

GLAXOSMITHKLINE PLC

Form 6-K

October 23, 2013

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 23 October 2013

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

--

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

--

Issued: Wednesday, 23 October 2013, London U.K.

Results Announcement for the third quarter 2013

GSK delivers Q3 core EPS of 28.9p (+16% CER) and dividend of 19p (+6%)

- Full year 2013 guidance reaffirmed

Core results\*

	Q3 2013			9 months 2013		
	£m	CER%	£%	£m	CER%	£%
Turnover	6,510	1	-	19,599	-	-
Core operating profit	2,059	11	6	5,927	-	(1)
Core earnings per share	28.9p	16	10	82.1p	5	4

Total results

	Q3 2013			9 months 2013		
	£m	CER%	£%	£m	CER%	£%
Turnover	6,510	1	-	19,599	-	-
Operating profit	1,569	1	(5)	4,587	(14)	(15)
Earnings per share	20.0p	(4)	(12)	61.4p	(16)	(17)

Summary

Broadly-based sales growth with Group turnover +1% CER:

- Pharmaceuticals and Vaccines sales flat: US +2%, Europe +5%, Japan +2% offset by EMAP -9%, impacted by decline in China sales and Vaccines phasing
- Consumer Healthcare +4%
- Total Group turnover ex-divestments +1%

Further significant pipeline approvals and filings:

- 4 approvals; US: Tivicay for HIV and FluLaval Q-IV vaccine for flu; Europe: Tafinlar for metastatic melanoma; Japan: Relvar Ellipta for asthma
- Positive FDA Adcom recommendation for Anoro Ellipta in COPD and positive CHMP opinion for Relvar Ellipta in asthma & COPD
- 3 FDA filings: Arzerra for first-line CLL; dolutegravir-Trii for HIV; fluticasone furoate monotherapy for asthma

Continued delivery of operating and financial efficiencies, strong cash generation and returns to shareholders:

- Net cash inflow from operating activities of £2.1 billion; core tax rate 23.5%
-

- Core EPS 28.9p (+16%) benefiting from operating, financial and long-term cost efficiencies
- Q3 dividend: 19p (+6%)
- £1 billion of shares repurchased by the end of Q3; continue to target £1-2 billion for the year
  
- Successful implementation of measures to drive strategic focus and improve growth outlook:
  - Agreement to divest Lucozade and Ribena to Suntory for £1.35 billion and Arixtra/Fraxiparine and related manufacturing site to Aspen for £700 million
  
- Full year 2013 guidance reaffirmed:
  - Core EPS growth of 3-4% on sales growth of around 1% (both CER)

The full results are presented under 'Income Statements' on page 27 and Core results reconciliations are presented on pages 43 to 46.

\*For explanations of the measures 'Core results', 'Adjusted net cash inflow from operating activities' and 'CER', see page 25.

#### GSK's strategic priorities

We have focused our business around the delivery of three strategic priorities, which aim to increase growth, reduce risk and improve our long term financial performance:

- Grow a diversified global business
- Deliver more products of value
- Simplify the operating model

#### Chief Executive Officer's review

This quarter marks continued delivery for GSK of broadly-based sales growth, significant new product output from the pipeline and further growth in returns to shareholders.

In R&D, we received four approvals and importantly, we are making substantive progress to expand our respiratory portfolio.

Total sales grew 1%, core operating profit was up 11% and core earnings per share was up 16% at 28.9p.

The increase in core operating profit was driven by continued strong cost control, including a reduction in R&D expenditure, and the delivery of a further benefit from a programme of initiatives we started in 2012 to re-shape and reduce certain long-term operating expenses. As we saw last year, contributions from this programme are unevenly phased. We will continue to look for more of these opportunities to help deliver sustained reductions in costs and balance sheet liabilities.

As far as full year 2013 is concerned, we continue to expect core EPS growth of 3-4% on sales growth of around 1% (both at CER).

Contributions from across the Group helped to deliver sales growth in Q3 despite a significant decline in sales from our Chinese business and lower vaccine shipments in emerging markets due to the phasing of tender orders.

In the US, Pharmaceuticals and Vaccines sales grew 2%, negatively impacted by wholesaler and retailer de-stocking in the quarter. Excluding this impact, growth is estimated at 5%. This continues the momentum demonstrated by the US recently, and is encouraging given the intensifying price competition we are seeing. With our substantial new product flow and the changes we have made to our commercial model, we continue to be optimistic about future growth in this market.

