverb, for breast cancer, achieved sales of £19 million for the quarter. An extensive development programme involving 10 phase III clinical trials is ongoing, including metastatic, first line and adjuvant breast cancer. Last week new data were presented at the European Breast Cancer Conference in Berlin which demonstrated the efficacy of **Tykerb** in shrinking tumours prior to surgery and reducing the number of chemotherapy-resistant cancer stem cells responsible for tumour regeneration. Enrolment was completed for TEACH in the quarter a phase III study investigating whether adjuvant treatment with **Tykerb** will improve survival in early breast cancer by preventing the disease from recurring.

Veramyst/Avamys, for allergic rhinitis, generated sales of £13 million across the USA and Europe for the quarter.

Other key pharmaceutical products

Sales of **Avandia** products, for the treatment of type 2 diabetes, fell 56% to £191 million. Sales in the USA for the quarter were £99 million, down 66%, with **Avandia**'s share of total prescriptions in the US oral anti-diabetic market currently stable at around 4%. In Europe sales were £54 million, down 14%, and in International markets £38 million, down 44%.

Sales of **Coreg** products, for heart disease, fell 77% to £48 million, following the introduction of generic competition to **Coreg IR** in September 2007. Sales of **Coreg CR** were £35 million with increasing share gains made in the US hypertension market.

Total sales of HIV products were £358 million, down 5%. Competition to older products, **Combivir** (-13% to £105 million) and **Epivir** (-22% to £34 million), was partially offset by strong sales growth of **Epzicom/Kivexa** (+25% to £99 million).

Sales of **Lamictal**, for the treatment of epilepsy and bipolar disorder, were £290 million driven by strong performance in the USA with sales up 22% to £240 million.

Sales of **Relenza**, an antiviral treatment for flu, were £29 million (£92 million in Q1 2007), reflecting the variable timing of tender orders from governments stockpiling against a possible flu pandemic.

Sales of **Requip**, for Parkinson's Disease/Restless Legs Syndrome, grew 15% to £94 million for the quarter. **Requip XL**, a new once-daily formulation for Parkinson's Disease, has now been launched in 12 European markets. In the USA, GSK expects a response from the FDA on its application for **Requip XL** during the second quarter of 2008.

Sales of **Valtrex**, for herpes, rose 9% to £249 million, with US sales up 7% to £173 million, driven by increased use of the product for prevention of herpes transmission. Sales in Europe grew 18% to £37 million and in International sales grew 9% to £39 million.

Product sales affected by generic competition were **Wellbutrin** (-3% to £126 million), **Flixonase/Flonase** (-33% to £46 million) and **Zofran** (-69% to £29 million).

UNAUDITED PHARMACEUTICAL TURNOVER
Three months ended 31st March 2008

	Total			USA			Europe			International		
	£m	CER%	£%	£m	CER%	£%	£m	CER%	£%	£m	CER%	£%
RESPIRATORY	1,355	6	11	616	8	6	495	4	15	244	5	16
<i>Seretide/Advair</i>	954	10	14	499	10	9	351	9	19	104	16	27
<i>Flixotide/Flovent</i>	162	(1)	5	75	7	6	45	(7)	7	42	(7)	
<i>Serevent</i>	67	(5)	3	17	(11)	(11)	37	6	16	13	(21)	(7)
<i>Flixonase/Flonase</i>	46	(33)	(27)	4	(84)	(84)	14		8	28		12
<i>Veramyst</i>	13			12			1					
CENTRAL												
NERVOUS SYSTEM	829	3	4	594	7	5	131	(7)	2	104	(8)	1
<i>Seroxat/Paxil</i>	121	(15)	(10)	31	(16)	(16)	29	(21)	(15)	61	(11)	(3)
<i>Paxil IR</i>	88	(13)	(5)	2			29	(21)	(15)	57	(12)	(3)
<i>Paxil CR</i>	33	(20)	(20)	29	(22)	(22)				4		
<i>Wellbutrin</i>	126	(3)	(5)	121	(4)	(5)	3	>100	>100	2	(33)	(33)
<i>Wellbutrin IR, SR</i>	13	(43)	(43)	11	(45)	(45)	1			1	(50)	(50)
<i>Wellbutrin XL</i>	113	6	4	110	4	2	2			1		
<i>Imigran/Imitrex</i>	165	(1)	(1)	134		(1)	23	(5)	10	8	(11)	(11)
<i>Lamictal</i>	290	16	16	240	22	20	34	(11)	(3)	16		7
<i>Requip</i>	94	15	18	60	9	7	29	24	38	5	67	67
ANTI-VIRALS	739	(8)	(4)	347	(9)	(10)	213	(15)	(6)	179	6	14
HIV	358	(5)		152	(6)	(7)	159	(6)	5	47	2	9
<i>Combivir</i>	105	(13)	(9)	45	(8)	(10)	43	(20)	(12)	17	(6)	6
<i>Trizivir</i>	54	(16)	(13)	27	(16)	(16)	24	(19)	(11)	3		
<i>Epivir</i>	34	(22)	(17)	11	(21)	(21)	15	(22)	(17)	8	(22)	(11)
<i>Ziagen</i>	25	(8)	(4)	10	(9)	(9)	9	(11)		6		
<i>Agenerase, Lexiva</i>	35	(3)		18	(10)	(10)	15	8	15	2		
<i>Epzicom/Kivexa</i>	99	25	32	40	17	14	48	33	45	11	29	57
Herpes	274	6	10	174	7	5	45	11	25	55	2	15
<i>Valtrex</i>	249	9	11	173	7	5	37	18	32	39	9	22
<i>Zovirax</i>	25	(15)	(4)	1	(50)	(50)	8	(13)		16	(13)	
<i>Zeffix</i>	46	8	15	3			7		17	36	10	16
<i>Relenza</i>	29	(71)	(68)	8	(82)	(82)				21	19	31
VACCINES	436	10	18	109	34	33	202	5	17	125	2	10
Hepatitis	139	16	23	53	66	66	57	(5)	2	29		16
Influenza	5						4			1		
<i>Infanrix/Pediarix</i>	153	6	14	51	21	19	82	(1)	12	20		11
<i>Boostrix</i>	13	(8)		5	(29)	(29)	5		25	3	50	50
<i>Rotarix</i>	27	79	93				9	100	>100	18	70	80
<i>Cervarix</i>	12						10			2		
	398	(12)	(9)	232	(22)	(23)	119	6	19	47	19	31

