

GLAXOSMITHKLINE

**FULL YEAR 2016 RESULTS
PRESENTATION TO ANALYSTS**

Wednesday, 8 February 2017

GLAXOSMITHKLINE
FULL YEAR 2016 RESULTS
PRESENTATION TO ANALYSTS
Wednesday, 8 February 2017

Sir Andrew Witty (CEO): Good afternoon and welcome to this call for GSK's full year 2016 results. I am pleased to report that sales and profits were up in all three of our businesses: Pharmaceutical, Vaccine and Consumer Healthcare. Total Group sales were £27.9 billion, up 6% CER, and core EPS was at 102.4 pence, up 12% CER. This was towards the top end of our financial guidance, which, as you know, we increased during the year.

In sterling terms, core EPS was up 35%, reflecting the significant movement in the currency in 2016 and, if sterling rates were to remain in line with January average rates for the rest of 2017, we would expect a 9% benefit to core EPS during the year.

Total EPS for the Group was 18.8 pence, down on last year primarily as a consequence of the comparator to the £9.2 billion gain in the Novartis transaction during 2015.

We have declared a dividend of 23 pence for the quarter bringing the total dividend to 80 pence for 2016, and we continue to expect to pay a dividend of 80 pence for 2017.

The positive momentum we saw in 2016 delivered Pharmaceutical sales of £16.1 billion, up 3%, Vaccine sales of £4.6 billion, up 14%, and Consumer Healthcare sales of £7.2 billion, up 9%. On a pro forma basis, sales growth was respectively +4%, +12% and +5%.

On a geographic basis, the US accounted for £10 billion, Europe £7.5 billion and International £10 billion. Operating margins also improved in all three businesses, reflecting good cost control and delivery of organic and transaction-related savings, with the Group core profit margin of 27.9%, up 3.9 points on last year. These performances reflect the investments we have made to build scale and sustainability in the Group and to deliver new products. Sales of the 11 Pharmaceutical and Vaccine products that we have launched in the last four years more than doubled to £4.5 billion in 2016, and in the fourth quarter alone sales were £1.4 billion.

In Pharmaceuticals, new products in the fourth quarter accounted for 27% of sales. This new sales growth is being driven by products for the treatment of HIV, *Tivicay* and *Triumeq*, respiratory disease *Relvar*, *Breo*, *Anoro*, *Incruse* and *Nucala*, and vaccines to prevent meningitis, *Bexsero* and *Menveo*. We are very focused on ensuring that the sales momentum of these new products continues and we expect to bolster this portfolio with

several new arrivals in 2017/18. This follows good progress last year to file a number of new product opportunities including *Shingrix*, a potential new vaccine to prevent shingles, and Closed Triple, potentially the first ever three-in-one treatment for COPD. We expect regulatory decisions on these before the end of the year.

Last year, we also initiated a number of Phase III trials for assets in HIV, respiratory and anaemia, and started Phase II trials for five new assets.

Over the course of 2017/18, we expect important data for between 20-30 assets in clinical development to read out.

Product innovation is also important for our Consumer business and accounted for 13% of sales in 2016. Today, in the US we are launching *Sensimist*, our second allergy prescription product to be switched to over-the-counter status in the last three years, and we are very optimistic that we can follow the huge success of *Flonase*.

All of this bodes well for GSK going forward and reflects our strategy to create a Group that can both access growth opportunities from new innovation and navigate changes both in our portfolio and the challenges we face in today's operating environment. We continue to be confident in the financial outlooks to 2020 that we first laid out to investors in May 2015.

For 2017 we do face some uncertainty as to the level of our earnings performance given the possibility of a substitutable generic competition to *Advair* in the US, and this is reflected in the guidance we have issued you today. This event is something we have anticipated and prepared for and is consistent with the assumptions we provided back in 2015. Given our new product portfolio and the innovation we have in our pipeline, we fully expect to maintain our leadership in Respiratory.

In summary, the Group has performed positively in 2016 with momentum set to continue this year. I have been working closely with Emma as she transitions into the CEO role and as we enter a new period of leadership for the company, and I believe that GSK is well-positioned to deliver long-term performance for its shareholders. With that, I would like to hand over to Simon to give you more details.

Simon Dingemans (CFO): Thanks, Andrew. The results that we have reported today demonstrate the progress we have made in delivering on our strategy as well as the financial goals we set out in our financial architecture. All three of our businesses are contributing to the delivery of more broadly-based revenue growth. Our continued focus on the execution of our integration and restructuring programmes has accelerated the delivery

of the targeted benefits allowing us to improve our margins and operating leverage, while still making substantial investments behind our new products, supply chain improvements as well as progressing the R&D pipeline.

We have also maintained our focus on financial efficiency in the P&L and in the allocation of our capital, allowing us to deliver core EPS growth ahead of sales and at the top end of our EPS guidance, as well as a significant improvement in our cash generation and a dividend of 80 pence per share. We expect continued progress from the business in 2017 with all three businesses continuing to benefit from recent new product launches and other investments including supply chain capacity as well as the completion of the integration and restructuring programmes.

The guidance we've given today for core EPS performance in 2017 reflects that momentum, but also takes account of the possibility that a substitutable generic alternative to *Advair* may be launched in the US this year. This is a situation that is bound to evolve during the year and we will update our guidance as and when there is more certainty on the competitive position. Given that this will depend on a number of variables, including pricing and supply availability of any generic, it seems unlikely that we will have any greater clarity before the middle of the year. I will come back to details of the guidance shortly.

Our earnings release provides an extensive amount of detail on the results for both the fourth quarter and the year and so as usual my comments will focus on the major points, our expectations for 2017 and some comparative points you might want to take note of for your modelling. As always, all my comments will be at CER except when I specifically refer to currency.

Sales growth +6% reported, +5% pro-forma

New products helped deliver growth across all three businesses

Group sales up 6% reported, 5% pro-forma, core EPS up 12%. On currency specifically the weakness in sterling resulted in a tailwind of 11% to sales. The tailwind on EPS was higher at 23% which I have said before is due to the Group having a higher proportion of costs than sales in sterling. With sterling weakness continuing into the start of 2017, we currently expect a further tailwind from currency in 2017, particularly during the first half of the year unless rates start to reverse the moves we saw last year.

