

GLAXOSMITHKLINE PLC
Form 6-K
February 05, 2014

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 5 February 2014

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, 5 February 2014, London U.K.

Unaudited Preliminary Results Announcement for the year ended 31 December 2013

GSK delivers 2013 core EPS of 112.2p (+4% CER) and dividend of 78p (+5%)

Core results*

	2013	Growth		Q4 2013	Growth	
	£m	CER%	£%	£m	CER%	£%
Turnover	26,505	1	-	6,906	5	2
Core operating profit	8,015	-	(3)	2,088	(1)	(8)
Core earnings per share	112.2p	4	1	30.1p	1	(7)

Total results

	2013	Growth		Q4 2013	Growth	
	£m	CER%	£%	£m	CER%	£%
Turnover	26,505	1	-	6,906	5	2
Operating profit	7,028	(1)	(4)	2,441	36	27
Earnings per share	112.5p	27	23	51.3p	>100	>100

Summary

- GSK delivers 2013 reported turnover of £26.5 billion, up 1% (CER), and core EPS of 112.2p, up 4% (CER), in line with financial guidance
- £5.2 billion of cash returned to shareholders through 5% increase in 2013 dividend to 78p, (Q4 23p) and repurchase of £1.5 billion of shares
- Exceptional year for R&D delivery with approvals for 6 major products and 5 additional regulatory filings completed, helping to drive continued improvement in estimated R&D internal rate of return to 13%
- New product launches strengthen businesses in Respiratory, Vaccines, HIV and Oncology. Around 30 brand innovations/extensions expected in Consumer Healthcare in 2014
- Expanding respiratory portfolio with 2 significant recent approvals and 7 potential new products in late-stage development provides platform to maintain market leadership to 2020 and beyond
- Pipeline opportunity remains substantial with Phase III data for 6 potential new drugs and vaccines and around 10 NME Phase III

starts across 2014 and 2015

- Portfolio re-shaping continues with £2.5 billion raised from divestments completed in 2013 to increase focus of Consumer Healthcare and Pharmaceutical businesses. New Established Products Portfolio provides further opportunities to optimise value
- Operating and financial efficiencies driving EPS leverage. Year-on-year cost savings of around £400 million delivered in 2013 with similar amount expected in 2014 helping to offset mix pressure and fund ongoing investment requirements
- Continued strong cash generation, with adjusted net cash inflow from operating activities of £7.3 billion (+5%)
- Expect 2014 core EPS growth of 4 to 8% CER, on turnover growth of around 2% CER, on an ex-divestment basis (2013 EPS base 108.4p)

The full results are presented under 'Income Statements' on page 29 and Core results reconciliations are presented on pages 45 to 48.

*For explanations of the measures 'Core results', 'Adjusted net cash inflow from operating activities' and 'CER', see page 27.

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

GSK's performance in 2013 represented further strong delivery for the Group. We met our guidance with core EPS growth of 4% and sales growth of 1% (+3% ex-divestments) and returned £5.2 billion to shareholders via further growth in the dividend and our continuing share buy-back programme.

We also delivered the most productive period of R&D output in the Company's history and led the sector for new medicine approvals.

Of the 6 major new medicine files we profiled at the start of 2013, 5 have been approved: Breo and Anoro for respiratory disease, Tafinlar and Mekinist for melanoma and Tivicay for HIV and

we are expecting regulatory decisions for albiglutide, the remaining asset in this group, in the first half of 2014. In addition, we launched our new injectable quadrivalent flu vaccine in the US. Overall, GSK accounted for 19% of FDA new drug approvals during 2013 and since 2009 we have achieved more NME approvals in the United States than any other company.

The conversion of our advanced pipeline to approved products represents the next key step in our strategy to deliver sustainable organic growth and value to shareholders. The products we are currently launching will strengthen our existing businesses in Respiratory, Vaccines and support new growth in HIV and Oncology. While achievement of market access in the current pharmaceutical environment is clearly slower than it was in the past, we are pleased with the early indicators of progress for our new launches.

Physician response to Tivicay has been extremely positive and the product has achieved rapid uptake in the US with more than 1,700 prescriptions filled during the 23rd week on the market, a trend on pace with the best recent launches in the HIV space. As a result of this successful early launch of Tivicay we now believe ViiV Healthcare is at an inflection point and we expect this business to return to growth in 2014.

Our melanoma products Mekinist and Tafinlar already have around 60% combined share of prescriptions in the v600 targeted therapy market in the US. The products were approved for use in combination in January and we also received FDA Breakthrough Designation for Tafinlar in non-small cell lung cancer in the same month.

For Breo Ellipta in the US we have continued to build coverage with recent significant gains. 66% of patients insured through commercial plans and 25% of Medicare Part D patients now have unrestricted access to Breo and 90% of surveyed physicians are aware of the product. We are also preparing to launch Anoro in the US, which will take us into the COPD bronchodilator market with the first dual agent available in the US. With Advair, Flovent, Ventolin, Breo, Anoro and 7 other respiratory products in late stage development we are confident in the strength and future prospects of this broader portfolio of products and in our ability to maintain our leadership in respiratory well into the next decade.

Our pipeline remains extensive. We have around 40 NMEs in Phase II/III clinical development. In 2014 and 2015 we expect Phase III read-outs for 6 NMEs and are planning Phase III starts for around 10 new products in key areas such as respiratory, oncology and immuno-inflammation. This is in line with our strategic approach of a continued flow of multiple product launches which will help us drive future competitive advantage by diversifying our portfolio and reducing reliance on any one drug.

Our DPU based discovery research strategy is also continuing to progress very well. I am delighted with the sustained improvement in both quality of our compounds and more especially the research areas currently being prospected. Our work in areas such as immuno-inflammation, antibody platforms, epigenetics and heart failure is particularly encouraging.

The combination of innovation, effective asset progression and successful approvals with reductions in R&D spend has led to a further improvement in the estimated IRR of our R&D investments to 13%. We continue to target 14% on a longer-term basis.

This improvement in IRR is an important measure of our financial discipline and our strategic progress to improve the economics of research and development. It also underpins our strategy to create more flexibility around the pricing of our new medicines to meet the needs of payers

and governments.

GSK's trading performance in 2013 was in line with our guidance, despite some unexpected challenges and reflected the improving balance of our sales base. I was encouraged by the improved performance of our US business (+1%, +4% excluding Vesicare divestment). We also saw stabilisation of our European business (flat sales) with the benefits of our restructuring programme helping to offset the ongoing economic and pricing pressures in the region.

We are committed to investing behind continuing growth in our important Emerging Markets business. Sales in the region were up 5% for the year and 11% in the fourth quarter, excluding the impact of the ongoing investigation by the Chinese authorities. During the year, we also took steps to increase our equity holdings in our fast-growing Indian pharmaceuticals and consumer subsidiaries and announced plans to build new manufacturing capacity in the country.

Increasing focus and investment around our core businesses is driving enhanced performance. Over the last two years we have taken steps to streamline our Consumer product portfolio and we have divested more than 50 non-core products, including, last year, Lucozade and Ribena for £1.35 billion. Consumer Healthcare grew 4% excluding divested brands with growth across all regions.

In Pharmaceuticals, last year we divested our anti-coagulant products for more than £700 million. With our newly formed Established Products Portfolio (EPP), we see more opportunities to reduce complexity, enhance profitability and optimise the value of this group of products.

Operationally, we continue to restructure and simplify our business to reduce our long term cost base. In 2013 we delivered incremental year-on-year savings of around £400 million from both ongoing and structural initiatives. We are particularly focusing on the efficiency of our commercial organisation as well as standardisation of enterprise-wide platforms including IT and procurement. This is creating greater flexibility to allocate resources behind our growth markets and new product launches. Together with continued improvement in our financial efficiency, this strengthens our ability to deliver earnings per share growth ahead of sales.

For 2014, we are targeting core earnings per share growth of 4-8% CER on sales growth of around 2% CER on an ex-divestment basis. The range in our guidance reflects the transition we expect to see in our portfolio during the year as we roll-out new products but also face potential competition from generics to older products such as Lovaza.

The business remains highly cash generative and we continue to focus on improving conversion of earnings into cash. We generated £4.8 billion in adjusted free cash flow in 2013. In addition, we realised £2.5 billion from divestments leaving net debt at the end of the year at £12.6 billion. This gives us the flexibility we need to protect our credit profile and fund organic investment and restructuring programmes as well as our ongoing commitment to a growing dividend, further share buy-backs and bolt-on acquisitions whichever offers the most attractive return. Based on current market conditions we are targeting share repurchases of £1-2 billion in 2014.

Looking further ahead, we continue to make fundamental changes to our business, including how we interact with our customers; investments in technologies to support research and manufacturing; new policies to determine the pricing and value of our products, and in the culture of our organisation. We believe these changes are vital in an industry with a 20-year

business cycle and which operates in an environment as dynamic and as challenging as global healthcare.

I would like to thank all our employees, partners and suppliers for their continued commitment and support. Our continued aim is to deliver innovation and access to our products for patients and customers, and improved, sustainable financial performance for our shareholders.