I am also pleased with the performance of our European Pharmaceuticals and Vaccines business, with sales up 5%. Some of this improvement reflects the annualisation of government price cuts and it is clear that the commercial environment in Europe remains challenging. Nevertheless, I believe we are now seeing benefits from the measures we have taken to restructure and focus this business around core assets such as Seretide and key growth opportunities such as vaccines and our oncology portfolio.

EMAP Pharmaceuticals and Vaccines sales were down 9%, impacted by the timing of vaccine tender shipments and a significant sales decline in China (-61%), where operations have been disrupted by the ongoing investigation into our business. We continue to co-operate with the authorities and we remain fully committed to supplying our products to patients in the country. At this stage, it is still too early for us to quantify the longer-term impact of the investigation on our performance in China. Excluding the decline in China sales, our EMAP Pharmaceuticals business grew 5%.

As we have previously highlighted, 2013 is a key year for R&D delivery.

Of the 6 assets we highlighted at the beginning of the year, 4 have now been approved. We have also received approvals for our quadrivalent flu vaccine, FluLaval, and significant new indications for 3 other products. These represent substantial new growth opportunities in key areas of our portfolio.

In Oncology, we have launched both Tafenlar and Mekinist for metastatic melanoma in the US and have started to launch Tafenlar in Europe as well. We also received European approval for use of Tyverb in combination with trastuzumab for metastatic breast cancer in the quarter, and filed Arzerra, one of several biologic medicines we are developing, for first-line chronic lymphocytic leukaemia, in the US and Europe.

This quarter also saw the launch of Tivicay, a new treatment for HIV. This is a positive step forward for a disease area in which new drug development has proved challenging and is testament to the success of ViiV Healthcare, the company we established to focus on HIV treatment and research in 2009. We have also filed a once-daily single tablet combination of dolutegravir, abacavir and lamivudine to offer an additional potential new treatment regimen for patients with HIV.

In Respiratory, I am pleased to report that last week we began the shipping to wholesalers in the US of Breo Ellipta for treatment of COPD. The medicine is now approved in Japan for the treatment of asthma and we received a positive opinion for both COPD and asthma in Europe. In the US, an FDA Advisory Committee also voted positively to recommend approval

of Anoro Ellipta for COPD and a regulatory decision is expected before the end of the year. Today, we have announced the US filing of fluticasone furoate monotherapy for treatment of asthma. All these milestones are clear indicators of our ability to expand our current respiratory portfolio with new medicines and inhaler technology to build on more than 40 years of leadership in this therapy area.

Of the 14 Phase III assets we highlighted at the beginning of this year, we have received all data on 5. Three of these assets have progressed to filing and 2 reported negative data: drisapersen for Duchenne's Muscular Dystrophy and vercirnon for Crohn's disease. Both of these were disappointing given the need for new treatments in these areas. As we previously highlighted, data with our Zoster vaccine is now expected to read-out in 2015. We continue to expect Phase III data on 8 more assets before the end of 2014.

Finally in R&D, we took another major step forward this month in development of the world's first vaccine to prevent malaria, with positive 18 month follow-up data generated for the candidate vaccine. This vaccine has the potential to make a significant contribution to public health in Africa and we now intend to file it for approval in 2014.

As we focus on launching our new pipeline, we continue to make progress on the sale of non-core assets and parts of the business where we can realise attractive value for our shareholders. This quarter we announced agreements for divestitures totalling more than £2 billion. We have agreed to sell Lucozade and Ribena to Suntory for £1.35 billion and have accepted an offer of £700 million from Aspen for our anticoagulant products Arixtra and Fraxiparine and their related manufacturing site.

We continue to improve shareholder returns through both dividend payments and our long-term share buy-back programme. Today, we announced a dividend of 19p, up 6%. By the end of the third quarter we had repurchased £1 billion of shares and we continue to target share repurchases of £1-2 billion by the end of 2013.

Sir Andrew Witty  
Chief Executive Officer

A video interview with CFO Simon Dingemans discussing today's results is available on [www.gsk.com](http://www.gsk.com)

All forward looking statements are based on 2012 restated numbers adjusted for IAS 19R, at CER and barring unforeseen circumstances. See 'Cautionary statement regarding forward-looking statements' on page 25.

