

## **Pre-Quarterly Results Communication Q2 2016**

Issued: Monday, 11 July 2016

## New information for Q2 2016

## Foreign exchange

Average rates Quarterly	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016
Key currencies						
US\$	1.52	1.54	1.53	1.53	1.43	1.41
€	1.34	1.38	1.39	1.37	1.30	1.28
Yen	182	186	187	185	167	153
Other currencies						
Australian dollar	1.94	1.98	2.14	2.06	1.96	1.92
Brazilian real	4.33	4.73	5.49	5.81	5.54	4.96
Canadian dollar	1.88	1.90	2.01	2.01	1.95	1.83
Chinese yuan	9.49	9.57	9.68	9.66	9.33	9.31
Indian rupee	94.9	97.9	99.7	99.5	96.1	95.1
Russian rouble	94.7	84.1	97.5	101.3	104	93.6
FX impact on turnover	-1%	-1%	-2%	-2%	+ 3%	+6% to 7%
FX impact on CORE EPS	-2%	-9%	-5%	-6%	+6%	n/a

Average rates for the quarter ended 30<sup>th</sup> June 2016 were \$1.41/£, €1.28/£ and Yen 153/£. On the basis of these rates, it is expected that the positive impact of foreign exchange on Q2 2016 sales will be around 6% to 7%. As a result of the mix of currency movements relative to the mix of costs we expect that the positive impact of foreign exchange on Q2 2016 sterling core EPS growth will likely be greater than the positive impact on sales.

Average rates Cumulative - YTD	3M 2015	6M 2015	9M 2015	12M 2015	3M 2016	6M 2016
Key currencies						
US\$	1.52	1.53	1.53	1.53	1.43	1.42
€	1.34	1.36	1.37	1.37	1.30	1.29
Yen	182	184	185	185	167	160
Other currencies						
Australian dollar	1.94	1.96	2.02	2.03	1.96	1.94
Brazilian real	4.33	4.53	4.85	5.09	5.54	5.25
Canadian dollar	1.88	1.89	1.93	1.95	1.95	1.89
Chinese yuan	9.49	9.53	9.58	9.60	9.33	9.32
Indian rupee	94.9	96.4	97.5	98.0	96.1	95.6
Russian rouble	94.7	89.4	92.1	94.4	104	98.8
FX impact on turnover	-1%	-1%	-1%	-2%	+ 3%	+4% to 5%
FX impact on CORE EPS	-2%	-6%	-5%	-6%	+6%	n/a



Average rates for the six months ended 30<sup>th</sup> June 2016 were \$1.42/£, €1.29/£ and Yen 160/£. On the basis of these rates, it is expected that the positive impact of foreign exchange on H1 2016 sales will be around 4% to 5%. We also expect that the positive impact of foreign exchange on H1 2016 sterling core EPS will likely be greater than the positive impact on sales.

The Q2 2016 period-end rates were \$1.33/£, €1.20/£ and Yen 137/£.

Period end rates	Mar 2015	Jun 2015	Sep 2015	Dec 2015	Mar 2016	Jun 2016
Key Currencies						
US\$	1.48	1.57	1.51	1.47	1.44	1.33
€	1.38	1.41	1.36	1.36	1.26	1.20
Yen	178	192	181	177	162	137

## **Exchange Gains or (Losses)**

Sharp movements and volatility in currencies during a quarter can result in Exchange Gains or Losses (EGOLs) which are recorded in SG&A. During Q2 2016 there was continued volatility in a number of currencies relative to sterling.

EGOLs as reported (£m)	Q1	Q2	Q3	Q4	Full Year
2014	(20)	(27)	10	(19)	(56)
2015	(6)	(61)	0	13	(54)
2016	(3)				

## Ready reckoner

In the 2015 full year results presentation on 3 February 2016, the following read reckoner was provided on slide 28 to help estimate the expected impact of foreign exchange movements on core EPS\*:

Currency	Impact on 2016 Full Year Core EPS
US dollar	10 cents movement in average exchange rate for full year impacts EPS by approximately +/-3.5%
Euro	10 cents movement in average exchange rate for full year impacts EPS by approximately +/-2.0%
Japanese yen	10 yen movement in average exchange rate for full year impacts EPS by approximately +/-1.0%

<sup>\*</sup>Please note that the ready reckoner does not include the impact of inter-company exchange gains or losses

The slide also included 2015 currency sales exposure for GSK:

Currency	2015 Currency sales exposure
US dollar	34%
Euro	19%
Japanese yen	6%
Other‡	41%

<sup>‡</sup>The other currencies that each represent more than 1% of Group sales are: Australian dollar, Brazilian real, Canadian dollar, Chinese yuan and Indian rupee. In total they accounted for 12% of Group revenues in 2015



## **Currency impact 2016**

In the Q1 2016 press release we made the following comment on the potential impact of currencies on sales and EPS in 2016:

"If exchange rates were to hold at the March closing rates (£1/\$1.44, £1/€1.26 and £1/Yen 162) for the rest of 2016, the estimated positive impact on 2016 Sterling turnover growth would be around 5% and if exchange losses were recognised at the same level as in 2015, the estimated positive impact on 2016 Sterling core EPS growth would be around 8%."