Sir Andrew Witty
Chief Executive Officer

Presentations of today's results are available on www.gsk.com

All forward looking statements are based on 2013 core numbers adjusted to exclude divestments, at CER and barring unforeseen circumstances. See 'Cautionary statement regarding forward-looking statements' on page 27.

Contents	Page
2013 results summary	1
Chief Executive Officer's review	2
Group performance	5
Divisional performance	15
Research and development	23
Definitions	27
Contacts	28
Income statements	29
Statement of comprehensive income	30
Pharmaceuticals and Vaccines turnover – year ended 31 December 2013	32
Pharmaceuticals and Vaccines turnover – three months ended 31 December 2013	33
ViiV Healthcare turnover – twelve months and three months ended 31 December 2013	34
Balance sheet	35
Statement of changes in equity	36
Cash flow statement – 2013	37
Segment information	38
Legal matters	41
Taxation	41
Additional information	42
Reconciliation of cash flow to movements in net debt	44
Core results reconciliations	45
Group reporting in 2014	49

Group performance

Group turnover by division, geographic region and segment

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

Group turnover by division	2013		Q4 2013	
	£m	Growth CER%	£m	Growth CER%
Pharmaceuticals	17,898	1	4,721	5
Vaccines	3,420	2	967	12
Pharmaceuticals and Vaccines	21,318	1	5,688	6
Consumer Healthcare	5,187	2	1,218	-
	26,505	1	6,906	5

Group turnover by geographic region	2013		Q4 2013	
	£m	Growth CER%	£m	Growth CER%
US	8,730	2	2,272	6
Europe	7,511	(1)	1,900	(2)
EMAP	6,746	2	1,755	5
Japan	1,890	2	525	16
Other	1,628	4	454	16
	26,505	1	6,906	5
Group turnover outside US and Europe	10,264	2	2,734	9

Group turnover by segment	2013		Q4 2013	
	£m	Growth CER%	£m	Growth CER%
Pharmaceuticals and Vaccines				
-US	7,192	1	1,850	5
-Europe	5,166	-	1,330	(2)
-EMAP	4,698	1	1,306	5
-Japan	1,657	1	467	17
-ViiV Healthcare	1,386	-	385	15
-Other trading and unallocated pharmaceuticals	1,219	5	350	19
Pharmaceuticals and Vaccines	21,318	1	5,688	6
Consumer Healthcare	5,187	2	1,218	-

Turnover – 2013

Total Group turnover for 2013 was £26,505 million, up 1%. 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 3%. Reported Pharmaceuticals and Vaccines turnover grew 1% and excluding disposals, grew 2%. Pharmaceuticals turnover grew 1% and, excluding disposals, grew 2%, as growth in the US, Japan and EMAP was partially offset by continued pricing pressures and generic competition in Europe. ViiV Healthcare turnover for 2013 was flat. Vaccines turnover grew 2%, despite the adverse comparison with strong Cervarix sales in Japan in 2012. Excluding Cervarix in Japan, Vaccines sales grew 5%, reflecting the strong growth in the US of Infanrix/Pediarix and Boostrix, both of which benefited from competitor supply issues, and Fluarix/FluLaval, which benefited from the launch of the new Quadrivalent formulation, as well as a better performance by the business in Europe. Consumer Healthcare turnover increased 2% to £5,187 million, but excluding the non-core OTC brands divested in H1 2012, turnover grew 4%.

In the US, Pharmaceuticals and Vaccines turnover was up 1%, but grew 4% excluding the impact of the conclusion of the Vesicare co-promotion agreement in Q1 2012. Pharmaceuticals turnover was down 1% but excluding Vesicare, grew 2%. Sales of Respiratory products grew 7% to £3,655 million, led by an 8% growth in Advair, although this performance included the benefit of favourable stocking patterns in the fourth quarter. Oncology products also performed well, growing 17% to £380 million, led by strong performances from Votrient and Promacta and the initial impact of the launches of Tafenlar and Mekinist monotherapies during the year. Benlysta sales more than doubled to £134 million. These gains were partially offset by the impact of generic competition to Lamictal, down 18% to £276 million, and a number of Dermatology products, down 40% to £140 million. The 17% increase in Vaccines sales primarily resulted from the increases in Infanrix/Pediarix sales of 23% to £271 million and Boostrix sales of 23% to £183 million, both of which benefited from competitor supply shortages. Fluarix/FluLaval sales were also strong, up 65% to £146 million, following the launch of the Quadrivalent flu formulation in 2013.

Europe Pharmaceuticals and Vaccines turnover was £5,166 million, flat compared with 2012, as the benefits of the recent restructuring and refocusing of the business were offset by continued pricing pressures and generic competition to a number of products. Pharmaceutical sales were down 1% to £4,117 million. Seretide sales declined 2% to £1,458 million on a 2% volume decline but flat pricing. 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, which were particularly impacted by continued pricing measures and generic competition. Vaccines sales grew 3%, largely due to an improved tender performance.

EMAP Pharmaceuticals and Vaccines turnover was up 1% to £4,698 million in 2013, adversely affected by the ongoing investigation in China, with Pharmaceuticals up 2% to £3,574 million and Vaccines up 1% to £1,124 million. In China, Pharmaceuticals and Vaccines sales were down 18%, driven primarily by declines in Respiratory and Hepatitis products. Excluding China, EMAP Pharmaceuticals and Vaccines sales grew 5% driven by Pharmaceuticals growth in the Middle East/Africa, up 5% to £1,018 million, Latin America, up 6% to £650 million, and South East Asia, up 4% to £257 million, partially offset by declines in India, down 7% to £220

million, and Korea, down 4% to £200 million. Vaccines sales were up 1% to £1,124 million, and up 3% excluding China, reflecting strong tender performances from Cervarix and Infanrix/Pediarix, which were partially offset by a tough comparison with 2012.

Japan Pharmaceuticals and Vaccines turnover grew 1% to £1,657 million, as a 9% growth in Pharmaceuticals sales was partially offset by a 76% decline in Vaccines sales. Strong growth in Respiratory products as well as for Relenza, Avodart and Lamictal was partly offset by generic competition to Paxil sales. Vaccines sales primarily reflected the impact on Cervarix of the suspension of the recommendation for the use of HPV vaccines in Japan during the second half of 2013 and the adverse comparison with 2012, which benefited from the final stages of the catch-up HPV vaccination programme.

ViiV Healthcare turnover was flat at £1,386 million as the growth generated by Epzicom and Selzentry, together with the introduction of Tivicay, was offset by the impact of continued competition to older products.

Consumer Healthcare turnover, excluding the non-core OTC brands divested in H1 2012, grew 4%, with growth in all four categories. Growth in the US, up 2%, and Europe, up 3%, primarily arose from Specialist oral health, including Sensodyne, Denture care and the re-stocking of alli, which was out of stock for much of 2012. Rest of World turnover grew 6% with strong growth in India, the Middle East and Latin America partly offset by a decline in sales in China, driven by the impact of the shelving restrictions on Contac and mandatory price reductions for Fenbid. Reported Consumer Healthcare turnover grew 2% to £5,187 million.

Turnover – Q4 2013

Total Group turnover for Q4 2013 was £6,906 million, up 5%, with growth across all geographic regions except Europe, which was down 2%. Disposals did not materially affect the reported growth rate for the Group in the quarter. Pharmaceuticals and Vaccines turnover was up 6%. Pharmaceuticals turnover grew 5%, as higher sales in the US, Japan and ViiV Healthcare were partly offset by a decline in sales in Europe and EMAP. Vaccines turnover grew 12%, as strong performances in the US and EMAP were partially offset by lower sales in Japan. Consumer Healthcare turnover was flat at £1,218 million.

In the US, Pharmaceuticals and Vaccines turnover grew 5% to £1,850 million, with Pharmaceuticals up 3% and Vaccines up 23%. Pharmaceuticals and Vaccines turnover in the quarter benefited from re-stocking by wholesalers and retailers from the low levels seen during earlier periods of the year. This re-stocking, together with the positive impact of a comparison with relatively weak Q4 2012 stocking patterns, is estimated to have benefited reported turnover growth by approximately 5 percentage points, largely in Respiratory. The underlying performance of US Pharmaceuticals and Vaccines sales primarily reflected volume declines in Respiratory products and Lovaza, offset by price and mix benefits although pricing pressures in the market remain significant. Reported sales of Advair were up 17%, particularly benefiting from the wholesaler and retailer stocking movements. The launch of Breo Ellipta began in the quarter and recorded sales of £6 million. Oncology products contributed strongly to the quarter, with sales up 21% to £102 million, benefiting from strong performances from Votrient and Promacta, and the recent launches of Tafinlar and Mekinist. Benlysta also reported strong growth, with sales up 26% to £33 million. Reported Lovaza sales fell 5% to £139 million, due to increased competition as well as a slower overall market. Generic competition impacted Lamictal, Arixtra and Dermatology products. The 23% increase in Vaccines sales primarily reflected the benefit of the launch of the new Quadrivalent flu formulation and a 97% increase in Boostrix sales to £65 million, which benefited from a competitor supply shortage.