If FX rates remain in line with January average rates for the rest of 2017, we expect a 9% tailwind core EPS.

Starting with our total results, the year-on-year decline in earnings is primarily driven by the comparison with the £9.2 billion profit we made in 2015 on the disposal of our

Oncology business. We also had higher charges in 2016 for transaction-related revaluations during the year as the sterling values of the contingent consideration liability to Shionogi and the ViiV and Consumer put options increased due to the post-Brexit weakness in sterling as well as an improved outlook for the businesses concerned.

As you will recall, both our minority partners in the HIV business had put options against us for their shareholdings which we included on the balance sheet at Q1. We have recently restructured the shareholders agreement with Shionogi to remove that put option and the associated estimated liability of £1.2 billion. We continue to carry the Pfizer option on the balance sheet at £1.3 billion.

Total results were also significantly impacted by restructuring charges associated with the integration and restructuring programme that benefited comparatively as the charges were significantly lower than the previous year as the programme comes to an end. We charged approximately £1 billion during the year, almost half the level charged in 2015.

Core operating margin

Pro-forma margin up +2.6% CER, with improved leverage across all three businesses

Turning to our core results, all three businesses delivered growth in line with or above the medium-term growth expectations we laid out for them at our Capital Markets Day in 2015.

Pharma was up 4% pro-forma with new products now significantly more than offsetting the decline in *Seretide/Advair* sales.

In addition to a continuation of the strong growth in HIV, Respiratory also returned to growth overall, up 2% in line with our expectations. This reflects the continued progress in transitioning our Respiratory business to the new *Ellipta* portfolio globally.

For Pharma in 2017, in addition to expecting continued growth from recently launched new products in Respiratory and HIV, we are preparing for the launch of closed triple which is on track for a potential approval in Q4. We think this is a very important addition to the *Ellipta* portfolio and has significant potential, but as we have flagged before, given the payor environment in the US and Europe it will take time to build coverage and so you should not expect significant sales before 2018.

Focussing on *Advair*, before any impact from a substitutable generic in the US we expect *Seretide/Advair* to continue to decline globally in the face of price and other competitive pressures, but also as we continue the transition to new products. Overall we expect *Seretide/Advair* to be down around 15-20% globally, similar to the trend of the last

couple of years with the US in line with this range, but Europe more at the 20% end given the different stage of transition in our portfolio.

In HIV we expect dolutegravir to continue to be a strong growth driver but from a higher base so the overall percentage growth in HIV sales is likely to be lower, particularly when you take into account that there are now *Epzicom/Kivexa* generics in most of our major markets.

Elsewhere in the Pharma portfolio, 2016 saw a better performance from our Established Products business as improved supply and mix partly offset the impact of biennial price revisions in Japan and the reshaping of our China business away from older products.

Going forward we continue to expect similar mid-to-high single digit declines from this portfolio before any disposals given its generic profile, but we will also continue to manage it to optimise its cash returns either through operating performance or targeted disposals such as those recently agreed with Aspen.

The products being sold to Aspen contributed approximately £100 million of sales to 2016 that will act as a further drag to the Established Products business during 2017 of around 4%.

Moving to Vaccines, sales up 12% pro-forma. This is driven by strong execution across the business particularly around the meningitis franchise, and *Bexsero* in particular. We continue to invest to expand production capacity but this is a long cycle process and supply is likely to remain tight for some time.

We also had a very successful 'flu season, especially in the US, driving overall pro-forma growth in Vaccines to 12%. This was above our medium-term expectations for the business and creates a tough comparator for 2017, but underlying momentum remains encouraging even though, quarter to quarter, Vaccines remains a lumpy business.

Looking forward, we expect regulatory decisions on *Shingrix* in the US and Europe in Q4 2017 and our launch preparations are progressing well. That said, the timing of any approval remains uncertain and so, while there may be some sales reported in 2017, we would not expect a meaningful contribution from *Shingrix* until we get into 2018.

Moving to Consumer, we delivered a strong performance in the first full year of the joint venture sales, up 5% pro-forma, consistent with our medium term outlook for this business. In line with our strategy, this growth was driven primarily by the seven power brands, with the US and Europe contributing most strongly, driven by oral care and wellness – particularly *Sensodyne* and *Voltaren* – which both delivered double-digit growth. This

helped to offset a few tough comparators and headwinds in international, later on in the year, including the impact on the Indian business of demonetisation and a slowdown in the nutrition category, as well as the divestment of the Nigerian drinks business at the end of Q3.

Some of these pressures and comparator issues will continue as we go into 2017 and will likely take growth for Consumer overall this year down a notch, relative to the medium-term trend – especially when you factor in the possible impact of a general sales tax on reported sales in India. However, momentum in the rest of the business continue, with the launch of another OTC switch, *Sensimist*, already underway as we have announced today, and other innovation investments supporting continued growth of the key power brands globally.

Core operating margin

Turning to core operating profit, our core margins improved across the board, with increased leverage in all three of the businesses. The pro-forma margin was up 460 basis points in total, 200 from currency, and 260 points from operational improvements. This was driven by leverage from a growing top line, significant additional integration and restructuring benefits, as well as continued tight cost control that allowed us to deliver substantial margin improvement while still making important investments to build our new products, improve the supply chains and advance the R&D pipeline.

Looking to the future, we remain on track to achieve our 2020 divisional margin targets, though 2017 may see some fluctuation as we invest behind new products in Vaccines and Pharma, and continue the transition of our Respiratory business – particularly if we see a generic competitor to *Advair* this year. Also, remember that Vaccines benefitted from a royalty catch-up in 2016. We expect total royalties to be around £300 million in 2017.

In Consumer, we expect continued progress on margins and we remain on track to achieve our 20%-plus target by 2020.

Accelerated delivery of structuring benefits

Accelerating the delivery of the targeted benefits of the integration and restructuring programme was a key objective when we closed the Novartis transaction, and we are very pleased with the progress we have made through a sustained focus across the company on executing this programme. We have now delivered annualised benefits of £2.8 billion excluding £200 million of currency benefits - almost the full targeted total benefits from the programme a year earlier than originally planned. We are confident in delivering the remaining £200 million during 2017.