We will update you on our latest view on the estimated impact of currencies in 2016 in our Q2 2016 press release on 27 July.

## Basic weighted average number of shares (WANS)

The basic weighted number of shares in issue during Q2 2016 was 4,859m compared with 4,832m in Q2 2015 (an increase of 0.6%).

The basic weighted number of shares in issue during H1 2016 was 4,853m compared with 4,826m in H1 2015 (an increase of 0.6%).

In millions	Q4	Q1	Q2	Q3	Q4	Q1	Q2
	2014	2015	2015	2015	2015	2016	2016
WANS: Quarter	4,809	4,820	4,832	4,835	4,838	4,847	4,859
WANS: Cumulative	4,808	4,820	4,826	4,829	4,831	4,847	4,853
- Year to date							
Period end shares *	4,811	4,830	4,834	4,836	4,840	4,858	4,861

<sup>\*</sup>excludes Treasury shares and shares held by ESOP Trusts

## Dividend

In the Q1 2016 press release we made the following comment on returns to shareholders: "GSK expects to pay an annual ordinary dividend of 80p for each of the next two years (2016-2017).

In April 2016, GSK also returned approximately £1 billion (20p per share) to shareholders via a special dividend paid alongside GSK's Q4 2015 ordinary dividend payment.

Any future returns to shareholders of surplus capital will be subject to the Group's strategic progress, visibility on the put options associated with ViiV Healthcare and the Consumer Healthcare joint venture and other capital requirements."

Dividend per share (p)	Q1	Q2	Q3	Q4	Full Year
2014	19	19	19	23	80
2015 – ordinary dividend	19	19	19	23	80
2015 – special dividend	-	-	-	20	20
2016	19				80†
2017					80†

<sup>†</sup>The actual dividend amount is determined by the Board of Directors.



## Factors impacting recent quarterly comparisons

As usual there were a number of events in 2016 to date and during 2015 which impact the year on year comparison for Q2 2016 and H1 2016. This includes the following noteworthy items which you may wish to consider in your modelling.

Please note that the items listed below are not intended to be a complete list of all items that may impact the comparisons for Q2 2016 versus Q2 2015.

For further comments, please refer to quarterly press releases and webcast/analyst presentation transcripts.

## General comment on Q1 2016 performance

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments on the Q1 2016 performance:

"Our results for the first quarter show a strong start to the year and, while it is still early days for 2016, we are encouraged by the breadth of momentum we are seeing across the Group even after factoring in the benefits in the quarter of some phasing gains, particularly in Vaccines."

#### **Pharmaceuticals**

Pharmaceuticals	Q1	Q2	Q3	Q4	FY	Q1
(£m)	2015	2015	2015	2015	2015	2016
Total Turnover	3,523	3,540	3,340	3,763	14,166	3 <i>,</i> 586
CER growth						
Reported	-7%	-6%	-7%	-9%	-7%	-1%
Pro forma*	-5%	+2%	+1%	-1%	-1%	+5%

<sup>\*</sup>pro forma growth rates for Pharmaceuticals for Q1 to Q4 2015 were calculated by comparing reported turnover for the quarter with the corresponding quarter of 2014 adjusted to exclude the sales of the former GSK Oncology business. Pro-forma growth rates for Q1 2016 are calculated comparing reported turnover for Q1 2016 with the turnover for Q1 2015 adjusted to exclude sales of the former GSK Oncology business for January and February 2015.

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments on the Pharmaceuticals business:

"Overall, I continue to expect Pharma sales to return to growth in 2016, with contributions from new products offsetting the declines in Seretide/Advair, Established Products, and Avodart."



## Respiratory

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments on Respiratory:

"Total Respiratory sales in the US grew 2% as growth from our new products more than offset a 19% decline for Advair. We continue to expect US Advair sales to be down around 20% for the full year. In Europe Pharma sales were down 6% pro-forma, mainly reflecting a 24% reduction in Seretide due to the growing impact of generics, but more importantly the ongoing transition to our new Ellipta products; more of Seretide's volume decline went to Relvar than the generics. We continue to expect Seretide to decline around 20% in the region this year, although it may be a little higher, depending on the pace of transition to the new products."

Seretide/Advair (£m)	FY 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015	FY 2015	Q1 2016
US	1,972	392	484	397	592	1,865	339
Europe	1,330	291	267	224	232	1,014	226
International	927	215	209	173	205	802	188
Total	4,229	898	960	794	1,029	3,681	753
CER growth							
US	-25%	-21%	-17%	-18%	+2%	-13%	-19%
Europe	-5%	-11%	-16%	-23%	-22%	-18%	-24%
International	n/a	-4%	+0%	-13%	-14%	-8%	-11%
Total	-15%	-14%	-13%	-19%	-8%	-13%	-19%

## HIV

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments with regard to the HIV business:

"HIV sales grew 57% in the quarter as Triumeq and Tivicay continued to grow strongly and I expect the HIV portfolio to continue to build during the course of the year, although the rate of growth should be expected to slow as we move through 2016 given the higher comparators we are up against, particularly as we move into the second half. Also, remember that Epzicom goes generic in the US in Q3, but we may also see some generic activity in Europe in the second half"

Please note that a generic version of Kivexa (Epzicom) was launched in Germany in June.