Europe Pharmaceuticals and Vaccines turnover fell 2% to £1,330 million. Pharmaceutical sales fell 2% to £1,055 million, reflecting continued pricing pressures and generic competition to a number of older products, partially offset by benefits arising from the recent restructuring and refocusing of the business. Seretide sales declined 4% to £368 million, with volumes down 5% partially offset by a 1% positive impact of price and mix. Strong growth in Oncology, up 26% to £89 million, was led by Votrient and Promacta, together with the initial stages of the Tafenlar launch. Sales of Avodart increased 13% to £72 million. Vaccines sales were flat, reflecting an adverse comparison with a strong Q4 2012, which benefited from some competitor supply issues.

EMAP Pharmaceuticals and Vaccines turnover increased 5% to £1,306 million, reflecting the net impact of the ongoing investigation in China offset by favourable vaccine tender phasing. Pharmaceuticals were down 1% and Vaccines up 22%. Excluding China, EMAP Pharmaceuticals and Vaccines sales grew 11%. In China, Pharmaceuticals and Vaccines sales were down 29% with Hepatitis and Respiratory products continuing to be particularly affected. Excluding China, EMAP Pharmaceuticals turnover grew 6% with continued strong growth from Seretide, up 17%, Avodart, up 43% and Oncology, up 16%. Augmentin grew 5%. There were strong contributions from Middle East/Africa, Latin America and North Asia. Vaccines sales were up 22% to £389 million, despite some supply disruptions during the quarter, largely reflecting the phasing of tenders, with strong tender deliveries, particularly of Synflorix in Brazil, and Fluarix/Flulaval in China and Latin America.

Japan Pharmaceuticals and Vaccines turnover grew 17% to £467 million in the quarter, with Pharmaceuticals sales increasing 19% and Vaccines sales declining by 44%. The growth in Pharmaceuticals reflected particularly strong sales of Respiratory products, up 12%, particularly Adair, up 11%, and Xyzal, up 19%, together with tender shipments of Relenza. Relvar was launched in the quarter. Lamictal grew 26% and Avodart was up 25%, partially offset by a 9% 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.

ViiV Healthcare turnover grew 15% to £385 million, including a favourable adjustment to US accruals for returns and rebates. The growth generated by Epzicom and the recent launch of Tivicay was partially offset by the impact of continued competition to older products and the phasing of tenders.

Consumer Healthcare turnover was flat, but grew 1% excluding disposals made in 2012. US turnover fell 2% as a strong performance from Sensodyne was offset by decreases in Total wellness sales, impacted by stocking patterns and some supply disruptions. The 4% decline in Europe turnover was also affected by wholesaler and retailer stocking patterns but also some supply interruptions, particularly for Aquafresh. Rest of World turnover grew 5%, with strong growth in India, Japan, Middle East and Latin America partly offset by the continuing impact in China of the new shelving requirements for Contac and mandatory price reductions for Fenbid.

Core operating profit and margin

Core operating profit	2013			Q4 2013		
	£m	% of	Growth	£m	% of	Growth

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

		turnover	CER %		turnover	CER %
Turnover	26,505	100	1	6,906	100	5
Cost of sales	(7,549)	(28.5)	6	(2,006)	(29.0)	10
Selling, general and administration	(7,928)	(29.9)	1	(2,005)	(29.0)	6
Research and development	(3,400)	(12.8)	(3)	(905)	(13.1)	9
Royalty income	387	1.4	25	98	1.3	28
Core operating profit	8,015	30.2	-	2,088	30.2	(1)
Core profit before tax	7,366		-	1,944		1
Core profit after tax	5,671		2	1,513		1
Core profit attributable to shareholders	5,421		2	1,444		-
Core earnings per share	112.2p		4	30.1p		1

Core operating profit by division

2013

Q4 2013

	£m	Margin %	Growth CER %	£m	Margin %	Growth CER %
Pharmaceuticals	6,633	37.1	3	1,774	37.6	13
Vaccines	1,096	32.0	(8)	309	32.0	13
Pharmaceuticals and Vaccines	7,729	36.3	1	2,083	36.6	13
Consumer Healthcare	913	17.6	3	225	18.5	5
Corporate & other unallocated costs	8,642		2	2,308		12
	(627)		30	(220)		>100
Core operating profit	8,015	30.2	-	2,088	30.2	(1)

Core operating profit by segment

2013

Q4 2013

	£m	Margin %	Growth CER %	£m	Margin %	Growth CER %
Pharmaceuticals and Vaccines						
-USA	4,993	69.4	3	1,285	69.5	7
-Europe	2,829	54.8	3	697	52.4	(2)
-EMAP	1,468	31.2	(3)	473	36.2	6

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

-Japan	978	59.0	4	299	64.0	27
-ViiV Healthcare	885	63.9	3	223	57.9	26
-Pharmaceutical R&D	(2,823)		1	(735)		5
-Other trading and unallocated pharmaceuticals	(601)	(49.3)	31	(159)	(45.4)	(33)
Pharmaceuticals and Vaccines	7,729	36.3	1	2,083	36.6	13
Consumer Healthcare	913	17.6	3	225	18.5	5
	8,642		2	2,308		12
Corporate & other unallocated costs	(627)		30	(220)		>100
Core operating profit	8,015	30.2	-	2,088	30.2	(1)

Core operating profit – 2013

Core operating profit was £8,015 million, flat in CER terms on a turnover increase of 1%. The core operating margin of 30.2% was 1.0 percentage points lower than in 2012. Excluding currency effects, the margin declined 0.5 percentage points. This reflected the negative impact of an expected increase in cost of sales, partially offset by higher royalty income and lower R&D expenditure, as the Group's continuing restructuring programmes contributed incremental year-on-year savings of around £400 million from both ongoing and structural initiatives. The contribution in 2013 from structural benefits was approximately £115 million lower than in 2012. Total savings realised from the previously announced changes to post-retirement medical obligations in 2013 were approximately £280 million, after final adjustments made during the fourth quarter. In 2012, the Group realised £395 million of savings from the capping of future pensionable salary increases and a change in the basis of future discretionary pension increases from RPI to CPI in certain legacy plans.

Cost of sales was 28.5% of turnover compared with 26.9% in 2012. Net of currency effects of 0.3 percentage points and the impact of a 0.3 percentage point reduction to the 2012 cost of sales percentage due to the settlement in H1 2012 of a royalty agreement and the conclusion of the Vesicare agreement, the cost of sales percentage increased 1.0 percentage points. This reflected the expected impact of the unwinding of costs of manufacturing volume shortfalls, adverse mix and the impact of preparing for the launches of new pipeline products, partially offset by ongoing cost management, better price realisation and restructuring benefits.

SG&A costs as a percentage of sales were 29.9%, flat on 2012, as the net favourable year-on-year benefits of the Group's restructuring programmes and ongoing cost management efforts funded investments in growth businesses and preparations for new product launches.

R&D expenditure declined 3% to £3.4 billion (12.8% of turnover) compared with £3.5 billion (13.2% of turnover) in 2012. This reflected the completion of a number of large trials, the phasing of ongoing project spending as well as continuing cost management. In 2014, core R&D expenditure is expected to remain broadly stable at around £3.5 billion in aggregate.

Royalty income was £387 million (2012: £306 million) and included a prior year royalty catch-up adjustment recorded in Q1 2013. Following conclusion of a number of royalty agreements in the year, royalty income is likely to be lower in 2014 at around £300 million.

Core operating profit – Q4 2013

Core operating profit was £2,088 million, a 1% decrease on a turnover increase of 5% CER. Compared with Q4 2012, the core operating margin decreased by 3.1 percentage points to 30.2%. Excluding currency effects, the operating margin decreased by 1.8 percentage points, reflecting lower restructuring and operating efficiency benefits compared with Q4 2012, which included the delivery in that quarter of pension savings of £290 million. This impact was partially offset by growth in SG&A below turnover growth, a decline in R&D expenditure and higher royalty income.

Cost of sales was 29.0% of turnover compared with 27.0% in Q4 2012, with 0.8 percentage points of the increase due to currency translation. Excluding currency effects, the cost of sales percentage increased 1.2 percentage points, reflecting the benefit of the pension restructuring in Q4 2012, higher stock write-offs and the expected impact of the unwinding of prior year costs of manufacturing volume shortfalls, partly offset by ongoing cost management, better pricing and restructuring benefits.

SG&A costs as a percentage of sales were 29.0% compared with 28.5% in Q4 2012. Excluding currency effects, SG&A increased 0.4 percentage points, reflecting the benefit of the pension restructuring in Q4 2012, as well as continued investments in growth businesses and new product launches partly offset by restructuring benefits and ongoing cost management.

R&D expenditure increased 9% to £905 million (13.1% of turnover) compared with £837 million in Q4 2012 (12.3% of turnover) reflecting the benefit of the pension restructuring in Q4 2012, and the phasing of ongoing project spending, offset by completion of a number of programmes and continuing cost management.