Contents	Page
Q3 2013 results summary	1
Chief Executive Officer's review	2
Group performance	5
Divisional performance	15
Research and development	22
Definitions	25

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

Contacts	26
Income statements	27
Statement of comprehensive income	28
Pharmaceuticals and Vaccines turnover – three months ended 30 September 2013	30
Pharmaceuticals and Vaccines turnover – nine months ended 30 September 2013	31
ViiV Healthcare turnover – three and nine months ended 30 September 2013	32
Balance sheet	33
Statement of changes in equity	34
Cash flow statement – nine months ended 30 September 2013	35
Segment information	36
Legal matters	39
Taxation	39
Additional information	40
Reconciliation of cash flow to movements in net debt	42
Core results reconciliations	43
Independent review report	47

Group performance

Group turnover by division, geographic region and segment

Group turnover by division	Q3 2013		9 months 2013	
	£m	Growth CER%	£m	Growth CER%
Pharmaceuticals	4,210	(1)	13,177	-
Vaccines	987	3	2,453	(2)
Pharmaceuticals and Vaccines	5,197	-	15,630	-
Consumer Healthcare	1,313	4	3,969	2
	6,510	1	19,599	-

Group turnover by geographic region

Group turnover by geographic region	Q3 2013		9 months 2013	
	£m	Growth CER%	£m	Growth CER%
US	2,231	2	6,458	-
Europe	1,871	4	5,611	-
EMAP	1,590	(6)	4,991	1
Japan	420	3	1,365	(2)

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

Other	398	3	1,174	-
	6,510	1	19,599	-
Group turnover outside US and Europe	2,408	(3)	7,530	-

Group turnover by segment	Q3 2013		9 months 2013	
	£m	Growth CER%	£m	Growth CER%
Pharmaceuticals and Vaccines				
-US	1,856	2	5,342	-
-Europe	1,274	5	3,836	-
-EMAP	1,068	(9)	3,392	-
-Japan	360	2	1,190	(4)
-ViiV Healthcare	344	(5)	1,001	(5)
Other trading and unallocated pharmaceuticals	295	3	869	-
Pharmaceuticals and Vaccines	5,197	-	15,630	-
Consumer Healthcare	1,313	4	3,969	2
	6,510	1	19,599	-

Turnover – Q3 2013

Total Group turnover for Q3 2013 was £6,510 million, up 1%, with growth across all geographic regions except EMAP. Disposals did not materially affect the reported growth rate for the Group in the quarter. Pharmaceuticals and Vaccines turnover was flat. Pharmaceuticals turnover declined 1%, as lower sales in the US, EMAP and ViiV Healthcare were partly offset by growth in Europe and Japan. Vaccines turnover grew 3%, as strong performances in the US and Europe were partially offset by lower reported sales in EMAP and Japan. Consumer Healthcare turnover increased 4% to £1,313 million.

In the US, Pharmaceuticals and Vaccines turnover grew 2% to £1,856 million, with Pharmaceuticals down 3% and Vaccines up 24%. Pharmaceuticals turnover in the quarter was impacted by wholesaler and retailer de-stocking, which is estimated to have reduced reported turnover growth by approximately 3 percentage points. US Respiratory sales were down 3%, reflecting the wholesaler and retailer de-stocking but also stronger competitive pricing pressure. Advair sales were down 1%, Flovent sales were down 8% and Ventolin was down 10%. Newer products continued to contribute strongly, with Oncology sales up 14% to £99 million, led by Votrient, up 38% to £36 million, and Promacta, up 27% to £19 million. Tafinlar and Mekinist were both launched in late Q2 2013. Benlysta also reported strong growth, with sales doubling to £39 million. Lovaza sales fell 12% to £134 million, due to the combined effect

of market contraction and increased competition. Generic competition impacted Lamictal, down 16% to £70 million, and Dermatology sales, which declined 18% to £40 million. The 24% increase in Vaccines sales primarily resulted from a 69% increase in Infanrix/Pediarix sales to £100 million, which continued to benefit from a competitor supply shortage, and a 29% increase in Fluarix/FluLaval sales to £104 million following the launch of the Quadrivalent flu formulation.

Europe Pharmaceuticals and Vaccines turnover grew 5% to £1,274 million. Pharmaceutical sales grew 5% to £1,001 million reflecting the annualisation of a number of government price cuts and other austerity measures together with the impact of the recent restructuring and refocusing of the business. The reported growth in the quarter also benefited from a number of one-off product contracting adjustments. Seretide volumes were flat, but continued pricing pressures led to a sales decline of 1% to £344 million. Oncology reported strong growth, up 32% to £91 million, led by Votrient and Promacta. Sales of Avodart increased 17% to £67 million. Vaccines sales grew 4%, largely due to the combination of an improved tender performance and some beneficial tender phasing.