HIV (£m)	Q1	Q2	Q3	Q4	FY	Q1
	2015	2015	2015	2015	2015	2016
Tivicay	112	145	157	174	588	188
Triumeq	81	149	211	289	730	328
Epzicom	176	185	175	162	698	154
Other	77	80	79	70	306	59
Total Turnover	446	559	622	695	2,322	729
CER growth	+42%	+59%	+65%	+51%	+54%	+57%



#### **Vaccines**

Sales of vaccines are vulnerable to volatility on a quarterly basis – particularly in emerging markets. Since quarterly sales can be very lumpy due in part to the impact of large tenders as well as competitor outages we highlight in the tables below the 2015 and 2016 to date quarterly results for the Vaccines business together with the 12 month pro forma results in and 2014 and 2015.

Here are the quarterly results for the Vaccines business in 2015 and 2016 to date:

GSK Vaccines	Q1	Q2	Q3	Q4	FY	Q1
(£m)	2015	2015	2015	2015	2015	2016
US	217	240	526	275	1,258	262
Europe	224	274	308	291	1,097	339
International	258	300	347	397	1,302	281
Total turnover	699	814	1,181	963	3,657	882
Operating profit	161	177	464	164	966	253
Operating margin	23.0%	21.7%	39.3%	17.0%	26.4%	28.7%
CER growth						
US – reported	+14%	+13%	+42%	+15%	+24%	+13%
US – PF*	+11%	-5%	+22%	+0%	+9%	+6%
Europe – reported	+4%	+27%	+31%	+30%	+23%	+48%
Europe –PF*	- <b>3</b> %	+12%	+14%	+11%	+9%	+33%
International – reported	+13%	-2%	+22%	+16%	+12%	+10%
International – PF*	+3%	-16%	+3%	-8%	-5 <b>%</b>	+3%
Total turnover – reported	+10%	+11%	+32%	+20%	+19%	+23%
Total turnover – PF*	+3%	-5%	+13%	-1%	+3%	+14%
Operating profit						
– reported	-31%	-32%	+30%	-23%	-9%	+56%
– PF*	-24%	-10%	+44%	-5%	+7%	>100%

<sup>\*</sup>PF (pro forma) growth rates for vaccines for Q1 to Q4 2015 were calculated by comparing reported turnover for the quarter with the corresponding quarter of 2014 adjusted to include the equivalent one month's sales of the former Novartis vaccines business in Q1 and three months of the former Novartis vaccines business in Q2, Q3 and Q4. Pro forma growth rates for Q1 2016 are calculated comparing reported turnover for Q1 2016 with the turnover for Q1 2015 adjusted to include the two months of sales for January and February 2015 of the former Novartis Vaccines business.

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments with regard to Vaccines:

"On Vaccines: a particularly strong quarter, with sales up 14% pro-forma benefitting from some earlier than expected phasing of international tenders and some additional purchases from the CDC in the US. A significant part of this phasing is likely to reverse in Q2 and Q3. In the US in addition to the CDC orders several products continue to grow market share strongly, including Bexsero, but also Boostrix and Pediarix, although Pediarix also benefitted from a competitor shortage. In Europe, Vaccines had a particularly strong performance, up 33% pro-forma, and the business continues to develop its portfolio well particularly in meningitis in both private and public markets. International Vaccines grew 3% pro-forma, helped by the phasing of tenders for Synflorix which grew 53% and



strong meningitis sales. These growth contributions were significantly offset by the impact of some of the supply constraints we have talked about before and that we are working on to deal with.

We are continuing to invest in our supply chain and particularly to improve our supply capacity for Bexsero given the rapid growth in its demand. This will take some time, but we are optimistic that we will see improved Bexsero supply in the second half. We continue to expect that overall the Vaccines business will achieve mid-single digit pro-forma growth this year."

On the same call, Andrew Witty made the following additional comments with respect to Vaccines:

"As far as the Vaccine margin is concerned, we made it clear that we are aiming for a Vaccine margin north of 30%\*. We had that before the Novartis transaction. Obviously, the Novartis business had a very much lower loss-making position actually. We are working our way through very quickly to that, I fully expect us to be above 30%. Again, you will see quarter-to-quarter volatility just depending on the kind of tender flow and those sorts of things but this margin, just like the Consumer one, is signalling to you where we are headed, and our goal is to be there as many quarters as possible, but we are not yet in a position where we are going to say to you every quarter, and that's more or less where we stand on that."

\*Please note that 30%+ refers to our target for the Vaccines operating margin in 2020.

#### **Consumer Healthcare**

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments with regard to Consumer Healthcare:

"Consumer Healthcare sales up 26% and 4% on a pro-forma basis, with the business delivering another strong quarter for Flonase in the US, which benefitted from launching a number of innovative line extensions. Competitor activity in the category increased during the quarter, particularly private label, and is expected to be tougher in Q2.

.... Overall for 2016 we continue to expect pro-forma top-line growth for the Consumer business to be in the mid-single digit range."