Royalty income was £98 million (Q4 2012: £76 million).

Core profit after tax and core earnings per share – 2013

Net finance expense was £692 million compared with £724 million in the twelve months to December 2012, despite higher average net debt levels during the year, reflecting GSK's strategy to improve the funding profile of the Group. Net debt at 31 December 2013 was £1.4 billion lower than at 31 December 2012, reflecting receipts of £2.5 billion from the disposals of businesses, intangible assets, Aspen shares and other investments during the year.

Tax on core profit amounted to £1,695 million and included recognition of US R&D credits reflected in the effective core tax rate of 23.0% (2012: 24.4%). The core tax rate for 2014 is expected to be around 22%.

Core EPS of 112.2p increased 4% in CER terms and 1% at actual exchange rates.

Core profit after tax and core earnings per share – Q4 2013

Net finance expense was £155 million (Q4 2012: £194 million) despite an increase in average net debt compared with Q4 2012. Net debt decreased by £2.4 billion in the quarter, primarily due to receipts of £2.3 billion from the disposals of businesses, intangible assets, Aspen shares and other investments during the quarter.

Tax on core profit amounted to £431 million and reflected an effective core tax rate of 22.2% (Q4 2012: 22.2%).

Core EPS of 30.1p increased 1% in CER terms but declined 7% at actual exchange rates due to the impact of currencies on the translation of overseas results.

Revision of IAS 19 'Employee benefits'

IAS 19 (Revised) has been implemented by GSK from 1 January 2013. The main effect is that the expected returns on pension scheme assets have been replaced by income calculated using the same discount rate as that used to measure the pension obligations. This discount rate is based on market rates for high quality corporate bonds. As a consequence, pension scheme costs in the income statement are higher under IAS 19 (Revised) and this impacted 2013 core operating profit by approximately £160 million and core EPS by 2.5p. Core operating profit for Q4 2013 was impacted by £40 million and core EPS by 0.7p. The results for 2012 have been restated, and the effect of the change on 2012 results was to reduce core operating profit for the year by £92 million and for Q4 2012 by £23 million and core EPS for the year by 1.3p and the quarter by 0.4p.

Outlook for 2014

In 2014, GSK expects core EPS growth of 4-8% CER (from 2013 base of 108.4p adjusted for divestments completed during 2013) on turnover growth of around 2% CER (from 2013 base of £25,602 million adjusted for divestments completed during 2013). See page 49 for more details.

Currency impact

The 2013 results are based on average exchange rates, principally £1/\$1.57, £1/€1.18 and £1/Yen 153. Comparative exchange rates are given on page 42. The period end exchange rates were £1/\$1.66, £1/€1.20 and £1/Yen 174.

In the year, turnover grew 1% CER and was flat at actual exchange rates. Core EPS for the year of 112.2p was up 4% in CER terms and up 1% at actual rates. The negative currency impact reflected the strengthening of Sterling against particularly the Japanese Yen but also a number of other currencies, partially offset by the weakening of Sterling against the US Dollar and the Euro. Losses on settled intercompany transactions were £27 million in the year (2012: £26 million).

Turnover in the quarter grew 5% in CER terms and 2% at actual rates. Core EPS for the quarter was 30.1p, up 1% in CER terms and down 7% at actual rates as Sterling strengthened relative to a broad range of currencies, particularly the US Dollar but also the Yen. Currencies in the EMAP region also saw weakness and, with the relatively lower proportion of the cost base in these countries, contributed to the greater adverse currency impact on EPS compared with that on sales.

Average rates for January were £1/\$1.65, £1/€1.21 and £1/Yen 171. If exchange rates were to hold at these rates for the rest of 2014, the estimated adverse impact on 2014 sterling turnover would be around 5%, and if there were no further exchange gains or losses, the estimated adverse impact on 2014 sterling core EPS would be around 6%.

Core adjustments

The adjustments that reconcile core operating profit, profit after tax and earnings per share to total results are as follows:

2013

2012

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

	Operating profit £m	Profit after tax £m	Operating profit EPS p	Profit after tax £m	Profit after tax £m	EPS (restated) p
Core results	8,015	5,671	112.2	8,238	5,705	111.4
Intangible asset amortisation	(547)	(398)	(8.2)	(477)	(332)	(6.8)
Intangible asset impairment	(739)	(513)	(10.7)	(693)	(497)	(7.3)
Major restructuring costs	(517)	(378)	(7.8)	(557)	(843)	(17.4)
Legal costs	(252)	(243)	(5.0)	(436)	(286)	(5.8)
Acquisition accounting and other	1,068	1,489	32.0	1,225	931	17.5
	(987)	(43)	0.3	(938)	(1,027)	(19.8)
Total results	7,028	5,628	112.5	7,300	4,678	91.6

Q4 2013

Q4 2012

	Operating profit £m	Profit after tax £m	Operating profit EPS p	Profit after tax £m	Profit after tax £m	EPS (restated) p
Core results	2,088	1,513	30.1	2,264	1,619	32.2
Intangible asset amortisation	(150)	(109)	(2.3)	(131)	(91)	(1.9)
Intangible asset impairment	(453)	(299)	(6.2)	(293)	(216)	(1.7)
Major restructuring costs	(175)	(67)	(1.4)	(245)	(597)	(12.3)
Legal costs	(89)	(106)	(2.2)	(91)	(94)	(1.9)
Acquisition accounting and other	1,220	1,573	33.3	413	202	3.1
	353	992	21.2	(347)	(796)	(14.7)
Total results	2,441	2,505	51.3	1,917	823	17.5

Full reconciliations between core results and total results are set out on pages 45 to 48 and the definition of core results is set out on page 27.

Total operating profit and total earnings per share – 2013

Total operating profit was £7,028 million compared with £7,300 million in 2012. The non-core items resulted in total net charges of £987 million in 2013 (2012: £938 million).

The intangible asset amortisation of £547 million (2012: £477 million) included £94 million related to the amortisation of the Benlysta intangible asset acquired as part of the HGS acquisition. Intangible asset impairments of £739 million (2012: £693 million) included write-offs of several R&D assets, together with the partial impairment of Lovaza, reflecting a

reassessment of the Group's expectations on the likelihood of potential generic competition.

Major restructuring charges of £517 million (2012: £557 million) comprised £238 million under the Operational Excellence programme, £260 million under the Major Change programme and £19 million related to the acquisition of HGS.

The Major Change programme focuses on opportunities to simplify our supply chain processes, build the Group's capabilities in manufacturing and R&D, and restructure our European Pharmaceuticals business. The programme is expected to cost £1.5 billion, of which the non-cash charge will be £350 million, and is expected to deliver annual pre-tax savings of at least £1.0 billion by 2016.

Legal charges of £252 million (2012: £436 million) principally related to provisions for existing product liability matters.

Acquisition accounting and other credits of a net £1,068 million (2012: £1,225 million credit) included items related to major acquisitions, business, equity investment and asset disposals, one-off required regulatory charges in R&D and certain other adjusting items. The 2013 net credit included gains on the disposals of the Lucozade and Ribena business and the anti-coagulant products of £1,331 million. The 2012 net credit included gains on the profit on disposal of the non-core OTC brands of £559 million and the gain of £581 million arising on the revaluation of pre-existing collaborations as part of the HGS and ViiV Healthcare/Shionogi joint venture acquisitions.

Total profit before tax also included the profit on disposal of associates and joint ventures of £282 million.

The charge for taxation on total profits amounted to £1,019 million and represented a total effective tax rate of 15.3% (2012: 29.1%), reflecting the differing tax effects of the various non-core items. It also included a net deferred tax charge of £234 million related to the unwinding of deferred profit in inventory as existing inventory produced prior to the 2012 restructuring of the supply chain is sold, offset by deferred tax credits of £393 million, primarily reflecting continuing restructuring of the supply chain. See 'Taxation' on page 41.

Total EPS was 112.5p for the year, compared with 91.6p in 2012 an increase of 20.9p. Non-core items totalled a credit of 0.3p compared with charges of 19.8p in 2012.

Total operating profit and total earnings per share – Q4 2013

Total operating profit was £2,441 million compared with £1,917 million in Q4 2012. The non-core items resulted in total net credits of £353 million in the quarter (Q4 2012: charges of £347 million).

Intangible asset amortisation amounted to £150 million in the quarter (Q4 2012: £131 million). Intangible asset impairments of £453 million (Q4 2012: £293 million) included write-offs of several R&D assets, together with the partial impairment of Lovaza.

Major restructuring charges of £175 million (Q4 2012: £245 million) principally comprised £46 million under the Operational Excellence programme and £128 million under the Major Change programme.

Legal charges were £89 million in the quarter (Q4 2012: £91 million).