EMAP Pharmaceuticals and Vaccines turnover declined 9% to £1,068 million, with Pharmaceuticals down 7% and Vaccines down 14%, reflecting vaccine tender phasing and the impact of the ongoing investigation in China. Pharmaceuticals and Vaccines sales in China were down 61%. Respiratory and Hepatitis products were particularly affected with Seretide down 56%, Zeffix down 73% and Hepsera down 76%. Excluding China, EMAP Pharmaceuticals and Vaccines turnover grew 2%, with Pharmaceuticals up 5%, reflecting continued growth from Seretide, up 6%, and Oncology up 29%. There were strong contributions from Latin America, up 7% to £162 million and Russia, up 26% to £43 million but India was down 15% to £49 million due to the impact of recent price reductions and wholesaler negotiations. EMAP Vaccines sales were down 14% to £263 million, largely reflecting the phasing of tender orders and a challenging comparison with Q3 2012, which benefited from strong tender deliveries, particularly of Rotarix and Infanrix/Pediarix.

Japan Pharmaceuticals and Vaccines turnover grew 2% to £360 million, with Pharmaceuticals sales increasing 7% and Vaccines sales declining by 75%. The growth in Pharmaceuticals reflected stronger sales of Respiratory products, up 5%, particularly Adair, up 8%, and Xyzal, up 23%. Lamictal grew 30% and Avodart was up 30%. This was partly offset by a 5% decline in Paxil sales. The decline in Vaccines sales reflected the impact on Cervarix of the suspension of the positive recommendation for use of HPV vaccines in Japan. There was also increased competitive pressure to Rotarix.

ViiV Healthcare turnover fell 5% to £344 million as the growth generated by Epzicom and Selzentry was more than offset by the impact of continued competition to older products and the phasing of tenders. Tivicay was launched in the quarter.

Consumer Healthcare turnover grew 4%, with growth in Oral care and Nutrition; turnover in Total wellness and Skin health was flat. In the US, a strong performance from Sensodyne was partially offset by a decrease in Smoking control sales. Growth in Europe was primarily driven by strong performances from Nutrition and Total wellness products, which also included some beneficial wholesaler and retailer stocking patterns. In the Rest of World markets, strong growth in India, Japan and Asia was partly offset by the continuing impact in China of the new shelving requirements for Contac and adverse wholesaler and retailer stocking patterns on Fenbid in advance of mandatory price reductions.



Turnover – 9 months 2013

Total Group turnover for the nine months was flat at £19,599 million. Excluding the impact of disposals, primarily the conclusion of the Vesicare co-promotion agreement in the US in Q1 2012 and the non-core OTC brands divested in H1 2012, turnover grew 2%. Reported Pharmaceuticals and Vaccines turnover was flat, but grew 1% excluding disposals. Pharmaceuticals turnover was flat, but excluding disposals, grew 1%, as growth in EMAP, Japan and an improved performance in Europe were offset by lower sales in the US and ViiV Healthcare. Vaccines turnover fell 2%, reflecting the adverse comparison with strong Cervarix sales in Japan in the first nine months of 2012 that benefited from the final stage of the HPV catch-up vaccination programme. Excluding Cervarix in Japan, Vaccines sales grew 3%, reflecting the strong growth in the US of Infanrix/Pediarix, which benefited from a competitor supply issue, and Fluarix/FluLaval, as well as better performance in Europe, partly offset by the net negative impact of tender phasing in EMAP. Consumer Healthcare turnover increased 2% to £3,969 million; excluding the non-core OTC brands divested in H1 2012, turnover grew 5%.

In the US, Pharmaceuticals and Vaccines turnover was flat, with Pharmaceuticals down 2% and Vaccines up 15%. Pharmaceuticals turnover was significantly impacted by the loss of sales of Vesicare following the conclusion of the co-promotion agreement in Q1 2012. Excluding Vesicare, US Pharmaceuticals turnover grew 4%. Sales of Respiratory products grew 4% to £2,680 million, led by 5% growth in Advair. Oncology products also performed well, growing 16% to £278 million, led by strong performances from Votrient and Promacta. Benlysta sales more than doubled to £101 million. These gains were partially offset by the impact of generic competition to Lamictal, down 19% to £199 million, and Dermatology sales, down 30% to £119 million. The 15% increase in Vaccines sales primarily resulted from the increase in Infanrix/Pediarix sales of 38% to £210 million, which continued to benefit from a competitor supply shortage, and the increase in Fluarix/FluLaval sales of 35% following the launch of the Quadrivalent flu formulation.