On the same call, Andrew Witty made the following additional comments with respect to Consumer Healthcare:

"So on the 17% margin, I don't think we'll see 17% every quarter of the year, but it's clear that 17% is, if you will, a new high water mark on our journey to 20%-plus\* so you will see a bit of volatility as you go through the year.

You know, what you see a little bit this quarter, quite a lot of Flonase sales in the quarter, quite a lot of the Flonase A&P will be in the next quarter. Little things like that at the margin might move things about a bit. Half a percentage point of the 17 is for Fx. Obviously, we need to see what happens with Fx as we go forward, but we are clearly starting to move into a new level, so we are clearly moving up from - you remember when we put this business together last year it was 11%. We began to make



progress last year into the kind of 12-13% territory for the year. I think we have clearly made a step up.

Why? Because we've got more concentration on the power brands and we are seeing the benefits of the integration really start to flow through. 80% of the site closures are done, 90% of the people decisions are done, so all of that kind of benefit, the cost benefit is flowing through into the business.

Will it bounce up and down a little bit? Yes. Are we on a good curve towards the 20%-plus? Absolutely. Might we get there a little bit earlier than we anticipated? It's possible on that one."

Here are the quarterly results for the Consumer Healthcare business in 2015 and 2016 to date:

GSK Consumer Healthcare (£m)	Q1 2015	Q2 2015	Q3 2015	Q4 2015	FY 2015	Q1 2016
Turnover	1,381	1,509	1,576	1,562	6,028	1,761
Reported growth - CER	+24%	+51%	+55%	+47%	+44%	+26%
Pro forma* growth – CER	+8%	+6%	+7%	+5%	+6%	+4%
Operating profit	182	108	210	180	680	303
Reported growth - CER	+53%	+41%	+92%	+73%	+66%	+59%
Pro forma* growth - CER	+35%	+0%	+22%	+38%	+24%	+49%
Operating margin	13.2%	7.2%	13.3%	11.5%	11.3%	17.2%

<sup>\*</sup>pro forma growth rates for Consumer Healthcare for Q1 to Q4 2015 were calculated by comparing reported turnover for the quarter with the corresponding quarter of 2014 adjusted to include the equivalent one month's sales of the former Novartis vaccines business in Q1 and three months of the former Novartis vaccines business in Q2, Q3 and Q4. Pro forma growth rates for Q1 2016 are calculated comparing reported turnover for Q1 2016 with the turnover for Q1 2015 adjusted to include the two months of sales for January and February 2015 of the former Novartis Consumer products.

<sup>\*</sup>Please note that 20%+ refers to our target for the Consumer Health operating margin in 2020.



## Corporate and other unallocated turnover and costs

In the Q4 2015 press release we made the following comments on corporate and other unallocated turnover:

"The Corporate and unallocated turnover of £72 million represented sales of several Vaccines and Consumer Healthcare products, which were being held for sale in a number of markets. GSK was required to dispose of these products in specific markets in order to meet the requirements of the anti-trust approvals for the Novartis transaction. The disposals were completed in Q3 2015."

On the Q1 2016 results analyst/investor call on 27 April 2016, in response to a question, Simon Dingemans made the following comments relating to corporate and other unallocated costs:

"We are a bit higher than trend in the quarter, probably about £50 to £70 million higher, so if you were taking £70 or £80 million as a quarterly run-rate that is probably more normalised. It is a little bit part of the quarterly volatility point we were just flagging in our earlier remarks."

Corporate and other unallocated as reported* (£m)	Q1 2015	Q2 2015	Q3 2015	Q4 2015	FY 2015	Q1 2016
Turnover	19	25	30	(2)	72	0
Total core operating profit (costs)†	(31)	(52)	(35)	(50)	(168)	(150)

<sup>\*</sup>Corporate and other unallocated costs include the results of several Vaccines and Consumer Healthcare products which were held for sale in a number of markets in order to meet anti-trust approval requirements and divested in Q3 2015, together with the costs of corporate functions. †In 2015, the total core operating costs were net of the profit from the unallocated turnover.



## **Operating and financial performance**

#### **Operating performance**

## Year-on-year annual cost savings (per 2015 full year results presentation)

Restructuring and structural savings (£bn)*	2014	2015	2016	2017
Restructuring savings (cumulative)	0.6	1.6	2.4	3.0
Structural savings	0.2	-	-	-
Total savings delivered/expected	0.8	1.6	2.4	3.0
Incremental savings		+1.0**	+0.8	+0.6

<sup>\*</sup> Expected phasing of annual savings. All expectations and targets regarding future performance should be read together with the "Assumptions related to the 2016-2020 outlook," the "Assumptions and cautionary statement regarding forward-looking statements" sections of the Q4 2015 Results Announcements dated 3rd February 2016 and the cautionary statement slide included with the 2015 full year results presentation.

In the Q1 2016 press release we made the following comments on restructuring:

"Major restructuring and integration charges accrued in the quarter were £188 million (Q1 2015: £366 million), reflecting the phasing of planned restructuring projects following the completion of the Novartis transaction in Q1 2015, as well as reduced charges for Pharmaceuticals restructuring projects as this programme enters its later stages. Cash payments made in the quarter were £267 million (Q1 2015: £254 million) including the settlement of certain charges accrued in previous quarters.