**CARDIOVASCULAR
AND UROGENITAL**

<i>Coreg</i>	48	(77)	(78)	48	(78)	(78)						
<i>Coreg CR</i>	35	>100	>100	35	>100	>100						
<i>Coreg IR</i>	13	(94)	(94)	13	(94)	(94)						
<i>Levitra</i>	14			13			1					
<i>Avodart</i>	85	30	35	49	22	20	28	39	56	8	75	100
<i>Arixtra</i>	35	70	75	19	73	73	14	33	56	2		
<i>Fraxiparine</i>	51	(4)	9				44	(7)	5	7	20	40
<i>Vesicare</i>	14	36	27	14	36	27						
<i>Lovaza</i>	50			50								

ANTI-BACTERIALS

ANTI-BACTERIALS	365	(2)	5	45	(13)	(15)	181	(7)	3	139	10	16
<i>Augmentin</i>	156	(1)	6	17	(29)	(29)	82		12	57	10	14
<i>Altabax</i>	2			2								

METABOLIC

METABOLIC	274	(45)	(42)	133	(57)	(58)	74	(6)	4	67	(30)	(24)
<i>Avandia products</i>	191	(56)	(54)	99	(66)	(66)	54	(14)	(5)	38	(44)	(40)
<i>Avandia</i>	122	(62)	(61)	71	(69)	(69)	22	(35)	(29)	29	(48)	(44)
<i>Avandamet</i>	62	(29)	(25)	24	(49)	(49)	31	8	19	7	(30)	(30)
<i>Avandaryl</i>	7	(63)	(56)	4	(73)	(73)	1			2		100
<i>Bonviva/Boniva</i>	49	50	53	33	48	43	15	44	67	1		

ONCOLOGY AND**EMESIS**

ONCOLOGY AND EMESIS	113	(27)	(23)	58	(41)	(42)	38	6	19	17		13
<i>Zofran</i>	29	(69)	(67)	3	(95)	(95)	16	(30)	(20)	10	(9)	(9)
<i>Hycamtin</i>	30	(3)		17	(5)	(11)	11	11	22	2	(50)	
<i>Tykerb</i>	19	>100	>100	10	>100	>100	7	>100	>100	2		

OTHER

OTHER	284	13	18	4	(91)	(88)	73	20	30	207	32	36
	4,793	(4)		2,138	(10)	(12)	1,526	(1)	10	1,129	6	13

Pharmaceutical turnover includes co-promotion income.

CONSUMER HEALTHCARE UPDATE**Consumer Healthcare sales grew 8% to £893 million, driven by innovation and geographic expansion**

In Europe, sales grew 7% to £413 million with strong performances in Central and Eastern Europe. In International, sales grew 18% to £285 million with strong performances from key markets, Latin America, India and the Middle East.