Europe Pharmaceuticals and Vaccines turnover was £3,836 million, flat compared with the first nine months of 2012, as the benefits of the restructuring and refocusing of the business began to come through. Pharmaceutical sales were down 1% to £3,062 million. Seretide sales declined 1% to £1,090 million, reflecting price and volume reductions. Oncology products, particularly Votrient and Promacta, performed well, as did Avodart, but growth from these products was more than offset by lower sales of a number of older products, particularly impacted by continued austerity measures. Vaccines sales grew 4%, largely due to the combination of an improved tender performance and some beneficial tender phasing.

EMAP Pharmaceuticals and Vaccines turnover was flat at £3,392 million in the nine months, with Pharmaceuticals up 3% to £2,657 million and Vaccines down 8% to £735 million. The Pharmaceuticals business was adversely affected by the ongoing investigation in China. Excluding China, Pharmaceuticals and Vaccines sales grew 3%, with Pharmaceuticals up 5% reflecting growth in Latin America, Russia and Brazil partially offset by declines in India and Korea. Vaccines sales fell 8% to £735 million, largely reflecting the phasing of tenders, particularly of Synflorix and tough comparators with strong growth in the same period in 2012.

Japan Pharmaceuticals and Vaccines turnover fell 4% to £1,190 million, as a 5% growth in Pharmaceuticals sales was more than offset by the 79% decline in Vaccines sales. Strong growth in Respiratory products as well as for Avodart, Lamictal and Relenza was partly offset by generic erosion of Paxil sales. Vaccines sales were impacted by the impact on Cervarix of the

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

suspension of the recommendation for the use of HPV vaccines in Japan and the adverse comparison with the first nine months of 2012, which benefited from the final stages of the catch-up HPV vaccination programme.

ViiV Healthcare turnover fell 5% to £1,001 million as the growth generated by Epzicom and Selzentry was more than offset by the impact of continued competition to older products.

Consumer Healthcare turnover, excluding the non-core OTC brands divested in H1 2012, grew 5%, with growth in all four categories. Growth in both the US and Europe primarily arose from Sensodyne and the re-stocking of alli, which was out of stock for most of the first nine months of 2012. In the Rest of World markets, strong growth in India, the Middle East and Asia was partly offset by a decline in sales in China, driven by the impact of Contac and Fenbid. Reported Consumer Healthcare turnover grew 2% to £3,969 million.

Core operating profit and margin

Core operating profit	Q3 2013			9 months 2013		
	£m	% of turnover	Growth CER %	£m	% of turnover	Growth CER %
Turnover	6,510	100	1	19,599	100	-
Cost of sales	(1,878)	(28.8)	2	(5,543)	(28.3)	5
Selling, general and administration	(1,876)	(28.8)	(6)	(5,923)	(30.2)	-
Research and development	(791)	(12.2)	(10)	(2,495)	(12.7)	(7)
Royalty income	94	1.4	1	289	1.4	24
Core operating profit	2,059	31.6	11	5,927	30.2	-
Core profit before tax	1,895		12	5,422		-
Core profit after tax	1,449		13	4,158		3
Core profit attributable to shareholders	1,400		15	3,977		3
Core earnings per share	28.9p		16	82.1p		5

Core operating profit by division	Q3 2013			9 months 2013		
	£m	Margin %	Growth CER %	£m	Margin %	Growth CER %
Pharmaceuticals	1,409	33.5	(2)	4,859	36.9	-
Vaccines	359	36.4	(2)	787	32.1	(14)
Pharmaceuticals and Vaccines	1,768	34.0	(2)	5,646	36.1	(3)
Consumer Healthcare	239	18.2	6	688	17.3	2

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

	2,007		(1)	6,334		(2)
Corporate & other unallocated costs	52			(407)		
Core operating profit	2,059	31.6	11	5,927	30.2	-

Core operating profit by segment	Q3 2013			9 months 2013		
	£m	Margin %	Growth CER %	£m	Margin %	Growth CER %
Pharmaceuticals and Vaccines						
-USA	1,253	67.5	3	3,708	69.4	2
-Europe	708	55.6	9	2,132	55.6	5
-EMAP	283	26.5	(22)	995	29.3	(7)
-Japan	207	57.5	5	679	57.1	(4)
-ViiV Healthcare	228	66.3	-	662	66.1	(3)
-Pharmaceutical R&D	(697)		2	(2,088)		-
-Other trading and unallocated pharmaceuticals	(214)	(72.5)	35	(442)	(50.9)	80
Pharmaceuticals and Vaccines	1,768	34.0	(2)	5,646	36.1	(3)
Consumer Healthcare	239	18.2	6	688	17.3	2
Corporate & other unallocated costs	2,007		(1)	6,334		(2)
	52			(407)		
Core operating profit	2,059	31.6				