Charges for the combined restructuring and integration programme to date are £2.9 billion. The total cash charges of the combined programme are expected to be approximately £3.65 billion and the non-cash charges up to £1.35 billion. The programme delivered incremental cost savings of £0.4 billion in the quarter and has now delivered approximately £2 billion of annual savings on a moving annual total basis. It remains on track to deliver £3 billion of annual savings in total. The programme is expected to be largely complete by the end of 2017. "

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following additional comments with regard to cost savings:

"Restructuring and integration had a strong start to the year with incremental savings compared to the first quarter last year of nearly £400 million and we saw good execution in all three businesses. The level of incremental savings going forward will be up against tougher comparators but we are still on track to deliver incremental savings for the year as a whole of £800 million in total, in-line with our objectives to accelerate the overall programme. These savings are inevitably going to be unevenly phased through the year. Equally the need for investments in the business is also likely to vary quarter-to-quarter and this is really what is driving our expectation of some quarterly volatility on margins as we execute on our plans."

<sup>\*\*</sup> Net incremental savings of £0.8bn after taking into account structural savings credit in 2014 SG&A



## **Royalty income**

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following additional comments with regard to royalty income:

"Moving down the P&L, it is also worth flagging that the royalty income for Q1 included a positive catch-up from last year. Full year royalties are expected to be around £250 to £300 million."

CORE royalties (£m)	Q1	Q2	Q3	Q4	Full Year
2014	70	72	101	67	310
2015	77	62	99	91	329
2016 outlook	91				around £250 to £300
					million

## Financial performance

#### **Net finance costs**

On the Q4 2015 results analyst/investor call on 3 February 2016, Simon Dingemans made the following comments:

"Turning to the bottom half of the P&L on the next slide, our core finance expenses of £636 million were £10 million lower than 2014 and while we continue to focus on financial efficiency, I am expecting finance costs to be a little bit higher in 2016 as net debt increases from using some of the cash we're holding from the transaction to fund the restructuring programmes, continue to upgrade capacity but in particular to fund the return of the £1 billion special dividend from the transaction proceeds."

CORE net finance costs (£m)	Q1	Q2	Q3	Q4	Full Year
2014	(161)	(156)	(161)	(168)	(646)
2015	(156)	(178)	(148)	(154)	(636)
2016 outlook	(159)				Modest increase
					reflecting higher debt

## Associates and joint ventures

CORE associates and joint ventures (£m)	Q1	Q2	Q3	Q4	Full Year
2015	7	(2)	(2)	(5)	(2)
2016	0				



#### **Taxation**

In the Q1 2016 press release we made the following comments on taxation:

"In the quarter, tax on core profits amounted to £294 million and represented an effective core tax rate of 21.0% (Q1 2015: 20.0%).

The core tax rate for the full year is also expected to be in the range of 20-21%."

CORE tax rate	Q1	Q2	Q3	Q4	Full Year
2014	22.0%	22.0%	20.0%	15.3%	19.6%
2015	20.0%	20.0%	20.0%	17.9%	19.5%
2016 outlook	21.0%				20% to 21%

## Profit/(loss) attributable to non-controlling interests (minority interests)

In the Q1 2016 press release we made the following comments

"The allocation of earnings to non-controlling interests amounted to £147 million (Q1 2015: £91 million), including the non-controlling interest allocations of Consumer Healthcare profits of £46 million (Q1 2015: £12 million) and the allocation of ViiV Healthcare profits, which increased to £66 million (Q1 2015: £51 million) including the impact of changes in the proportions of preferential dividends due to each shareholder based on the relative performance of different products in the quarter."

CORE profit/(loss) attributable to non- controlling interests (£m)	FY 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015	FY 2015	Q1 2016
ViiV	132	51	62	65	46	224	66
Novartis Consumer Healthcare	n/a	12	29	57	40	138	46
Other	90	28	8	19	23	78	35
Total	222	91	99	141	109	440	147



#### **Total results**

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments with regard to total results:

"Total EPS for the quarter was 5.8p, down significantly compared to Q1 last year, which remember benefitted from a £9.3 billion gain on the disposal of the Oncology business.

Total results also reflect the accelerated pace of restructuring charges that we told you would continue to be a major factor in 2016, before falling away in 2017 as the restructuring and integration programmes start to come to an end.

The other major factor impacting total results are non-cash transaction related charges, as we unwind the discount on the Consumer put and the contingent consideration we have due for ViiV and the Novartis Vaccines acquisitions. About £200 million of the £460 million that has been charged this quarter is unwind and you should expect similar amounts going forward each quarter until the puts become due. The rest reflects re-measurement of the liabilities as the value of the businesses concerned are updated each quarter."

#### Net debt

On the Q1 2016 results analyst/investor call on 27 April 2016, Simon Dingemans made the following comments with regard to net debt:

"Net debt at the end of the quarter was £12.5 billion compared to £10.7 billion at the year end. After factoring in a drag of about £0.5 billion in translation, this was in-line with our expectations as we accelerate the investments to complete the restructuring and integration programmes.

