GLAXOSMITHKLINE

FIRST QUARTER 2016 RESULTS
PRESENTATION TO ANALYSTS

Wednesday, 27 April 2016 @ 14.00 hrs BST

GLAXOSMITHKLINE
FIRST QUARTER 2016 RESULTS
PRESENTATION TO ANALYSTS
Wednesday, 27 April 2016 @ 14.00 hrs

Sir Andrew Witty (Chief Executive Officer): Good afternoon and welcome to this Q1 call. As you can see from the results we have just published, we have had a strong first quarter performance demonstrating continued momentum across the Group. Reported sales grew 8% in the quarter and, at 19.8 pence, core earnings per share also grew at 8%, both at constant currencies. This provides further evidence that our strategy is delivering and, although early in the year, gives us increased confidence in our ability to deliver against both short and medium-term targets. We now expect core EPS percentage growth to be 10-12% for 2016 at constant exchange rates.

We have set a dividend of 19 pence for the quarter and continue to expect to pay 80 pence for the full year. I am pleased to say that all three businesses have contributed well to performance through Q1, demonstrating our focus on executing the strategy and our ability to allocate capital flexibly to generate the best return.

Group sales were £6.2 billion, up 6% on a pro-forma basis. Importantly, we saw continued momentum from our portfolio of new Pharma and Vaccine products with sales of £821 million. HIV products *Tivicay* and *Triumeq* continue to grow very strongly with combined sales of £516 million. Sales of our new Respiratory portfolio offset 70% of the decline we saw in *Seretide/Advair*.

It is worth noting that in the US alone, sales of *Tivicay* and *Triumeq* equalled the sales of *Advair*, and I think this demonstrates the pace at which the new products are beginning to now rotate in, in place of the older, more established products.

I also just want to call out one other statistic that clearly demonstrates this progress. Sales of new Pharma products now represent 20% of our total Pharma sales and that is up from 16.5% in Q4.

In our other businesses, Vaccines grew 14% pro-forma, benefiting from good growth in Meningitis Vaccines, which I think clearly demonstrates the value that GSK has brought as the owner of this portfolio.

Consumer Healthcare grew 4%, again pro-forma, with continued very strong performance from the sales of *Flonase* OTC in America but alongside other brands such as *Sensodyne* and *Theraflu*.

Improved sales momentum, combined with a continued focus on costs, has led to an improvement in the margins of all three businesses, and we remain on track to reach the targets we set out last year.

Turning to R&D, we continue to see good progress in our core therapy areas of Respiratory, HIV, Immuno-Inflammation, Oncology and Rare Disease. In Vaccines, we are on track to file *Shingrix*, our candidate vaccine for shingles, in the second half of this year. During the quarter, I was very pleased to see that *Strimvelis*, our potential product for ultra-rare disease ADA-SCID, received a positive opinion in Europe. This is an important milestone and, if ultimately approved, will be the first corrective gene therapy treatment for children with this devastating disease.

I am also pleased with the progress we are making with our Oncology assets, with FDA Breakthrough Therapy designation awarded for NY-ESO in synovial sarcoma, and positive data for our BET inhibitor. We now have 11 Oncology assets currently in Phase I or Phase II.

In conclusion, what we have seen in Q1 demonstrates that the strategy we have been pursuing is capable of delivering both sales and earnings growth from a set of balanced businesses, underpinned by a productive R&D organisation. That is important as the trading and pricing environment remains as challenging as ever over the next couple of years. With that, I shall hand over to Simon to talk you through the detail of the financials.

Simon Dingemans (Chief Financial Officer): Thank you, Andrew. 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.

New products in Pharmaceuticals and Vaccines continue to build and contributed £821 million in the quarter, up over £500 million from Q1 last year. The new meningitis portfolio is driving strong growth for Vaccines, and Consumer continues to deliver innovation-led progress.

This more balanced and consistent growth, together with continued tight control of our ongoing costs, and the significant progress we made in the quarter in executing on our restructuring and integration plans helped deliver better operating leverage and improved margins in all three businesses.

The quarter also highlights how much better placed we are post the Novartis transaction to deliver on our financial architecture and drive earnings per share growth ahead of sales, while also providing the flexibility we need to invest in the business and continuing to support the dividend expectations we have laid out.