The costs we have incurred to get to this stage have also been better than originally expected, with total cash costs accrued to date of £2.9 billion compared to the initial estimate of £3.65 billion. Delivery of the remaining £200 million of benefits is also expected to cost less than originally anticipated, at around an additional £300 million of cash costs to be charged in 2017 to deliver the full total of benefits.

Operating profit to net income

In the bottom half, the P&L net finance costs were up slightly, mainly due to currency. The higher core tax rate in 2016 reflects the increasing proportion of earnings in the US and the increase in non-controlling interest reflects the growth of our Consumer and HIV businesses. In 2017, we expect a modest uptick in interest costs, reflecting the higher debt levels and, as for tax, we expect a core rate of 21% to 22%, again reflecting the changing geographical mix of our business. Non-controlling interests will reflect, primarily, the performance of our Consumer and HIV businesses.

Cash generation and net debt

On cash flow and net debt, reported free cash flow for the Group, was £3.1 billion significantly improved on the small outflow we saw in 2015. This was driven by our continued sales momentum, better operating leverage, as well as an ongoing focus on controlling working capital, capex and restructuring spend, together with the benefit of currency tailwinds that I have already discussed.

Tangible and intangible capex in 2016 was £2.35 billion, including £0.2 billion spent on acquiring the late-stage BMS HIV assets. In 2017, we expect total capex to be slightly lower, at around £2.2 billion, as we continue to invest and expand in capacity new product platforms and upgrading our systems.

Restructuring spend came in under our original expectations, with cash spend in 2016 of £1.1 billion, compared to the £1.3 billion we had previously indicated. This reflects the continued scrutiny and tight approval processes we have in place before we implement any of our restructuring or integration initiatives. As I highlighted earlier, cash spend on the integration and restructuring programme is expected to decline sharply in 2017 to around £300 million as the programme completes the delivery of its targeted benefits.

Net debt increased by £3.1 billion, driven by an aggregate currency impact of £2.2 billion, that affected cash balances and other financing items, but primarily impacted the translation of foreign currency borrowings. We do not hedge the principal amounts of these borrowings, as they are matched to equivalent foreign currency earnings.

Excluding the exchange effect, net borrowings increased £0.9 billion, reflecting the payment of dividends during the year of £4.9 billion, including the special dividend of £1 billion declared in 2015, offset by free cash flow of £3.1 billion and asset disposals of £1 billion.

Continued progress expected in 2017

Looking to 2017, the outlook, clearly, depends on whether *Advair* encounters substitutable generic competition in the US. If there is no generic launched in the US this year, then we would expect core EPS growth of 5 to 7% on a constant currency basis. Again, this is based on an expected ongoing decline in 2017 US *Advair* sales of 15 to 20%, again on a constant currency basis.

However, it is now a real possibility that a substitutable generic to *Advair* could be launched in the US during 2017, given the filings already made. While the timelines for the introduction of a generic are far from clear and its impact will depend heavily on the pricing strategy and supply capacity deployed, we have assessed a number of scenarios in our planning for this year. Against this uncertainty, and to help you with your models, we have set out today our assessment of the impact on our 2017 growth in core EPS of a mid-year introduction of a substitutable generic to *Advair* in the US. In this event, we would expect that US *Advair* sales for 2017 as a whole, would decline to around £1 billion at constant exchange rates, i.e. at \$1.36 to the pound. However, we still expect to have enough momentum in the rest of the Group to deliver core EPS of flat to a slight decline in percentage terms compared with 2016, again on a constant currency basis.

While this is only one scenario, it seems reasonable relative to the outstanding filing timelines, but clearly the impact could be somewhat better or worse, depending on how the generic threat actually plays out.

We will update you as and when we have more clarity, but realistically it is likely to take some time for the potential impact to be clearer, and probably not before the middle of the year.

To wrap up, our focus on execution has served us well. I am pleased with the progress we have made, including delivering sales growth across the board, improving the operating leverage in all the businesses and also improving our cash generation to support future investment requirements and sustainable returns to shareholders. We expect to return another 80p of dividend for 2017.

With that, I will hand back to Andrew.

Sir Andrew Witty: Thanks very much, Simon. Let's open up the call to questions. If maybe the operator could just remind everybody the protocol of how to request a question?

Question and Answer Session – 24 mins

Graham Parry (Bank of America Merrill Lynch): Great, thanks for taking my question. Firstly, on the guidance, if you could just run through some of the reasoning for your assumptions? For example, the mid-year approval of a generic when GDUFA is at the end of Q1, and what appears to be a 75% decline post-generic, given that you have previously questioned the ability of generics to erode sales due to pricing and manufacturing restraints, or potential pricing and manufacturing restraints.

Secondly, if I look at consensus, at about the \$1.36 FX rate, *Advair* sales in consensus would look to be about £1.2 billion versus the £1 billion. Consensus EPS is flattish for the year. Is it fair to say that what you are trying to tell us is you think you could just about making something close to current consensus EPS, even if *Advair* sales in the US were about 20% lower than consensus is currently forecasting? Thank you.

Sir Andrew Witty: Thanks, Graham. Just on the assumption piece, it is clear that to get this right on all the dimensions, i.e. the timing of approval, the timing of the launch, the amount of supply, the pricing dynamics, it is impossible to get that right. What we have aimed to try and do is to come up with an answer which we think essentially covers most of the likely outcomes. Of course, it is possible people could launch a bit earlier, but it is also possible they don't have as much supply as you would need to get 75% erosion; maybe something else happens in the marketplace, but we think the combination of a mid-year launch with a pretty aggressive decline of 70/75% in the second half after a 15% decline in the first half, getting you to about that £1 billion, that feels like a reasonably sensible balance of probabilities, because you might say the timing moves a bit, you might say the erosion curves move a bit, but net-net you might come out at a broadly similar number. It could end up being a bit better, it could end up being a little bit worse, but I think this is a pretty reasonable estimate, realistic estimate, of what could happen. Obviously, if we see no product launched by the middle of the year then we are on the upside territory and the like.