As we pay out the fourth quarter dividend and the special distribution from Novartis this month, net debt will again increase in Q2, but is still expected to be below pre-Novartis levels and then should start to benefit from improved cash flows as the transaction and new product launches contribute more meaningfully and the integration and restructuring programmes begin to come to an end. We continue to expect a significant step-down in restructuring spend as we go into 2017."

Please note that the above comment on net debt level excludes the impact of translation including the impact from the recent sharp moves in Sterling.

Net debt (£m)	31 Mar	30 Jun	30 Sep	31 Dec
2014	13,660	14,423	14,788	14,377
2015	8,098	9,553	10,551	10,727
2016	12,495			



## Historic London Stock Exchange announcements (LSE announcements) and press releases

## **Acquisitions and divestments**

# GSK's global HIV business ViiV Healthcare completes transactions to acquire Bristol-Myers Squibb's R&D HIV assets

GlaxoSmithKline plc (LSE: GSK) today announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, has completed two previously announced transactions with Bristol-Myers Squibb to acquire its latestage HIV R&D assets and its portfolio of preclinical and discovery stage HIV research assets. The completion of both transactions follows antitrust approval by the relevant regulatory authorities in the US, with the integration process beginning immediately.

Under the terms of the transactions, ViiV Healthcare acquired late-stage HIV R&D assets from Bristol-Myers Squibb for an initial upfront payment of \$317 million followed by development and first commercial sale milestones of up to \$518 million, and tiered royalties on sales. ViiV Healthcare also acquired Bristol-Myers Squibb's preclinical and discovery stage HIV research business for an upfront payment of \$33 million, followed by development and first commercial sales milestones of up to \$587 million, and further consideration contingent on future sales performance.

## ViiV Healthcare has acquired:

- Late stage assets, including fostemsavir (BMS-663068), an attachment inhibitor currently in
  phase III development for heavily treatment experienced patients. Fostemsavir has received
  a Breakthrough Therapy Designation from the FDA and is expected to be filed for regulatory
  approval in 2018. The second late stage asset is a maturation inhibitor (BMS-955176), and is
  currently in phase IIb development for both treatment-naive and treatment experienced
  patients. A back-up maturation inhibitor candidate (BMS-986173) is also included in the
  purchase.
- Assets in preclinical and discovery phases of development including a novel biologic (BMS-986197) with a triple mechanism of action, an additional maturation inhibitor, an allosteric integrase inhibitor and a capsid inhibitor.

(LSE announcement 22 February 2016)

# GlaxoSmithKline Consumer Nigeria Plc receives offer from Suntory Beverage & Food Ltd to divest the bottling and distribution of its drinks business

Today, the board of Directors of GlaxoSmithKline Consumer Nigeria Plc (GSK Nigeria) announces that it has received a non-binding offer from Suntory Beverage & Food (SBF) for the divestment of its drinks bottling and distribution business.

(Nigerian Stock Exchange announcement 28 January 2016)

http://www.nse.com.ng/Listings-site/listed-securities/company-details?isin=NGGLAXOSMTH8



## News flow on key assets during the quarter and to date

Since the beginning of Q2 we have issued a number of LSE announcements and press releases, each of which can be accessed using the following link: <a href="http://www.gsk.com/en-gb/media/press-releases/">http://www.gsk.com/en-gb/media/press-releases/</a>

## GSK announces start of phase I oncology study with its ICOS agonist antibody

• GSK3359609 is the first investigational ICOS agonist antibody to enter human clinical trials GSK today announced the start of a phase I clinical trial with GSK3359609, an investigational inducible T-cell costimulator (ICOS) agonist antibody. ICOS is a co-stimulatory receptor that enhances T-cell responses and results in an increased anti-tumour response from the immune system. (Press release 30 June 2016)

FULFIL study shows superiority of closed triple combination therapy FF/UMEC/VI versus Symbicort® Turbohaler® in improving lung function and health-related quality of life in COPD patients

- Data supports regulatory submission by GSK in Europe by end of 2016
- GSK's US filing plans remain on track with submission also expected by end of 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced positive top-line results from the pivotal phase III FULFIL study of the investigational once-daily 'closed' triple combination therapy, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI: a combination inhaled corticosteroid, long-acting muscarinic antagonist, long-acting beta agonist), in patients with chronic obstructive pulmonary disease (COPD).

(LSE announcement 20 June 2016)

ViiV Healthcare announces FDA approval to lower the weight limit for dolutegravir in children and adolescents living with HIV

• Reduction of weight limit to at least 30kg means more children and adolescents will be eligible for dolutegravir.

ViiV Healthcare today announced that the US Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for dolutegravir 10mg and 25mg oral tablets, reducing the weight limit from at least 40kg to at least 30kg, in ages 6 to less than 12 years old, for the treatment of HIV-1 in children and adolescents. Dolutegravir, in line with the current label, will be available for use in two paediatric populations: paediatric patients weighing at least 30kg living with HIV-1 who are treatment naïve (not previously treated) and who are treatment experienced (previously treated), as long as they have not taken an integrase inhibitor.