Acquisition accounting and other credits of £1,220 million (Q4 2012: £413 million) included items related to major acquisitions, business, equity investment and asset disposals, one-off required regulatory charges in R&D and certain other adjusting items. The net credit in 2013 included profits on the disposal of businesses of £1,331 million (Q4 2012: £nil) arising from the disposals of the Lucozade and Ribena business and the anti-coagulant products. The 2012 net credit included the gain of £348 million arising on the revaluation of the pre-existing collaboration as part of the ViiV Healthcare/Shionogi joint venture acquisition.

The charge for taxation on total profits amounted to £41 million and represented a total effective tax rate of 1.6% (Q4 2012: 52.4%), reflecting the differing tax effects of the various non-core items, in particular the business disposal proceeds. It also included a deferred tax credit following continuing restructuring of the supply chain, partially offset by a deferred tax charge of £41 million related to the unwinding of deferred profit in inventory, as existing inventory produced prior to the 2012 restructuring of the supply chain is sold. See 'Taxation' on page 41.

Total EPS was 51.3p for the quarter, compared with 17.5p in Q4 2012, an increase of 33.8p. Non-core items totalled a credit of 21.2p (Q4 2012: charges of 14.7p).

Cash generation and conversion

Cash flow and net debt

	2013	2012	Q4 2013
Net cash inflow from operating activities (£m)	7,222	4,375	2,187
Adjusted net cash inflow from operating activities* (£m)	7,337	6,985	2,355
Free cash flow* (£m)	4,657	2,049	1,434
Adjusted free cash flow* (£m)	4,772	4,659	1,602
Free cash flow growth (%)	>100%	(51)%	37%
Free cash flow conversion* (%) (2012 – restated)	84%	97%	62%
Net debt (£m)	12,645	14,037	12,645

* Adjusted net cash inflow from operating activities, free cash flow, adjusted free cash flow and free cash flow conversion are defined on page 27.

The net cash inflow from operating activities for the year was £7,222 million (2012: £4,375 million). Excluding legal settlements (£115 million; 2012: £2,610 million), the adjusted net cash inflow from operating activities was £7,337 million (2012: £6,985 million), a 5% increase in sterling terms over 2012. This primarily reflected phasing of restructuring expenditure, together with lower tax payments and pension contributions partially offset by a smaller reduction in working capital compared with 2012 given supply chain investments in inventory and launch preparation.

Free cash flow was £4,657 million for the year. Excluding legal payments, adjusted free cash flow was £4,772 million (2012: £4,659 million). The increase on last year primarily reflecting the impact of lower tax payments and special UK pension contributions, partly offset by a

smaller reduction in working capital and increased expenditure on property, plant and equipment. The Group paid dividends to shareholders of £3,680 million, and spent £1,504 million on repurchasing shares.

At 31 December, net debt was £12.6 billion, compared with £14.0 billion at 31 December 2012, comprising gross debt of £18.2 billion and cash and liquid investments of £5.6 billion. The decrease in net debt reflected the receipts of £2.5 billion from the disposals of the Lucozade/Ribena and anti-coagulant products businesses, intangible assets, part of the Group's investment in Aspen Pharmacare Holdings Limited and other investments. The impact of these was partly offset by the consideration paid to increase the shareholding in the Group's Indian Consumer Healthcare subsidiary from 43.2% to 72.5% at a cost of £588 million and to acquire Okairos AG for £205 million. At 31 December 2013, GSK had short-term borrowings (including overdrafts) repayable within 12 months of £2,789 million with loans of £1,931 million repayable in the subsequent year.

In the quarter, net cash inflow from operating activities was £2,187 million. Excluding legal payments, the adjusted net cash inflow from operating activities was £2,355 million, a 15% increase in sterling terms over 2012. This primarily reflected the lower tax payments and reduced UK special pension contributions, partly offset by a smaller reduction in working capital compared with Q4 2012.

Working capital

	31 December 2013	30 September 2013	30 June 2013	31 March 2013	31 December 2012
Working capital conversion cycle* (days)	176	201	198	203	194
Working capital percentage of turnover (%)	19	22	22	22	21

* Working capital conversion cycle is defined on page 27.

The Group's working capital programme has continued to make progress with further improvements in the collection of receivables and more effective management of payables balances. During the year a number of initiatives were implemented across the Group's supply chains supporting the Pharmaceutical, Vaccines and Consumer Healthcare businesses that have provided stronger end-to-end accountability in each case. These programmes are at an early stage but have already reduced volatility and improved responsiveness allowing better inventory management. The net impact on inventory has been limited in 2013 as significant investments have also been made in improving service levels and preparing for new product launches.

The reported working capital conversion cycle days are distorted by divestments made during the year and the intangible asset impairments included in the denominator used in the conversion cycle computation. The year-end 2013 and 2012 conversion cycles adjusted for these factors, were around 190 days and around 200 days, respectively, a reduction of 10 days.

Returns to shareholders

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

GSK's commitment is to use free cash flow to support increasing dividends, undertake share repurchases or, where returns are more attractive, reinvest in the business, including bolt-on acquisitions.

Quarterly dividends

The Board has declared a fourth interim dividend of 23 pence per share (Q4 2012: 22 pence per share) making 78 pence for the full year.

Payment of dividends

The equivalent interim dividend receivable by ADR holders is 74.9616 cents per ADS based on an exchange rate of £1/\$1.6296. The ex-dividend date will be 19 February, with a record date of 21 February and a payment date of 10 April 2014.

	Paid/ payable	Pence per share	£m
2013			
First interim	11 July 2013	18	878
Second interim	3 October 2013	18	864
Third interim	9 January 2014	19	910
Fourth interim	10 April 2014	23	1,102
		78	3,754
2012			
First interim	5 July 2012	17	846
Second interim	4 October 2012	17	830
Third interim	3 January 2013	18	870
Fourth interim	11 April 2013	22	1,068
		74	3,614

Share repurchases

During the year, GSK repurchased 92.4 million shares at a cost of £1,504 million (2012: £2,493 million). The company issued 44.6 million shares under employee share schemes amounting to £585 million (2012: £356 million).

The weighted average number of shares for 2013 was 4,831 million, compared with 4,912 million in 2012, a reduction of 1.6%. The weighted average number of shares for Q4 2013 was 4,798 million, compared with 4,843 million in Q4 2012.

Divisional performance

Pharmaceutical sales summary

		2013	Q4 2013		
		£m	CER%	£m	CER%

Respiratory	7,516	4	1,982	7
Anti-virals	667	(6)	202	10
Central nervous system	1,483	(8)	384	(3)
Cardiovascular and urogenital	2,239	(8)	548	(2)
Metabolic	174	10	43	2
Anti-bacterials	1,239	-	309	(5)
Oncology and emesis	969	22	266	24
Dermatology	770	(8)	171	(19)
Rare diseases	495	7	130	(1)
Immuno-inflammation	161	>100	46	59
ViiV Healthcare (HIV)	1,386	-	385	15
Other	799	6	255	17
	17,898	1	4,721	5

Respiratory

2013 (£7,516 million; up 4%)

Respiratory sales in 2013 grew 4% to £7,516 million, with the US up 7%, Europe down 3%, EMAP up 4% and Japan up 9%. Seretide/Advair sales were up 4% to £5,274 million, largely driven by a strong US performance. Flixotide/Flovent sales increased 2% to £796 million, and Ventolin sales grew 2% to £642 million. Xyzal sales, almost exclusively made in Japan, grew 26% to £137 million, reflecting a strong allergy season.

In the US, Respiratory sales grew 7%, with Advair up 8% to £2,769 million, compared with 6% estimated underlying growth for the year (5% volume decline more than offset by an 11% positive impact of price and mix). Flovent sales were up 6% to £482 million with estimated underlying growth for the year up 6% (4% volume decrease offset by a 10% positive impact of price and mix). Ventolin grew 4% to £291 million, with estimated underlying growth of 8%, driven mostly by improved price realisation in the first half of the year. The launch of Breo Ellipta began in Q4 2013 with £5 million of sales recorded in the quarter.

European Respiratory sales were down 3% reflecting increased competition in many markets. Seretide sales were down 2% to £1,458 million, with a 2% volume decrease and no net impact of price and mix. Serevent and Flovent sales were down 17% and 7% respectively.

Respiratory sales in EMAP grew 4%, but 9% excluding China, led by Seretide, which grew 4% to £429 million (12% excluding China). Seretide continued to deliver strong growth across many EMAP markets. Veramyst, grew 16% to £71 million and Ventolin increased 2% to £171 million.

In Japan, Respiratory sales grew 9% to £567 million, with strong growth from both Xyzal and Veramyst. Adair sales grew 8% to £277 million. Relvar Ellipta was launched in December 2013, recording sales of £3 million.

Q4 2013 (£1,982 million; up 7%)

Respiratory sales in the quarter grew 7% to £1,982 million, with the US up 14%, Europe down 4%, EMAP up 5% and Japan up 12%. Seretide/Advair sales increased 9% to £1,398 million, Flixotide/Flovent sales increased 4% to £209 million, and Ventolin sales grew 1% to £175

million. Xyzal sales grew 22% to £36 million and Relvar/Breo Ellipta was launched in the US and Japan.