In terms of what we are trying to tell you, we are trying to tell you we think it is £1 billion if that scenario plays out. What is clear is, if any of those assumptions go our way a bit, so if we see the decline being a bit less than 15% in the first half, if we see the generic being a bit delayed, if the generic only has 50% supply, then clearly we are going to do

better than that number, but we are just trying to give you a sense of what we think is a reasonable estimate for what the bottom end of the bracket is for the year, so that you can model from there. We don't really think it is very far away from where consensus was this morning, it may be a point or two, but it certainly doesn't feel like it is very far away, and I think when we looked at the general view of the market, I think most people's view of the market is actual arrival of the product into the marketplace probably is mid-year.

I remind you, when we had *Advair* approved it took GSK six months to get from *Advair* approval to launch. Now, we are 15/16 years down the road, people are more sophisticated now, give people credit for doing things better now than we did in those days, everybody has had more experience, but not super-trivial to just produce 20 million packs of supply overnight for a product like *Diskus*. I think that is a fair area to think, even if you did get first-pass approval, not super-trivial to turn on maximum supply overnight, and so we think this is a reasonable – a reasonably simple way to pull together two or three elements of the assumption set, recognising they won't be right, but probably covering most of the outcomes and as we go through the year, obviously once facts become facts, we can start to fine tune this for you, but I don't think it is going to be a million miles away. If there is no generic, I think the 5 to 7 is a good estimate for where we would be and if there is a generic I think the flat to slightly down is a good estimate to where it could be at the bottom end of the curve.

Thanks, Graham. Next question?

Andrew Baum (Citi): Good afternoon, a couple of questions. Before that, I just want to say that I am sure, occasionally, dealing with Sell Side analysts has been as much as fun for Andrew as getting his teeth drilled, but I wanted to express my thanks for the candour, insights and openness over the years.

On the questions, a few things; number one, Andrew, could you address value-based pricing? It is obviously highly topical in the US, given the new Administration, among the industry. In particular how easy is it going to appear to implement, given the very significant challenges across the range of therapeutics?

Then, Simon, again in terms of the new Administration, obviously US tax reform, order tax proposals, look like they are going to happen. Can you talk how that will impact GSK? In particular, I note that you committed to new manufacturing sites in Scotland, rather than the US, and whether these are, indeed, going to be supplying the US? Then, second, I know you also relocated some IP out of the US into the UK?

Sir Andrew Witty: Thanks, Andrew, and thanks very much for your kind words at the beginning.

Value-based pricing, the first thing to say is I think if you asked four different people to describe value-based pricing you would probably get five different definitions, so I think there remains – this is a bit of a bucket description which different people interpret different things, and it does vary a bit by country and payor model what is viable. I think in the US it is quite tricky to see how you get to value-based pricing without more transparency in the pricing system, Andrew, in the first instance, and I suspect it is going to require some simplification of some of the regulatory thicket which exists in the US pricing environment. As you think about in any given zip code in the US you have got every single piece of legislation which touches Medicare, Medicaid, veterans, private, all over/superimposed on each other, and so to try and drive a new pricing model through that thicket of regulations, sometimes they are quite inhibitory in the way in which you might want to innovate your pricing approach. Those two areas, we probably need to be – frankly, we probably need to see a pretty coordinated effort from industry, intermediates, payors and Government, to try and rethink what this space is like, to create a more fertile environment for some innovation in this space.

For me, what it really all boils down to is companies starting to take more risk, in terms of the price that you charge for the product, and having more dynamism, in terms of the likely price received for the product over time, as your contribution basically ebbs and flows, according to data and all the rest of it.

I do think it is a viable way forward, but, as I have said, I think there is quite a lot of clearance to be done before it can progress, that would be the first thing to say.

I just want to – before Simon talks in more detail on the tax pieces – just to remind you we have nine factories in the US, one of our two Global R&D Centres in the US, we are just in the process of commissioning a brand new Vaccine Research Centre in the US, in Maryland, tremendous, and we have a policy, basically, Andrew, of whenever we launch a new product, like *Tivicay* or the *Ellipta* platform, even if it is initially launched in a factory outside of America, we, as quickly as possible, transfer production to our US factories, so things like *Tivicay*, things like *Breo*, are already now being manufactured in the US. There are some technologies and bulk primary manufacture, and some vaccines are probably a good example and we wouldn't be unique in this, where there is only one manufacturing site in the world that makes it and it is where it is.

So just from a factual point of view of network, I think we are in a pretty good position. The reality is it is going to be very difficult for the US to own every single piece of

input that goes into its system, I don't think anybody realistically believes that and we are definitely in the process, as we speak, of continuing to expand our physical footprint in America, as you rightly say we are also doing in Britain, but the US and Britain really represent the two very biggest parts of our networks but Simon can comment in more detail on the tax points.

Simon Dingemans: Thanks, Andrew. As you will anticipate, the devil is going to be in the detail of what the proposals finally turn out to be but, particularly in relation to any border adjustment and which products it covers and how it covers cross-border flows, because we are not alone in having our supply chain stretch across those borders, on balance, from what we can see today, we think it is likely to be a net positive. Exactly how much is impossible to say at this point, but we feel reasonably well hedged given the manufacturing footprint that Andrew just described, and we have retained structural flexibility to move parts of the Group around including our R&D investments and intellectual property to respond to where governments place the incentives, and that will include the US as well as the UK. At the moment, we are watching, participating in the debate and we shall see what proposals appear.

James Gordon (JP Morgan): My first question is how are you thinking about overall US integrase uptake over the next few years: I know you are going to have new doublets but there could also be a competitive integrase combo from Gilead. Do you think that will significantly increase the pace at which the integrase market expansion occurs, or will it be more of a share battle?

My second question, pipeline was not a big focus of the presentation but, in terms of pipeline readouts for this year, what is important particularly maybe in Oncology, and could we see any progress into Phase III in the pipeline this year?