(ViiV Healthcare press release 10 June 2016)



## GSK announces phase III study of sirukumab meets both co-primary endpoints in patients with rheumatoid arthritis

Plans on track to submit regulatory applications in Q3 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that a pivotal global phase III study investigating subcutaneous sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody, in adult patients with moderately to severely active rheumatoid arthritis (RA) met both co-primary end points.

The results from the positive SIRROUND-D study are being presented at the Annual European Congress of Rheumatology (EULAR 2016) in London, UK. Topline results were previously announced in December 2015.

(LSE announcement 08 June 2016)

# New Phase III data shows greater treatment response with GSK's Benlysta® (belimumab) vs placebo in patients with highly active SLE

GSK today announced data at the Annual European Congress of Rheumatology (EULAR 2016) showing that patients with highly active systemic lupus erythematosus (SLE) experienced a significantly greater response to treatment with Benlysta (belimumab) 200mg administered via subcutaneous injection plus standard of care (SoC), compared to placebo plus SoC. High SLE disease activity is associated with symptom flares and a range of organ manifestations in lupus patients. The pre-specified analysis reviewed a subset of patients from the overall BLISS-SC Phase III pivotal study of belimumab subcutaneous formulation. This high disease activity sample is reflective of the licensed population for Benlysta intravenous formulation in the European Union.

(Press release 08 June 2016)

## Regulatory update on US filing plans for closed triple combination therapy FF/UMEC/VI in patients with COPD

• Acceleration of filing of US New Drug Application now expected by end of 2016 GlaxoSmithKline plc (LSE:GSK) and Innoviva, Inc (Nasdaq: INVA) today announced that, following discussions with the US Food and Drug Administration (FDA), GSK has brought forward the plan to file a New Drug Application (NDA) in the US for the once-daily closed triple combination therapy, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI; a combination inhaled corticosteroid, long-acting muscarinic antagonist, long-acting beta agonist) for patients with chronic obstructive pulmonary disease (COPD). The US regulatory submission is now anticipated by the end of 2016, rather than the first half of 2018, as previously expected.

(LSE announcement 02 June 2016)

Strimvelis receives European marketing authorisation to treat very rare disease, ADA-SCID GSK, Fondazione Telethon and Ospedale San Raffaele gain approval to provide life-saving gene therapy to patients.

GlaxoSmithKline (GSK), Fondazione Telethon (Telethon) and Ospedale San Raffaele (OSR) today announced that the European Commission has approved Strimvelis, the first ex-vivo stem cell gene therapy to treat patients with a very rare disease called ADA-SCID (Severe Combined Immunodeficiency due to Adenosine Deaminase deficiency). A child born with ADA-SCID does not have a healthy, fully-functioning immune system and as a consequence, is unable to fight off



everyday infections. Strimvelis (autologous CD34+ cells transduced to express ADA) is the first corrective gene therapy for children to be awarded regulatory approval anywhere in the world. It is indicated for the treatment of patients with ADA-SCID for whom no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.

(LSE announcement 27 May 2016)

# GSK, Fondazione Telethon and Ospedale San Raffaele announce publication of pivotal safety and efficacy of gene therapy for children with ADA-SCID

GSK, Fondazione Telethon and Ospedale San Raffaele today announced the publication in BLOOD of the long-term safety and efficacy data from an analysis of 18 children with ADA-SCID treated with hematopoietic stem cell gene therapy between 2000 and 2010 at the San Raffaele Telethon Institute for Gene Therapy (SR-Tiget). Children with ADA-SCID, a very rare inherited disorder caused by a faulty gene, do not develop a healthy immune system which often proves fatal within the child's first year of life.

(Press release 25 May 2016)

# Salford Lung Study results show COPD patients treated with Relvar® Ellipta® achieve superior reduction in exacerbations compared with 'usual care'

 Pioneering GSK study provides important new data on the effectiveness of Relvar Ellipta (FF/VI) when used in everyday clinical practice

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced positive headline results from the innovative Salford Lung Study (SLS) in Chronic Obstructive Pulmonary Disease (COPD). The study showed that Relvar® Ellipta® 100/25mcg (fluticasone furoate 'FF'/vilanterol 'VI' or 'FF/VI') achieved a superior reduction in exacerbations versus usual care, in patients with COPD, in an everyday clinical practice setting. Usual care included long-acting muscarinic antagonists (LAMA), long-acting beta2-agonists (LABA), and inhaled corticosteroids (ICS) administered as monotherapy, dual or triple combinations.

For the primary effectiveness analysis, in patients treated with FF/VI 100/25mcg there was a statistically significant reduction of 8.41% (CI 1.12,15.17) in the rate of moderate or severe exacerbations compared with those receiving usual care (p=0.025).

Within the intent-to-treat (ITT) population, the incidence of serious adverse events (SAE) was similar between the groups (29% FF/VI, 27% usual care). For pneumonia, an SAE of special interest, FF/VI demonstrated non-inferiority versus usual care (7% FF/VI versus 6% usual care). This endpoint was a regulatory post-authorisation measure requested by the European Medicines Agency (EMA). (LSE announcement 24 May 2016)

## GSK presents new data from Breo® Ellipta® SUMMIT study in patients with COPD at ATS Conference

GlaxoSmithKline (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced that GlaxoSmithKline plc (GSK) presented new data at the American Thoracic Society (ATS) Conference from two pre-specified analyses from the Study to Understand Mortality and MorbidITy (SUMMIT) trial. One demonstrated that patients with Chronic Obstructive Pulmonary Disease (COPD) and moderate airflow limitation receiving Breo® Ellipta® (fluticasone furoate/vilanterol or FF/VI 100/25mcg) achieved improvements in exacerbations compared with placebo. The second analysis



demonstrated these patients reported similar rates of pneumonia when taking FF/VI 100/25mcg compared with placebo.