Inevitably, there is going to be some quarterly volatility as we execute on our plans, particularly in operating margin, but as we have said a number of times, we need to maintain flexibility across the P&L if we are to develop and deliver on the financial objectives we have set.

Our earnings release provides an extensive amount of detail about the results for the quarter, so my comments will primarily focus on the major points, my expectations for the remainder of 2016 as well as any comparator points you might want to take note of in your modelling.

As usual, comments will be focused on CER growth and core results. In the first quarter, we saw a positive tailwind of 3% on sales and 6% on core EPS as a result of currency swings, particularly the recent weakness of sterling against most of our major trading currencies. Taking the quarter end rates as constant for the rest of the year, it would indicate a tailwind to earnings in the full year of around 8%.

Turning to the headline results, Group sales were up 8% on a reported basis, 6% pro-forma. The Group's core EPS grew 8% to 19.8p, despite the tough comparison with Q1 last year, which included the higher margin Oncology business in the base for two months.

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.

Turning then to our three divisions.

Pharmaceuticals, which now includes HIV sales, was up 5% pro-forma with strong growth from new products more than offsetting lower sales of *Seretide/ Advair* and *Avodart*.

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.

US Pharma sales were down 4% pro-forma, primarily driven by the decline in *Avodart* following generic competition that began in Q4 last year. 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.

Within International, sales in Emerging Markets were down 1% pro-forma overall, impacted by the continued pressure on our China business from Healthcare sector reforms, including significant price reductions and the continued reshaping of our business. Beyond China, other Emerging Market sales grew 5% pro-forma, benefitting from some improved supply and despite a drag of around 4% from businesses that we have exited. In Japan, sales down 8% pro-forma, despite good growth in the Respiratory portfolio where we continue to see strength, up 4%, with the decline really reflecting the biennial price cuts and some short term supply disruptions.

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*.

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.

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.

Oral Care sales in the US were also strong with *Sensodyne* delivering double-digit growth, again following a number of new product introductions. In Europe *Voltaren* and *Otrivin* both delivered strong growth benefitting from the enhanced distribution of the combined business. Oral Care faced somewhat tougher competition which reduced the growth rates we saw on *Sensodyne* and Denture Care in the region. In International, good growth across most categories and sub-regions was partly offset by lower sales of *Horlicks* in India, which reflected a significant slowdown in rural markets and some wholesaler destocking. Significant innovation is planned for this brand during the course of the year.

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

Moving to core operating profit. Excluding currency, the reported core operating margin of 25% was up 110 basis points in constant currency terms and on a pro-forma basis up 430 basis points.

The significant move in the Group margin demonstrates the improved operating leverage we have built into all three businesses on the back of our restructuring and integration programmes and, in particular, the increased flexibility we now have in the cost base to reallocate resources and capital to where we see the most attractive returns. This has allowed us to step-up investment behind new product launches in HIV, Respiratory, Vaccines and Consumer as well as advancing our R&D pipeline and improvements to our supply chain. All of which we have been doing while releasing significant restructuring and

integration savings to offset the margin drag we are seeing from the decline of our older products.

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 and margins as we execute on our plans.

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.

On the bottom-half of the P&L core financing costs were broadly flat. I continue to expect a modest increase for the year as a whole. The core effective tax rate was 21% versus 20% in Q1 last year.

Here we still expect a core rate of 20 to 21 for the year as a whole as a result of the mix of profits being more weighted to the US.

On cash flow, excluding legal settlements of £73 million and adjusting for the tax payments on the Novartis transaction restructuring charges and the cost of the BMS acquisition, all of which were funded in the quarter from retained disposal proceeds, the underlying free cash flow was £456 million, an increase of over £100 million.

This improvement reflects higher operating profits primarily across all of the businesses, with some currency benefit which more than offset the increase we saw in the quarter behind seasonal working capital and working capital backing for new launches. We expect this to reverse during the balance of the year.

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.

In summary, Q1 has been an encouraging start to the year and we are pleased with the momentum across the business. Restructuring and integration is progressing well and the strong start to the year has provided us with the ability to give a more specific outlook for the rest of the year, even though we are likely to still see some volatility as we move through it. Overall we now expect core EPS growth in 2016 of 10 to 12% on a CER basis.