US Respiratory sales were up 14% to £975 million. Reported growth rates for Advair, Flovent and Ventolin were impacted significantly by the benefit from re-stocking by wholesalers and retailers from the low levels seen at the end of Q3 2013 together with the positive impact of comparison with relatively weak Q4 2012 stocking patterns. Pricing pressure in the market remains significant. Advair sales were particularly affected by the stocking patterns up 17% to £741 million, compared with an estimated underlying growth of 1%, which represented a 6% volume decline offset by a 7% positive impact of price and mix. Flovent sales increased 8% to £124 million. On an estimated underlying basis, Flovent was down 6% (6% volume decline and net zero impact of price and mix). Ventolin reported sales in the US grew 3% to £80 million, with an estimated underlying decline of 9% (3% volume decrease and a 6% negative impact of price and mix).

European Respiratory sales were down 4%, partly reflecting increased competition in many markets. Seretide sales declined 4% to £368 million, representing a 5% volume decrease, partially offset by a 1% positive impact of price and mix.

Respiratory sales in EMAP grew 5% despite a 22% decline in China, primarily driven by Seretide, which was down 20%. Excluding China, EMAP Respiratory sales grew 13%, with Seretide up 17% and Ventolin up 8%.

In Japan, Respiratory sales grew 12% to £154 million, with continued growth from Adair, up 11% to £82 million and from Xyzal, which grew 19% to £31 million.

Anti-virals

2013 (£667 million; down 6%)

The decrease in sales of Anti-virals reflected declines in Zeffix and Hepsera in China partially offset by tender shipments of Relenza in Japan.

Q4 2013 (£202 million; up 10%)

Anti-virals sales increased 10% largely as a result of tender shipments of Relenza in Japan, partly offset by lower sales of Zeffix and Hepsera in China.

Central nervous system

2013 (£1,483 million; down 8%)

Seroxat/Paxil sales fell 16% to £285 million, primarily due to generic competition in Japan and Europe and Requip sales fell 18% to £125 million reflecting generic competition in the US and Europe. Lamictal sales fell 7% to £557 million, primarily as a result of generic competition to Lamictal XR in the US.

In the US, generic competition to Lamictal XR, which started in Q1 2013, led to the 18% fall in sales of the Lamictal franchise to £276 million.

Q4 2013 (£384 million; down 3%)

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

Declines in Seroxat/Paxil sales of 14% to £69 million and Lamictal sales of 3% to £152 million, both primarily as a result of generic competition, led to the 3% fall in sales of the category.

Cardiovascular and urogenital

2013 (£2,239 million; down 8%)

Sales in the category fell 8% as a result of the impact of the conclusion of the Vesicare co-promotion agreement in Q1 2012. Excluding Vesicare, sales declined 1%.

The Avodart franchise grew 10% to £857 million with 31% growth in sales of Duodart/Jalyn. Avodart sales grew 5% to £648 million.

Lovaza fell 5% to £584 million as a result of increased competition and the decline in the non-statin dyslipidemia prescription market. Arixtra sales fell 15% to £167 million.

Q4 2013 (£548 million; down 2%)

The 2% decline in the category was primarily driven by sales of Lovaza, down 5% to £140 million, as a result of increased competition and a market decline in the US and Arixtra, down 36% to £33 million. The Avodart franchise grew 13%, with strong growth in Europe, EMAP and Japan.

Metabolic

2013 (£174 million; up 10%)

The increase in Metabolic product sales primarily reflected higher sales of Prolia in Europe and EMAP.

Q4 2013 (£43 million; up 2%)

The increase in Metabolic product sales in the quarter also reflected higher sales of Prolia in Europe and EMAP.

Anti-bacterials

2013 (£1,239 million; flat)

Augmentin sales grew 5% to £630 million with strong growth in EMAP, reflecting, in part, a comparison with some supply interruptions in 2012. Zinacef sales fell 14% to £55 million.

Q4 2013 (£309 million; down 5%)

Augmentin sales grew 3% to £165 million as growth in EMAP offset a fall in Europe.

Oncology and emesis

2013 (£969 million; up 22%)

Oncology and emesis sales grew 22% to £969 million, marking the second consecutive year of double digit percentage growth for the business. US sales were up 17% with strong performances by Votrient, Promacta and Arzerra, but also contributions from the launches of two new metastatic melanoma products Tafinlar and Mekinist. Sales in Europe grew 28% and

EMAP grew 18%. Votrient sales grew 80% to £331 million, Promacta sales grew 46% to £186 million and Arzerra sales grew 23% to £75 million. Tykerb/Tyverb sales fell 13% to £207 million due to increased competition. Both Hycamtin in Europe and EMAP and Argatroban in the US continued to be adversely affected by generic competition.

In the US sales growth of 17% reflects continued strong growth contributions from Votrient (up 56% to £144 million) and Promacta (up 33% to £73 million), which benefited from a new indication for thrombocytopenia associated with Hepatitis C received during Q4 2012. Arzerra grew 18% to £46 million. The US performance also reflects contributions totalling £21 million from Tafinlar and Mekinist, which were both launched in Q2 2013 as monotherapy treatments and achieved strong uptake in the BRAF V600 melanoma market during the first few months on the market. In January 2014, Tafinlar and Mekinist were approved by the FDA for combination use.

In Europe, sales grew 28% to £339 million, led by sales of Votrient, which increased by 91% to £130 million, as it continued to build market share in many markets. Revolade received approval in Europe for use in thrombocytopenia associated with Hepatitis C at the end of Q3 2013 and sales in the year increased by 47% to £55 million. Tafinlar was launched in Q3 2013 in certain markets and has achieved strong uptake in these early launch markets.

EMAP sales grew 18% to £149 million led by strong growth of Votrient (up 77% to £37 million) and Promacta (up 92% to £22 million). In the region Tykerb was down 9% to £47 million, and Hycamtin was down 36% to £7 million.

Q4 2013 (£266 million; up 24%)

In the quarter, Oncology sales were £266 million, up 24%. US sales were £102 million, up 21%, Europe sales were £89 million, up 26% and EMAP sales were £46 million, up 22%.

Votrient, up 48% to £90 million, and Promacta, up 42% to £52 million, continued to drive the growth in Oncology. Tafinlar and Mekinist sales also contributed to this positive result. Tykerb/Tyverb sales fell 18% to £49 million as a result of increased competition. Both Hycamtin in Europe and Argatroban in the US continued to be adversely affected by generic competition.

Dermatology

2013 (£770 million; down 8%)

Sales declined 8% to £770 million, primarily as a result of the decline in the US, down 40% to £140 million, which continued to suffer from the impact of generic competition, particularly to Bactroban, Duac and Soriatane, together with the effect of the disposal of a number of tail brands in Q2 2013. EMAP sales grew 6% to £397 million, reflecting strong growth in Bactroban, Dermovate and Duac particularly in Middle East/Africa and Latin America. European sales grew 5% to £170 million.

Q4 2013 (£171 million; down 19%)

Sales declined 19% to £171 million, principally driven by the impact of generic competition, together with the effect of the disposal of a number of tail brands in Q2 2013 in the US, down 66% to £21 million. European sales fell 4% to £42 million and EMAP sales fell 1% to £93 million.

Rare diseases

2013 (£495 million; up 7%)

Volibris, up 21% to £147 million, and Mepron, up 8% to £101 million, were the main drivers of the 7% growth in the category. Flolan sales fell 16% to £103 million, primarily as a result of the biennial price reduction in Japan in Q2 2012 and continued generic competition in the US and Europe.

Q4 2013 (£130 million; down 1%)

Flolan sales fell 21% to £23 million, largely as a result of continued generic competition in the US and Europe, and Mepron sales fell 19% to £25 million. Volibris partially offset these declines, with growth of 23% to £40 million, led by a strong performance in Japan.

Immuno-inflammation

2013 (£161 million; up >100%)

Benlysta turnover in the year was £146 million, with £134 million in the US. Total in-market sales of Benlysta in the US in 2012 were £96 million.

Q4 2013 (£46 million; up 59%)

Benlysta sales were £37 million, up 28%. In the US, Benlysta sales in the quarter were £33 million, up 26%.

ViiV Healthcare (HIV)

2013 (£1,386 million; flat)

ViiV Healthcare sales of £1,386 million were flat as sales in the US were up 5%, Europe down 3% and EMAP down 12%. Epzicom/Kivexa sales increased 14% to £763 million and Selzentry was up 10% to £143 million. Tivicay recorded sales of £19 million from the early stages of its launch in the US, which started in August 2013. Tivicay was approved in Europe in January 2014 and launches are planned in several markets throughout 2014. Growth contributions within this business were offset by declines in the mature portion of the portfolio, mainly Combivir, down 36% to £116 million.

Q4 2013 (£385 million; up 15%)

ViiV Healthcare sales increased 15%, with the US up 30%, including a favourable adjustment to US accruals for returns and rebates, Europe up 1%, and EMAP up 7%. Sales growth in Epzicom/Kivexa, up 28% to £211 million, and the newly-launched Tivicay, with sales of £15 million, were partially offset by declines in the mature portfolio.