Sir Andrew Witty: Thanks very much. In terms of integrase, we have seen a very significant expansion of the integrase market since we launched dolutegravir and I would expect to see our progress continue. We have seen very little change in the uptake curves of the product, we are seeing a tremendous amount of new starts coming into our products as well as switches from non-integrase backbones. Clearly, if a competitor brings out another product, it just depends how good that product is but, at the very least, you would expect it to probably self-cannibalise some of its own portfolio, so again increasing the size of the market. I think it is a reasonably challenging ask to start to take business away from dolutegravir given the extraordinarily effective resistance profile that dolutegravir has, and the lead we have in terms of establishing ourselves. If we then are able to demonstrate

that the doublet approach really does deliver both the efficacy and the resistance protection at a wide range of viral loads, which is clearly what we want to achieve, then I think that really starts to reshape the whole game. So I think, one way or the other, it is a pretty safe bet, James, that integrase market size grows.

I think the degree to which it grows dramatically obviously revolves around whether we win in the doublet space and/or our competitors develop a product which has any point of differentiation which is meaningful to clinicians and patients. Those two things are going to get played out over the next 12 months, so we are going to know probably on both of those dimensions over the next 12 months the kind of shape we are going to get.

In terms of products coming through, there is an awful lot beginning to read out through the organisation. I think, as Emma takes over, my suspicion is that a lot of the conversations over the next two or three years with you are going to be, as these various data readouts play out, how we feel about them and how that drives our capital allocations going forward.

In terms of the key news flow events though for the next couple of years that really stand out, obviously the *Shingrix* and triple approvals, obviously the completion of the dual HIV programmes that we have just been talking about, the delivery of the long-acting cabotegravir programme is very important. Those really are some key points and then, as you look a little bit deeper into the pipeline, the BCMA data won't be too far away, the first RIP kinase data is not too far away, those are going to be important. The BET inhibitor is going to be important, the OX40 programme data starting to come through on that over the next couple of years. So you are going to start to see a lot of that type of data flow.

Back in Respiratory, you are looking at things like danirixin, you look at the PI3 delta kinase programme and then the GMCSF in rheumatoid arthritis. Those are going to be some of the products for which you will start to see some important data coming. As you go through the two years, the PHI programme should be starting to deliver its Phase III results. So a lot coming in a number of different areas and altogether we think 20-30 programmes have the potential to read out in this period. Some very interesting stuff in there, very interesting first-in-class products and, ultimately, it will be fascinating to see how big of the 11 oncology assets we have in the clinic we make through and then what do we see in the rest of these areas. A good portfolio of R&D work to come.

Next question?

Richard Park (Deutsche Bank): The first one is expanding on Graham's on the assumptions around generic *Advair*. Obviously, consensus is assuming a 30% decline in the US this year and I think you are assuming around a 45% decline. Is it safe to say that your assumption is what you would see as a worst case scenario if generic *Advair* is approved and there could be upsidings if the rate of erosion is slower. Is that the right way to think about it?

And then secondly the guidance for 5-7% underlying EPS growth, I am just wondering how much of that is driven by continued delivery on the cost saving versus organic growth and margin leverage. I am assuming it's largely the latter but just interested in your perspective on whether that's a good guide for the longer term organic growth potential from the business. Thanks.

Sir Andrew Witty: Thanks very much. On the second point, I think very much the latter, so very much driven, there are still some cost savings coming through but as Simon said, the lion's share of that is now delivered, we are in the tail end of that and we have done that early. That programme has come and done its job, so very much driven by what we expect to see which is top line growth, a lot of new product momentum carrying forward.

It is worth just reminding you, and I know you've seen it already, but £4.5 billion of new product sales in 2016, £1.4 billion in Q4 so that's annualising at £5.6 billion, so it's clear that there is significant further organic growth flowing through the business, so that is going to be essentially the driver of that 5-7%.

As far as the *Advair* assumption is concerned, what we have tried to lay out here, Richard, is what we think is a properly realistic conclusion and you can get there any way you want, you can decide to launch a bit earlier, you can decide to have a bit lower decline curve. What we simply picked was a scenario where we said it's the middle of the year and it's a pretty aggressive decline curve.

Could the actual situation be different from that? Absolutely. Could it be better than that? Yes. Could it be a bit worse than that? Yes. You know, so I am not saying to you this is the exact number and I am not saying to you this is the absolute worst case. Is it something where there is, in my view and I think in the company's view, something which is likely to be close to a realistic outcome? Yes, that's why we've made this estimate and we think it is a perfectly sensible scenario, given all of our experience in the complexity of manufacturing these products and given everything that has to go right for a full-on generic attack on *Advair* and we have essentially assumed that somebody figures that out in July and they get a good hit at the product from July onwards. That may or may not happen.

Next question.

Jo Walton (Credit Suisse): Thank you. I wonder if you could talk a little bit about your Vaccines and your Consumer businesses. In particular you have already reached the target margin for the Vaccines, so I wonder if you could tell us a little bit about the capacity constraints and how you are looking to free those up for this year or whether we should assume that effectively all of the extra Bexsero that you were able to deliver, you haven't actually got that much more runway for this year?

So just to help us think about that Vaccines business and to dive a little bit more into the Indian problems and the turnaround or when we should start to see Consumer improve again because I think that in Consumer, certainly the profitability was slightly less than expected in the fourth quarter of the year.

Sir Andrew Witty: Yes, thanks very much, Jo. I think in terms of the Vaccines business we have been investing very significantly in fixed infrastructure, capacity and also process redesign over the last many years actually, and we saw during 2016 and we continue to see the continued benefits of that, so capacities are going up all the time.

As Simon rightly said in for example *Bexsero* we acquired *Bexsero* with a certain demand curve and a certain capital base. It takes a while to adjust to the higher sales level that we are currently running at, so there will be within any given year probably situations where we are not in an unconstrained supply position for every vaccine and the reality is, actually, Jo, that at some price you can pretty much sell 100% of your vaccine output on a global basis so there is an almost unlimited marketplace and the pace at which you can expand is to some degree the limiting factor.