With that I'll hand back to Andrew.

Sir Andrew Witty: Great, thanks, Simon. Operator, could we open up for Q&A, please?

Question & Answer Session

Andrew Baum (Citi): Thank you. A couple of questions. The inflection rate in the US for *Incruse/Breo* is fairly clear now. What is less clear is the dynamics underlying that market. Perhaps you could share with us some information about how much of each is brand switches and whether there are any particular changes in the marketing message that have contributed to the improved performance?

Second on China, where the pace of decline seems to be accelerating not stabilising, how long do you think it will be before GSK can stabilise that business and turn it around? Can you share with us the absolute level of sales within China now and what would it take for you to reconsider whether at least part of your portfolio, especially the Respiratory franchise, would be better monetised in a third party's hand?

Then finally maybe just a few words on the hold on the Ionis amyloid CARDIO-TTR programme, whether it is safety related and which organ if so?

Sir Andrew Witty: Thanks very much, Andrew. In terms of *Incruse and Breo*, the drivers of change there are firstly better access in terms of coverage, particularly for *Incruse* as we went through the year, *Breo* also to some degree. The asthma indication for *Breo,* very important. The head-to-head data of *Incruse* versus Spiriva very important, and then DTC to some degree on *Breo.* Those have been the kind of elements which have really moved things along and we are seeing continued strong momentum here. I think over

the last 12 months, *Breo* has picked up six points of TRx share, *Anoro* ten points and *Incruse* six points, so a very good, solid progression.

If you look at our weekly prescription volume, we are doing about 250,000 scripts a week of *Advair*. The *Ellipta* portfolio, so *Breo* plus *Incruse* plus *Anoro* is doing about 80-plus thousand, so getting close to about a third of the equivalent of the volume of *Advair.*

Nucala has launched well, so that US Respiratory portfolio continuing to look good.

You continue to see some further price pressure on the *Advair* business, particularly in the first quarter as some of the contracts roll forwards. As you know, we sometimes sign two-year contracts and some of that price effect is playing forward. We have a very good contract in position for 2016, in fact we've got some contracts that run into '17 and we are right now signing further contracts for '17. So I think that now, after a difficult '14, we are in to a much more stable environment with a good progression.

In terms of China, actually the acceleration of what you are seeing in China, as Simon said, is partly to do with price cuts that we've taken but it's a lot to do with some disposals of products and businesses which we decided were non-core and have been backed out. I fully expect China to come back to growth in the second half led by the Respiratory business, so as we move through this year I think we'll see the underlying improvements. We've seen good improvement on an underlying basis but it's hard for you to see because we've done some disposals and you've got some price effect.

As you will also know, the entire market has slowed down dramatically and is rapidly moving towards a no-growth marketplace, or at least at the moment. So actually when you look at the performance of our underlying business you can see the recovery actually isn't too bad compared to what's going on in the macro environment.

In terms of the clinical, as you know there is a safety observation in a different trial, a non-GSK trial and I think for the purposes of caution, everybody, the regulator and everybody else wants to take it one step at a time, so nothing new to add there but there is not an observation that we've seen in GSK. It's been something which came from a separate trial outside of the company.

Thanks for the question – good to hear from you, Andrew and I'm glad your phone is working okay.

Next question.

James Gordon (JP Morgan): Hello, thanks for taking my questions. One bigger picture question and a couple of detailed ones.

The bigger picture one was just Andrew, your decision to start planning for your retirement, could you make a comment about what you still hope to achieve before you retire from GSK and what you think the key challenges will be for GSK's next CEO.

I also had one Respiratory question which was just the pace of the *Advair* volume decline which is referred to in the release as 2%, but when we look at Bloomberg or IMS we see more like an 8% volume decline, so is that volume difference a prescription decline in some way?

And the final question was just on Consumer, a very strong margin this quarter, just over 17%; is that something that you can build on as we move through the year or is there something quite exceptional there and so we should be careful about extrapolating from there?

Sir Andrew Witty: Yes, thanks very much James. 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.