Vaccines sales

	2013		Q4 2013	
	£m	CER%	£m	CER%
Total Vaccines sales	3,420	2	967	12

2013 (£3,420 million; up 2%)

Performance of the Vaccines business improved towards the end of the year, with a significant increase in tender sales in Q4. The 2% increase in Vaccines sales was principally attributable to the growth of Infanrix/Pediarix, Fluarix/FluLaval and Boostrix, which was largely offset by the decline of Cervarix in Japan, reflecting the suspension of the recommendations for the use of HPV vaccines in Japan, together with an adverse comparison with strong Cervarix sales in 2012, which benefited from the final stages of the HPV vaccination catch-up programme in Japan. Cervarix sales declined 37% to £172 million. Excluding Cervarix in Japan, Vaccines sales increased by 5%.

Infanrix/ Pediarix sales increased 9% to £862 million, with the growth primarily reflecting stronger tender shipments in Europe and EMAP as well as the benefit in the US of a competitor supply shortage. Boostrix sales, which also benefited from a competitor supply issue in the US, grew 19% to £288 million.

Sales of hepatitis vaccines fell 4% to £629 million, primarily reflecting lower sales in the US as a result of the return of competing vaccines to the market during the second half of 2012, together with declines in Europe and China.

Synflorix sales increased 2% to £405 million, helped by strong tender sales in Middle East/Africa and Latin America.

Rotarix sales grew 5% to £375 million, with strong growth in Middle East/Africa and Europe partially offset by the impact of increased competition in Japan.

Fluarix/FluLaval sales increased 25% to £251 million, following the launch of the Quadrivalent formulation in the US.

Q4 2013 (£967 million; up 12%)

Vaccines sales grew 12% to £967 million and benefited from strong growth of Synflorix in EMAP and Fluarix/FluLaval and Boostrix in the US. The 44% decline in sales in Japan reflected the impact on Cervarix of the suspension of the recommendation for the use of HPV vaccines.

Infanrix/Pediarix sales decreased 11% to £208 million, mainly driven by a strong comparative in EMAP where sales more than doubled in Q4 2012. Sales in the US were down 10%, primarily reflecting ordering patterns from the CDC in Q3 2013, when Infanrix/Pediarix grew 69%. Boostrix sales grew 65% to £91 million, with strong growth in the US.

Sales of hepatitis vaccines fell 4% to £152 million, principally reflecting a decline in the US.

Synflorix sales increased 49% to £161 million, reflecting strong tender sales, particularly in Brazil, in the quarter.

Rotarix sales were up 17% to £100 million, with growth in Europe and EMAP being partially offset by a decline in the US.

The new Quadrivalent formulation benefited sales of Fluarix/FluLaval, which were up 76% at £87 million. In the US, Fluarix/FluLaval sales more than doubled to £36 million following the launch of the Quadrivalent formulation and a favourable comparison with 2012, where the

majority of the Fluarix/FluLaval shipments were made in Q3 2012.

Sales from new pharmaceutical and vaccine launches

	2013		Q4 2013	
	£m	CER%	£m	CER%
Pharmaceuticals				
Arzerra	75	23	19	36
Benlysta	146	>100	37	28
Duodart/Jalyn	209	31	56	27
Lamictal XR	98	(34)	29	(24)
Mekinist	10	-	7	-
Potiga/Trobalt	11	43	3	(33)
Prolia	51	96	16	89
Relvar/Breo Ellipta	8	-	8	-
Tafinlar	16	-	11	-
Tivicay	19	-	15	-
Votrient	331	80	90	48
Xgeva	7	>100	3	>100
Dermatology				
	8	20	4	>100
Vaccines				
Synflorix	405	2	161	49
Nimenrix	12	>100	6	>100
	1,406	33	465	50

New products are those launched in the last five years (2009 to 2013 inclusive). Sales of new products were £1,406 million in 2013, grew 33% in the year and represented 7% of Pharmaceuticals and Vaccines turnover. In Q4 2013, sales of new products were £465 million, grew 50% and represented 8% of Pharmaceuticals and Vaccines turnover.

Tafinlar and Mekinist, both for metastatic melanoma, were approved and launched in the US in Q2 2013. In Q3 2013, Tivicay, for the treatment of HIV-1 patients, was approved and launched in the US and Tafinlar was granted approval and launched in Europe. In Q4 2013, Breo Ellipta was launched in the US for COPD and Relvar Ellipta was granted approval in Europe for COPD and asthma and launched in Q1 2014. In addition, launch activities are currently underway for Anoro Ellipta, which was approved in the US for the treatment of COPD in December 2013.

Consumer Healthcare

	2013		Q4 2013	
	Turnover	Growth	Turnover	Growth

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

	£m	CER%	excluding non-core OTC products CER%	£m	CER%	excluding non-core OTC products CER%
Total wellness	1,935	(5)	1	469	(6)	(5)
Oral care	1,884	6	6	447	4	4
Nutrition	1,096	7	7	235	6	6
Skin health	272	5	5	67	5	5
Total	5,187	2	4	1,218	-	1

	2013			Q4 2013		
Turnover	£m	CER%	Growth excluding non-core OTC products CER%	£m	CER%	Growth excluding non-core OTC products CER%
USA	951	1	2	242	(2)	(2)
Europe	1,819	(1)	3	435	(4)	(3)
Rest of World	2,417	4	6	541	5	5
Total	5,187	2	4	1,218	-	1

2013 (£5,187 million; up 2%)

Consumer Healthcare turnover grew 2% in the year. Excluding the non-core OTC brands that were divested in H1 2012, turnover grew 4% reflecting overall growth in all three regions.

Total wellness sales, excluding the non-core OTC brands that were divested in H1 2012, grew 1%. In both the US and Europe all reported strong growth, in large part due to being out of stock for much of 2012. A severe cold and flu season in early 2013 helped drive growth of several respiratory brands including Coldrex, Beechams and Panadol Cold and Flu. This growth was partly offset by a 57% reduction in sales in China of Contac, due to new shelving requirements, and Fenbid, down 31%, in advance of mandatory price reductions.

Strong growth in Oral care sales was led by growth in Specialist oral health, with Sensodyne Sensitivity and Acid erosion up 15% and denture care brands up 9%.

Nutrition sales grew 7% with strong growth in Rest of World markets, led by Horlicks, up 14%, and Boost in India and key expansion markets in the sub-continent. Lucozade grew 4% and Ribena grew 3%. Sales of Maxinutrition products declined 25%.

Skin health sales grew 5%, led by Abreva in the US.

Excluding the non-core OTC products divested in 2012, US sales grew 2%, led by strong contributions from Oral care brands, alli and Abreva. This was partially offset by declines in Gastro-intestinal products, reflecting increased competitor activity, and Smoking control products impacted by supply disruptions. In Europe, sales grew 3% helped by sales of alli and strong growth in products for Respiratory health and Pain. Oral care sales in Europe were flat, as strong growth in Sensodyne and denture care brands was offset by a decline in Aquafresh, due in part to supply issues in Q4 2013. Rest of World markets grew 6%, reflecting growth across most categories and markets, particularly in India, offset by a 23% reduction of sales in China, mainly due to the reduction in sales of Contac and Fenbid.

Q4 2013 (£1,218 million; flat)

Consumer Healthcare turnover was flat in the quarter, but grew 1% excluding the non-core OTC brands that were divested in H1 2012. Growth in Rest of World markets was partially offset by declines in the US and Europe.

Total wellness sales declined 5%, reflecting lower sales from several brands within the category, including Breathe Right, down 21%, and Tums, down 15%, partly as a result of increased competitor activity. Contac sales fell 24% following new shelving requirements in China and there was a 33% reduction in sales of Fenbid in China. Smoking control products grew 3%.

Oral care sales were up 4% to £447 million. Strong growth contributions from the Sensodyne Sensitivity and Acid erosion business, up 16%, and denture care brands, up 9%, offset a decline in sales of Aquafresh of 19%, due in part to supply issues in Europe.

Nutrition sales grew 6% led by strong growth of Horlicks driven by improved consumer access in India, up 13% and bolstered by geographic expansion in the region. Sales of Boost energy drink were up 8% also reflecting a strong performance in India. Lucozade and Ribena sales grew 5% and 2%, respectively, mainly driven by a strong performance in Rest of World markets.

Skin health sales grew 5%, in part reflecting some retailer stocking movements on Abreva in the US.

In the US, sales declined 2%, as strong growth in Oral care products was offset by lower sales of Breathe Right, Tums and alli. In Europe, sales, excluding the non-core OTC brands divested, fell 3%, reflecting the impact of the temporary supply issues with Aquafresh. Growth in several cough and cold brands was also adversely affected by the phasing of shipments and comparison with a strong start to the cold and flu season in Q4 2012. Rest of World markets grew 5%, reflecting strong growth across most categories and markets, particularly India, partially offset by a 24% reduction of sales in China, primarily due to the reduction in sales of Contac and Fenbid.