As we look forward between '16 and '17, I fully expect us to continue to grow the Vaccines business, I just wouldn't expect it to grow as fast as it grew in '16. Now partly that was because we had the effect of *Bexsero* coming off a very, very low base into a very much bigger base, but partly it was a consequence of having a very big 'flu season which may or may not repeat but we all know 'flu can be seasonal. So there is a likelihood the Vaccines business might grow a bit slower, but it will still grow I think during the year.

In terms of margins, I think we've shown really very quickly how we could essentially take the Novartis and the GSK Vaccines businesses, essentially fix that margin issue that was there and return ourselves to where we believe we need to be and I think broadly speaking we will want to maintain that level, but in any particular year, particularly as I think

forward into 2017 as we invest to launch *Shingrix*, there are bound to be specific investment opportunities which might, excuse the pun, but at the margin affect the margin.

And that is the kind of thing you are going to see as we go through over the next couple of years, so I think we are very much where we want to be. Can I guarantee you it's going to look like that every quarter? No, because the Vaccines business is inevitably a bit lumpy and there will be some discrete investment opportunities we want to take to drive future growth.

In terms of the India situation, the demonetisation issue certainly affected us very significantly towards the end of the year, and we are probably a bit more exposed to this, compared to many other Indian businesses, in a sense that a lot of our *Horlicks* business is distributed and consumed at a very low level of the income pyramid, who essentially don't have bank accounts, they don't have credit cards and they don't, historically, deal in big, high value rupee notes. The reality is, this demonetisation affected the cashflows of those families quite significantly. We would expect that to probably take a couple more months to play through; it is beginning to – cash is beginning to be recycled into the marketplace. We think in the long run it is a positive for India, but it is definitely disruptive in the short run and, no question, we have seen that effect.

We are probably also going to see a bit of impact from the GST changes later in the year, so we probably have a little bit more of this kind of extraneous noise in the system.

If we look at the overall share performance of our Indian business, very, very strong in our core GSK Consumer Healthcare products, like *Sensodyne*, the pain meds, those sorts of things; a bit more challenged in a slowdown in the nutritional category, so that is the area we need to focus on, but in terms of, let's call it, the new generation consumer products, extremely robust and extremely strong and I am confident that the monetisation issue will wash through, but it was, as for everybody, a surprise and has a pretty significant short term impact.

Next question?

Tim Anderson (Bernstein): Thank you. If I can go back to the HIV category? In the integrase area Gilead has their bicitgravir, and it seems like there is a fair amount of excitement among KOLs about this. They certainly seem to be taking on dolutegravir head-on in a variety of their trials that are head-to-head studies versus your product. I am wondering if you can see at this point how you think they are going to try to differentiate their product? I know that once in a while with dolutegravir, for example, you

hear about CNS side effects; I am wondering if that is an area that they might try and go after. We have data coming up here this month, they are Phase II data, I am wondering if you have any visibility on that?

The second question is on your zoster vaccine. You recently initiated a Phase III study to look at the impact of the reactogenicity with the product on quality of life and I am wondering if you can give us additional context here? Whether that is just for commercial purposes or if that is actually regulatory requirement?

Sir Andrew Witty: Thanks very much, Tim, and thanks for the questions. I think on the HIV front, obviously it is not my job to figure out the position and strategy of a competitor, so I am going to resist the temptation to do that. I think, looking at dolutegravir, and I have worked in HIV since AZT days in 1989 and the same is true now as it was then – what people want are effective, resistant; effective drugs which have high barriers to resistance with a good safety profile in the short and the long run.

When you look at dolutegravir, you have a very attractive molecule there; no resistant islets identified during the Phase III programmes, extremely, extremely impressive resistance profile with over 300,000 people dosed and a very strong track record of efficacy into the marketplace and, as we start to develop the combination products, obviously that has opened up a lot of opportunity for further growth. Once you have a zero-resistance profile it is not easy to beat that, right? It is like an antibiotic which is 99.9% effective, how do you top that? In terms of the thing that really matters, I think dolutegravir remains an extremely impressive molecule. People may try to look for peripheral things; you know, the reality is, what it will boil down to is physicians' personal experience with what they have seen with patients. Yes, you might see a patient with some idiosyncratic kind of reaction to a drug, but that is true of any drug, in reality.

My understanding of the CROI data next week, and obviously, I have no idea what that data shows, but my understanding of the study that is going to be released next week is in 75 patients. I will just remind you, I just said 300,000 for dolutegravir, so I think there is still a while to go before we really understand what these relative profiles are. Meanwhile, what we are focussed on is being able to develop a doublet approach, which may allow us to drop one of the three drugs completely from the regimens, which then starts to reduce other side effect risks which might be present in the current triple regimen.

I think this is going to be a very competitive space, Tim. I think we are in a strong position. There is lots of data that is going to have to play out on both sides of the fence and it is going to be an interesting race to watch, but I think we start this with momentum behind us, we start with a very, very good molecule and then with some very, very innovative

strategies to potentially transform the way HIV is treated, but we don't know the answer to that yet.

As far as zoster is concerned, the Reactor study is not a regulatory requirement. This is, in some ways, reacting to some of the noise that has been generated since we first released the data where people have looked at the phenomenal efficacy of this vaccine and they said "But we see there is some reactogenicity". What we are keen to do is to make sure that is put into a real-world context. As you know, the clinical trials we ran were essentially against placebo and therefore you are bound to see a gap of reactogenicity between the two. We want to really put that into context and make sure that people understand it and that people can't make mischief with data potentially out of context. It is for that purpose only, Tim, it is not a regulatory requirement, but thanks very much for the questions and the next question.

Kerry Holford (Exane BNP Paribas): Thank you very much, two questions please.

Firstly, on cost savings and how that relates to your guidance, so the current £3 billion programme is nearing an end now and I know there is very little incremental savings to be booked this year and these savings seem to have come through faster than you anticipated, but could you see the ability to cut costs further, and then explicitly is that assumed within your 2017, if you like, worst case guidance for earnings this year? Are you assuming that there is some reduction in Sales reps or promotional spend, or something behind *Advair* within that guidance?

Then, secondly, on Viiv and the put options there, so following the news on Shionogi today, should we consider that you might be having similar discussions with Pfizer, do you have similar call options there that you could look to exchange? Thanks.