The SUMMIT trial was designed to evaluate the effect of FF/VI 100/25mcg once-daily on all-cause mortality compared with placebo in patients with moderate COPD who had, or were at high risk for Cardiovascular Disease (CVD). Results of the primary endpoint were announced in 2015 and showed that all cause mortality was not affected by combination therapy or the individual components. (Press release 18 May 2016)

# GSK presents efficacy data for Anoro® Ellipta® in COPD patients who remained symptomatic on tiotropium

GlaxoSmithKline (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced results from data presented at the American Thoracic Society (ATS) 2016 International Conference investigating the efficacy and safety of Anoro® Ellipta® (umeclidinium/vilanterol, 'UMEC/VI') in patients with moderate chronic obstructive pulmonary disease (COPD) who continued to have symptoms while on tiotropium monotherapy.

(Press release 18 May 2016)

# GSK's Bexsero® achieves primary and secondary endpoints with reduced 3-dose schedule (2+1) in safety and immunogenicity study in infants and children

GSK today presented new data for its meningococcal group B vaccine, Bexsero®,1 [Meningococcal group B Vaccine (rDNA, component, adsorbed)] comparing safety and immunogenicity with different dosing schedules in infants and young children, at the annual meeting of the European Society for Paediatric Infectious Diseases (ESPID). The phase IIIb study (V72\_28) met its primary and secondary endpoints, showing comparable immune response and safety in infants receiving a reduced schedule of two primary doses of Bexsero plus a booster dose compared to those receiving the current EU approved schedule of three primary doses of Bexsero plus a booster dose.

(Press release 13 May 2016)

## GSK announces start of a phase II study to evaluate an anti GM-CSF antibody for inflammatory hand osteoarthritis

GSK today announced the start of a phase II study to evaluate the efficacy and safety of GSK3196165, an investigational anti-granulocyte macrophage colony-stimulating factor monoclonal (anti GM-CSF) antibody, in patients with inflammatory hand osteoarthritis.

(Press release 18 April 2016)

#### GSK opens new state of the art respiratory manufacturing facility in Ware, UK

- Opening creates 150 jobs; more than 400 created at the site since 2013
- Facility needed to meet growing export demand for GSK respiratory medicines

GSK today opens a £56 million state of the art manufacturing facility, creating 150 new jobs in the UK, in response to demand for GSK's portfolio of respiratory medicines delivered by the innovative Ellipta inhaler.

The new 4,500m<sup>2</sup> facility will be opened by UK Life Sciences Minister George Freeman MP and GSK Chief Executive Officer Sir Andrew Witty. It is the latest expansion for Ellipta manufacturing at Ware, with investment totalling over £100 million over the past five years. The new facility opening today is



expected to nearly double production of Ellipta inhalers at Ware to at least 37 million per year by 2017, 95% of which will be exported.

(Press release 18 April 2016)

## GSK receives positive CHMP opinion in Europe for Strimvelis, the first gene therapy to treat very rare disease, ADA-SCID

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), in conjunction with the Committee for Advanced Therapies (CAT), has issued a positive opinion recommending marketing authorisation for Strimvelis to treat patients with a very rare disease called ADA-SCID (severe combined immunodeficiency due to adenosine deaminase deficiency). The medicine is a stem cell gene therapy created for an individual patient from their own cells which is intended to correct the root cause of the disease. If approved by the European Commission, the medicine - currently known as GSK2696273 (autologous CD34+ cells transduced to express ADA) - will be commercialised under the brand name Strimvelis, for the treatment of patients with ADA-SCID for whom no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.

(LSE announcement 01 April 2016)

#### Other newsflow during the quarter and to date

#### **Executive Director Change**

GSK today announces that Dr Moncef Slaoui, Chairman, Vaccines, has indicated to the Board his intention to retire from the Company in 2017. The Board supports Dr Slaoui's decision and has agreed he will retire on 30 June 2017.

Dr Slaoui will remain a member of the Board until 31 March 2017. From 1 April 2017 until his retirement on 30 June 2017, he will serve as an advisor to both GSK and the Board. Dr Slaoui joined GSK in 1988 and the Board in 2006.

(LSE announcement 14 June 2016)

## **Board and Committee changes**

The Company announces that Dr Vivienne Cox, CBE, has been appointed to the Board of the Company as a Non-Executive Director with effect from 1 July 2016. She has been appointed a member of the Corporate Responsibility Committee, also effective from 1 July 2016.

(LSE announcement 27 May 2016)



In order to illustrate underlying performance, it is the Group's practice to discuss its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Sterling had remained unchanged from those used in the comparative period. All commentaries are presented in terms of CER growth, unless otherwise stated.

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