Sales in North America declined 2% to £195 million due to strong competition to smoking cessation products from prescription medicines and retailers' own-label nicotine replacement products. Excluding the smoking cessation brands, North American consumer healthcare sales grew 6% to £157 million.

Over-the-counter medicine sales grew 4% to £411 million. Following its successful launch in June 2007, *alli* contributed sales of £9 million which were impacted by normalisation of inventory levels after a year-end promotion. Demand for *alli* continues to be strong and, based on retail market data, underlying demand is estimated to have been £35 million during the quarter. *Panadol* sales grew 19% to £80 million. Sales of *Breathe Right*, recently acquired from CNS, grew 14% to £17 million. The product will be launched in European, Asian and Latin American markets this year.

Oral healthcare sales were up 8% to £289 million for the quarter. Sales of *Sensodyne* grew 19% to £86 million, aided by the successful launch of *Sensodyne Pronamel*. Sales of *Aquafresh* grew 7% to £83 million, and sales of the denture care brands, *Poligrip*, *Corega* and *Polident*, grew 4% to £60 million.

Nutritional healthcare sales for the quarter increased by 14% to £193 million. *Lucozade* continued its excellent performance, up 18% to £86 million. *Horlicks* sales grew 18% to £56 million, whilst sales of *Ribena* declined 5% to £37 million.

UNAUDITED CONSUMER HEALTHCARE TURNOVER
Three months ended 31st March 2008

	Q1 2008		Growth
	£m	CER%	£%
Over-the-counter medicines	411	4	10
Analgesics	116	13	20
Dermatological	46	8	15
Gastrointestinal	68		3
Respiratory tract	71	18	27
Smoking control	58	(27)	(26)
Natural wellness support	32		7
Weight management	9		
Oral care	289	8	17
Nutritional healthcare	193	14	18
Total	893	8	14

PHARMACEUTICAL PIPELINE UPDATE

In February, the company published an update of its R&D pipeline. GSK currently has 157 projects in clinical development comprising 96 NCEs, 37 PLEs and 24 Vaccines. GSK has 34 key assets currently in phase III development or registration.

First major market approvals and filings

In April, GSK received FDA approval for *Treximet*, a new acute treatment of migraine. *Treximet* is the first and only migraine product designed to target multiple mechanisms of migraine by combining a triptan, a class of migraine-specific medicines pioneered by GSK, and an anti-inflammatory pain reliever in a single tablet. *Treximet* will be launched in the USA in May.

In March, the FDA granted priority review for *Promacta*, an oral thrombopoietin receptor agonist, for the short-term treatment of patients with chronic idiopathic thrombocytopenic purpura. The FDA's decision on *Promacta* is expected in the second quarter and, if approved, would be the first treatment of its type to be approved for this indication.

In February, the EMEA granted a positive opinion for approval of *Volibris* (ambrisentan) to treat functional class II and III pulmonary arterial hypertension.

Late-stage pipeline progress

Following analysis of the full data set for **darapladib**, which includes the dose ranging study presented at the American College of Cardiology in March and the IBIS-2 imaging study, GSK intends to progress darapladib into Phase III development and will shortly start discussions with regulators regarding the structure of the Phase III programme. GSK expects data from IBIS-2 to be presented and published in the second half of the year.

In March, positive phase III data were published demonstrating that *Bosatria* (mepolizumab) showed disease control with reduced corticosteroid use in treatment of hypereosinophilic syndrome. This is a group of rare disorders leading to significant respiratory, cardiac, skin and gastrointestinal problems and can be life-threatening in some people with advanced disease.

Positive results from the third pivotal phase III study for **GSK1838262** (XP13512) were also received in the quarter demonstrating its efficacy as a treatment of moderate-to-severe symptoms of primary restless legs syndrome. GSK expects to file 262 with the FDA for approval in the third quarter of 2008.

Acquisitions

On 22nd April GSK announced an agreement to acquire **Sirtris Pharmaceuticals**, a world leader in sirtuin research and development. Sirtuins are a class of enzymes that could be used to develop new medicines to address diseases associated with metabolism and ageing such as diabetes, muscle wasting and neurodegeneration.

Collaborations

On 17th April, GSK announced a worldwide strategic alliance with **Regulus Therapeutics** to discover, develop and market novel microRNA-targeted therapeutics, a new approach for the treatment of a wide range of diseases, including inflammatory diseases such as rheumatoid arthritis and inflammatory bowel disease.

FINANCIAL REVIEW

Operating profit business performance

**Q1 2008
% of**

**Q1 2007
% of**

**Growth
&nbs**