Sir Andrew Witty: Thanks, Kerry. I will ask Simon to comment on those two. Just on the specific of if there were a generic *Advair* then there is cost associated directly with the *Advair* promotion in the US, which we would obviously cease, so to that degree there is some related cost, it is not a huge amount, but there is some and, of course, that is factored in to the downside guidance that we have issued. But let me ask Simon to comment on the put and anything else you want to say on cost savings within the guidance structure.

Simon Dingemans: Yes, thanks, Kerry. I think, as I said in my remarks, you should assume the £200 million to complete the programme is what we have baked into our

5-7% guidance. Clearly, as we have done with previous restructurings, we will continue to look to see whether there are other opportunities, but there is nothing that you should be including at this stage and, as Andrew said, on the downside there is a small amount of cost still attached to *Advair*, not a lot because part of the restructuring we have been doing over the last two or three years is to get ahead of this moment and so that will drop out and is factored into the downside, although not all of it, as some of it will get reallocated to continuing to drive the new products, so the profitability position you are looking at is a net one.

On the put options, I think there is a distinction between Shionogi and Pfizer, in that this is a very significant part of Shionogi's business and, I think as we talked with them as shareholders, it seemed extremely unlikely to a non-existent risk that they were going to ever exercise the put and we thought it was a good idea to remove that uncertainty. Pfizer is perfectly comfortable with its position and we are perfectly comfortable with their position, so there is no discussions going on with them at the moment, in terms of a similar initiative and let's see what Pfizer want to do over the longer term.

Sir Andrew Witty: Great, thanks, Simon. Thanks, Kerry. Next question.

Seamus Fernandez (Leerink): Thanks for the questions, Andrew, I hope you have already got the invitation from Richard Branson!

But just as a follow-up on some of the questions asked earlier, as we think about the opportunity to really grow the profitability of the Respiratory franchise, we keep hearing about declines in pricing, when do you think that this really stabilises and the overall *Ellipta* franchise can actually drive incremental cash flow growth?

Then the second question, as we think about, we have heard some good things about your BCMA product, as we think about Oncology and sort of building around that, we have seen single asset Oncology areas be quite successful, but do you see GSK really working to continue to build around the BCMA asset? Thanks.

Sir Andrew Witty: Yes, thanks very much for the question. Yes, I haven't been practising my kitesurfing, so I haven't been doing that and you probably wouldn't want to see me try, I don't think!

In terms of your questions, thanks for those. I think what we are seeing with *Ellipta* is, first of all, I think pricing is stabilising, it doesn't mean there isn't still pressure out there, but I think the lion's share of the adjustments which we needed to make have been made and, to reassure everybody, as *Advair* pricing came down, the *Breo* pricing kind of came

down with it, so we are not sat here with some big discontinuity if and when a generic comes along, which gives us quite a lot of confidence. We have never had more contracted access for our products across the board in the US than we do this year, extremely good position in terms of access and, if you look at the NBRx as well as the NRx and TRx curves, you can see that there continues to be significant upswing momentum behind all of the new products, implying continued good performance there. So I think from that point of view very good. Of course, we are investing heavily in those new products, as you would expect, and *Advair* has been a very generous support during that period of the last two or three years, in terms of helping us fund the growth of the replacement products, but as we move forward the new products are going to be the ones that are going to be kicking in the cash flow and the profitability. As you can see, they are all now beginning to move into scales, which you would expect to be very much net contributors as we move forward over the next year or two.

I think that has played out very nicely and I think it has worked just as we hoped, really. I don't think any of us particularly welcomed the big adjustment in pricing that took place in '14. However, given that that happened, the way in which we have been able to manage the decline of *Advair* and get ready for a possible generic – maybe, maybe not – and drive through products now which are very substantial. *Tivicay* is now on a monthly basis ahead of *Advair*, with the new products in total representing, within just three years, a quantum bigger than total *Advair/Seretide* globally, actually annualising now - the new products we have launched are now annualising an annual revenue bigger than the peak sales of *Advair*, after just four years. That is what we always said we would try to do, that we would try to generate a portfolio of products which would allow us to move on after *Advair*. I think from that point of view I feel very good about that, and I think the company feels very good about that.

In terms of the Oncology business yes, the BCMA data looks very encouraging. We have shared with you before some encouraging data on the BET inhibitors, as I have mentioned earlier, whether it is ICOS or OX40. There are a number of other programmes moving through – 11 now in the clinic. I think one of the most intriguing questions for Emma over the next two or three years will be exactly what data we have on each of those assets, and how do we build up our presence.

We made a very conscious, strategic decision not to divest ourselves of the discovery oncology organisations when we sold the more mature, older tech products. I think that was the right call and I think we have been able to benefit. We have brought forward all the value from those older products in that transaction and we now have the option of opening up for a portfolio of oncology. I hope very much that we have multiple

assets here. I think the work we have done to collaborate with Merck in the Keytruda combinations – I think we made the right choices in terms of which programme to partner with, and we are very optimistic here. But the proof will be in the next 12 to 18 months and data is rolling in, basically, as we speak.

You have seen some of the BCMA data and you will see more this year and more next year, and then the company will make its choices about how it wants to establish here. What we know is that we can do this. We know, if we have good differentiated assets, we can establish a presence here. As you rightly say, some of these assets are in areas where, as individual products but certainly as a portfolio, they could represent a pretty meaningful contribution to the company. It will be an exciting, data-driven period, to make those decisions.

Next question.

Michael Leuchten (UBS): I have one question about your longer-term guidance, please, and one question about your net debt profile.

On the 2016 to '20 range that you have given, the mid-to-high single-digit EPS cover, does that include, at the upper end of the range, Novartis putting their stake in the Consumer business to you, or is that end of the range achievable without?

Then, on your net debt profile, could you help me to think about what that looks like as we go into 2017/18, given the slide you presented on the currency impact on your net debt, the restructuring charges that you talked about, but also *Advair* potentially going away in the US if we have a substitutable generic?

Sir Andrew Witty: Thank you very much. I will ask Simon to comment on the net debt.