Research and development

GSK remains focused on delivering an improved return on its investment in R&D. Sales contribution, reduced attrition and cost reduction are all important drivers of an improving internal rate of return. R&D expenditure is not determined as a percentage of sales but instead capital is allocated using strict returns based criteria depending on the pipeline opportunities available.

In 2009, we committed to publishing our estimated rate of return in R&D based on the investment made in our late-stage pipeline and our expectations regarding future long-term sales performance. This was estimated to be 11% in 2009 and 12% in 2011. Applying the same methodology, the estimated rate of return in 2013 has increased to 13% and we are on track to deliver on our long-term target of 14%. This increase is driven by a higher forecast risk adjusted NPV contribution from the late-stage pipeline than two years ago, as a number of significant assets achieved key milestones, and the continued benefit of our R&D cost management programmes.

As part of the process to calculate the 2013 data we also updated the 2011 IRR calculation to reflect actual sales in the 2011-2012 period and updated forecasts of the future pipeline. This results in a 60 basis points reduction in the previously disclosed estimated IRR for this period (from 11.9% to 11.3%). This reduction is mainly driven by lower than forecast sales for some products (primarily Tykerb and some 2010 and 2011 launch products) which are partially offset by greater than forecast sales for certain products and improvements in probability of success for a number of pipeline products which achieved key milestones since the analysis was last completed (including Anoro Ellipta, Breo Ellipta and Tivicay).

The operations of Pharmaceuticals R&D are broadly split into Discovery activities (up to the completion of Phase IIa trials) and Development work (from Phase IIb onwards) each supported by specific and common infrastructure and other shared services where appropriate. R&D expenditure for the year is analysed below. Facilities and Central Support functions include lower credits arising from the pension and post-retirement medical obligations restructuring in 2013 than in 2012.

	2013 £m	2012 (restated) £m
Discovery	742	800
Development	1,535	1,655
Facilities and central support functions	449	377
	2,726	2,832
Vaccines	496	498
Consumer Healthcare	178	155
Core R&D	3,400	3,485
Amortisation and impairment of intangible assets	428	483
Major restructuring costs	39	11
Acquisition accounting and other	56	-
Total R&D	3,923	3,979

GSK's Phase III/Registration Pharmaceuticals and Vaccines pipeline

The table below is provided as part of our quarterly update to show events and changes to the late-stage pipeline during the quarter and up to the date of this announcement. There were several news events for late-stage pipeline assets in this quarter and these are listed in the table

below. Promacta/Revolade and Tafinlar were announced as approved in US and EU last quarter and these entries have been removed from the table.

At the R&D Late-Stage Pipeline Review on 3 December 2012, the following 14 assets were listed as expecting to deliver Phase III data during 2013 and 2014: Votrient (ovarian), MAGE-A3 (melanoma & NSCLC), Tykerb (breast, head & neck and gastric cancers), darapladib (atherosclerosis – event driven), Arzerra (first line and relapsed CLL), drisapersen (DMD), dabrafenib + trametinib combination use (metastatic melanoma), fluticasone furoate (asthma), mepolizumab (severe asthma), Benlysta subcutaneous (SLE) (data now expected in 2015), vercirnon (Crohn’s disease), migalastat (Fabry’s disease), Herpes Zoster vaccine (data are event driven and now expected in 2015) and dolutegravir-Trii (HIV).

In 2014 and 2015 we expect potential Phase III starts for the following assets: ICS/LABA/LAMA (COPD); ICS/LAMA (asthma); afuresertib (AKT inhibitor for multiple myeloma); ‘744 long acting integrase inhibitor (HIV); losmapimod (Acute Coronary Syndrome); ‘728 antisense oligonucleotide (transthyretin amyloidosis); ‘275 gene therapy (Wiskott-Aldrich Syndrome); ‘944 topoisomerase inhibitor (antibacterial); retosiban (pre-term labour); tafenoquine (malaria); PRAME ASCI (NSCLC).

Since Q3 2013, the following pipeline milestones have been achieved:

- Announced that darapladib did not meet the primary endpoint in STABILITY study in patients with coronary heart disease;
- Announced the return of development and commercialisation rights for migalastat to Amicus;
- EU approval of Relvar Ellipta for asthma and COPD;
- CHMP positive opinion for Tivicay for HIV in EU;
- Japanese approval of Paxil for PTSD;
- FDA approval of pandemic H5N1 vaccine;
- EU approval of Synflorix for prevention of pneumonia caused by S. pneumoniae in children 6 weeks to 5 years old;
- Filed dolutegravir for HIV in Japan;
- Announced positive results from Phase III study of fluticasone furoate/vilanterol in asthma;
- FDA granted priority review for Arzerra as first line treatment for CLL;
- FDA approval of Anoro Ellipta for COPD;
- EU approval of 2 dose schedule for Cervarix;
- FDA approval of combination use of Mekinist and Tafinlar in unresectable or metastatic melanoma;
- FDA granted Breakthrough Therapy designation for tafenoquine for Plasmodium Vivax malaria;
- Announced the return of rights for drisapersen to Prosensa;
- FDA granted Breakthrough Therapy designation for Tafinlar for NSCLC with BRAF mutation;
- EU approval of Tivicay for HIV;
- CHMP positive opinion for albiglutide for Type 2 diabetes in EU;
- Announced headline data from Phase III COMBI-d study of the combination of Tafinlar and Mekinist in metastatic melanoma;
- Promacta granted Breakthrough Therapy Designation by the FDA for the treatment of severe aplastic anemia.

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

There are 7 filings of new drugs with US/EU regulators:

- Mekinist (trametinib, MEK) (approved in US; filed in EU);
- trametinib + dabrafenib in combination use (approved in US; filed in EU);
- Eperzan (albiglutide) (filed in US and EU; positive opinion from CHMP in EU);
- Anoro Ellipta (UMEC/VI) COPD (approved in US; filed in EU);
- umeclidinium (LAMA) monotherapy in COPD (filed in US and EU);
- fluticasone furoate monotherapy in asthma (filed in US);
- dolutegravir-Trii in HIV (filed in US and EU).

Biopharmaceuticals		US	EU	News update in the quarter
Arzerra (ofatumumab)	CLL (first line & relapsed)	Filed Oct 2013	Filed Oct 2013	FDA granted Priority Review for filing in first line CLL on 17 December 2013.
	NHL (FL)	Ph III	Ph III	
	NHL (DLBCL)	Ph III	Ph III	
Benlysta (s.c.)	Systemic lupus erythematosus	Ph III	Ph III	Data now expected in 2015.
Benlysta (i.v.)	vasculitis	Ph III	Ph III	
Eperzan (albiglutide)	Type 2 diabetes	Filed Jan 2013	Filed Mar 2013	Positive CHMP opinion on 24 January 2014.
sirukumab	Rheumatoid arthritis	Ph III	Ph III	
Cardiovascular & Metabolic		US	EU	News update in the quarter
darapladib	Atherosclerosis	Ph III	Ph III	Data from STABILITY study did not meet primary endpoint.
Oncology		US	EU	News update in the quarter
Votrient (pazopanib)	Ovarian	Ph III	Filed Aug 2013	
Tykerb/Tyverb	Metastatic breast cancer – dual blockade	Ph III	Approved Aug 2013	
	Adjuvant breast cancer	Ph III	Ph III	
Mekinist (trametinib, MEK inhibitor)	Metastatic melanoma	Approved May 2013	Filed Feb 2013	
trametinib + dabrafenib in combination use	Metastatic melanoma	Approved Jan 2014	Filed Feb 2013	FDA approval on 8 January 2014. Announced headline data from Phase III COMBI-d study on 24 January 2014.
	Adjuvant melanoma	Ph III	Ph III	
Respiratory		US	EU	News update in the quarter
Relvar/Breo Ellipta (FF/VI)	COPD	Approved May 2013	Approved Nov 2013	Approved in EU on 18 November 2013.
	Asthma	Ph III	Approved Nov 2013	Approved in EU on 18 November 2013. Announced positive asthma study results 6 December 2013.
Anoro Ellipta (umeclidinium bromide (UMEC) + vilanterol (VI))	COPD	Approved Dec 2013	Filed Jan 2013	FDA approval on 18 December 2013.

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

umeclidinium bromide (UMEC)	COPD	Filed Apr 2013	Filed Apr 2013	
vilanterol (VI)	COPD	Ph III	Ph III	
fluticasone furoate (FF)	Asthma	Filed Oct 2013	Ph III	
mepolizumab Rare Diseases	Severe asthma	Ph III US	Ph III EU	News update in the quarter Announced rights returned to Amicus on 20 November 2013.
migalastat HCl	Fabry disease	Ph III	Ph III	Announced rights returned to Prosensa on 13 January 2014.
drisapersen	Duchenne muscular dystrophy	Ph II	Ph III	
2696273 (Ex-vivo stem cell gene therapy)	Adenosine deaminase severe combined immune deficiency (ADA-SCID)		Ph II/III	
Vaccines Nimenrix (MenACWY)	MenACWY prophylaxis	US Ph II	EU Approved Apr 2012	News update in the quarter