As far as the shape we outlined in 2015, for the 2020 group, that assumed no change in the ownership of the Consumer company and so, if that were indeed to happen, that would obviously be an upside to that scenario. That was not part of the base scenario.

I will take the opportunity, though, to remind you that an assumption on essentially the more or less total loss of *Advair* in America during the period was part of the assumption, and so the guidance we are giving you today on *Advair* is absolutely consistent with what we had embedded within the 2020 outline we gave you back in 2015.

Simon, would you like to just comment on net debt?

Simon Dingemans: Yes. On net debt, given the investments that I have described in my remarks, I think we would expect debt to start to come down in '17, not by very much, and then fall further as we go forward from there, as the cash generation comes out of the other side of the *Advair* impact. So that is a trend that I have described earlier, back last year, and I think the picture still looks very much the same, going forward.

Sir Andrew Witty: Would you, Simon, just comment on how you feel about the currency effect on the debt, given where the debt is versus our business. I think that might also have been part of it.

Simon Dingemans: Yes, the translation effect is very significant, as I called out in the comments earlier. We saw £2.2 billion of impact from currency, just in terms of cash and translation of foreign currency borrowings on the balance sheet. Clearly, we could take a different approach and hedge those, but we don't, we match them up to the currencies that we generate earnings in, so that they are naturally hedged across the businesses. So that translation effect is something we keep an eye on but it is not driving the economic value or the capital allocation decisions we are making.

The comments I just made assume that currencies do not really move from the January rates that we have in front of us, and clearly that may swing the picture around a bit, but the underlying position, peaking at these sorts of levels and beginning now to start to come down as we come out of the other side of the restructuring and integration programmes, the impact of the *Advair* generic and then into the regeneration of the cash generating capability within the company on the back of the new products in Vaccines and Consumer as we have discussed before.

Sir Andrew Witty: Thanks, Simon, and I think we just have time for one last question.

Keyur Parekh (Goldman Sachs): Good afternoon, one big picture question for you, Andrew, and then one on the HIV business. First, on the big picture stuff, given everything that is happening in the world from a Pharma perspective - pricing, innovation, FDA etc. - how do you see the shape of the industry changing over the next few years and what do you anticipate Glaxo's role to be in that change?

Secondly, on the HIV stuff, what do you think doctors will need to see to feel comfortable about moving to the dual regimen: will it be longer-term data, will it be more experience when the product is on the market, how do you think that shift happens?

Sir Andrew Witty: On the second point, I think what they are going to want to see is a high barrier to resistance in a range of viral load patients, and that is clearly what we are aiming to show through our trials and I think that is key. What we know in this marketplace is that people are more than willing to try new medicines, new molecules, new combinations based on the typical kind of Phase III trial duration time. So it is really about the data that are generated in those trials.

I don't think that this will necessarily require a very different kind of set of experiences. I think people will look at it based on what they see. People are very used to looking at 48 or 96-week data, they will look for what is happening on the resistance profile, that is what I think will really drive this, just as it always has done. As we have gone up the drug regimen, I think it will drive any choices to come down the drug regimen, and we shall obviously see that as the Phase IIIs start to conclude.

The big picture question - good grief! In all the world, what do you see might happen? This industry is one of the most fascinating industries, it has always been fascinating, there has always been a major dynamic going on. I think what we are seeing now more than ever is a kind of global focus on pricing and affordability and, for the first time in the last two or three years, the US marketplace has really become a central player in that discussion. I think the No.1 question is whether or not something fundamental changes in the US. As I said at the very beginning of this call, there is tremendous complexity and rigidity in the US marketplace due to regulation and various other things, so a lot is going to have to change there. I think it should change, there needs to be some change, I think there needs to be a better balance in the system than there is today. There needs to be more transparency.

If you look at the University of Berkeley data showing that of \$100 paid to an innovative drug company, only \$63 on average makes it through to the company, so that is \$37 out of the \$100 being paid to non-innovators in a system which thinks it is paying high prices for innovation. That is something that is going to have to start to be addressed. I am not saying that the people in between aren't adding value but people need to understand that dynamic better than it is understood today, and those are the sorts of things that are going to have to be unlocked before something big changes.

On a global basis, the countervailing pressure is the enormous expansion of volume opportunity, and I think what we have seen at GSK over the last few years in the Vaccine, Consumer and even the Pharma business is that, with judicial adjustments to price, we have been able to open up gigantic volumes. What we have shown in these results and certainly in the last couple of years' results is that you can drive your margin up even if your prices are

not quite at the leading edge of price but at a level which can open up volume. That is a model which I like a lot, I think it is more sustainable than being preoccupied just with price, and it is certainly evident that in today's world, if you want to accelerate the arrival of your product into a marketplace, price is potentially an accelerator or a brake to that decision-making. As I said earlier, the fact that we have such wide availability now for our medicines in the US is indicative of what I think has been a pretty responsible approach to pricing. I think that is where the big debate is.

What does that mean for GSK? That is up to Emma. Going forward, she gets to make the choices about how we engage with this marketplace. What we have been able to do to this point is create a series of businesses which are leaders in their categories, which have got innovation and which have got to a point where their momentum is robust and they have margins which are highly competitive. I think that is a good starting place to then engage with what does the external world mean for a company and you evolve your strategy accordingly.

What does it mean for the rest of the industry? I suspect that, over time, there will be a bit of reset in terms of the excitement around individual products and super-specialty being the driver of economic value. I think that will always be important but it has been in a relatively extreme position over the last five or six years and there may be, at some point, some further M&A in the sector, although while it is obvious that happens at the small to medium size, it remains difficult to see just quite how large scale M&A gets done. I suspect the pressures on it increase rather than decrease.

I've had 30 years in this industry and there has never been a dull year and there has never been a year where it hasn't felt challenging and interesting. I suspect the next 30 years won't be any different, but the reality is the industry does something quite amazing for people around the world and as long as we keep doing that, it will be a very vibrant industry.

With that I would like to say thank you for all of your questions and of course the IR Team are available here at GSK should you want to ask any more questions on our guidance on *Advair* which I suspect some of you might. Please feel free to do so and we look forward to helping you as much as we can.

Thank you very much.

- Ends -