As far as Respiratory is concerned, if you look at the US Respiratory business, what you see is that overall actually *Advair* TRx share, when you look at *Advair* plus *Breo* TRx share we are broadly holding flat year-on-year. So if you look at the overall share and the

market is growing at around 4.8% for ICS/LABA marketplace, *Breo* has picked up as I said earlier on the call a significant amount of share, *Advair* has lost a little bit of share. Net-net we are more or less – well, we are actually – holding our share.

If you look at NBRx, what you see there is actually we are increasing our share of NBRx, so what that would imply to you as we go forward all else equal, we should start to see our TRx share start to move into a more positive dimension.

You always get a bit of volatility around our reported volumes and the script volumes, depending on things like script sizes, those sorts of things. There is always a bit of a dynamic in there, but if you look at the shares, then you will see that gives you quite a good picture of what's really going on there, and it's important I think to look at *Advair* plus *Breo*, not just one or the other because clearly the two play in exactly the same portfolio.

In terms of me - first of all, I am very focused on executing this year. We have laid out a clear set of ambitions, we have just tipped up a little bit our guidance for the year, so we want to make sure that we deliver a strong performance for the business this year. How do we do that? Really completing the successful integration of the Consumer and Vaccine businesses. Remember, it's only just a year since we closed that transaction, so it's important that we get all of that done. It's very important to me that we continue the momentum of our new products: to have 20% of our Pharma business now coming from new pharma products is very key, I want to keep those new products moving forward and, obviously, reload from R&D with a significant number of R&D progressions expected this year. In fact, in 2016/17 we have something like 30 Phase II starts and another 20 Phase III starts scheduled, so there is an awful lot of that that needs to be moved forward, and I think we can really lay the foundations for that in 2016.

In terms of what my successor has to deal with, partly that is up to whatever she or he chooses to focus on, and partly set by the world and, as we know, the world is focused on pricing, the world is focused on more regulatory pressure and the volatility of global economics. So I am sure that's going to be what drives the external agenda but it will be up to them individually to set their own priorities. Next question?

Graham Parry (Bank of America): Thanks for taking my questions. Firstly, on *Nucala*, any feedback you have on the launch experience so far, any areas of pushback you are getting and any reimbursement hurdles? Secondly, on the Vaccines margins, how sustainable will they be for the remaining quarters, and could you quantify the phasing benefit on sales but also on the margin if possible? Thirdly, now we have generic *Advair* PDUFA dates in 2017, as you think about a world with generic *Advair* potentially, to what

extent do you think that could impact on *Breo* and especially the potential for mandatory switching by payors, and how important do you think the Salford Lung Study mid-year will be in potentially being able to prevent this? Thank you.

Sir Andrew Witty: Thanks very much, Graham. I think on the last point, I am not sure the Salford Study is going to be super-critical to the point you raise. I think it can bring to life - it is a very unusual study, it's a unique study, it can bring to life the real benefits of compliance but I don't think it's going to have a huge impact in the US. It's not I think likely to be - well, it's certainly not going to be promotable in the timeframe of the US potential generics if they come at the front end of that window. So I don't think that is so important.

I think what is key is we obviously are building up now a significant market position on *Breo*. We are getting great feedback from customers and actually it's clear that payors want to have *Breo* on the list. We need to keep that momentum going through this year. Then the question is going to be, whether or not the generic comes, how much of the generic comes, how switchable it is or it isn't and what volume they have. I think all of that remains extremely up in the air and the difference between three, four, five, six, 12 months delays, or whether or not there is full or not full volume, whether or not it is perceived to be truly switchable, all of those things can have enormous implications.

I would remind you that about £300-400 million of the US number is MDI, not dry powder and, therefore, not in the target zone for switchability, and also we know that within the Diskus *Advair* business, we have an awful lot of people who it's going to take a lot of persuading for them to switch products.

It is also true to say that prices have come down a lot over the last three years. The reality is we have already absorbed the big chunk of the genericisation effect through price reduction. The upside of that is that it has started to move our products into a price range, which may be not such a straightforward genericisation proposition.

So I remain - obviously, it's true that there is a window that potentially opens sometime in a year from now maybe, if everything goes according to plan. I think that window has great uncertainty still in it. I think we have a number of defences to be able to maintain our portfolio, which we are obviously very much focused on and, on top of that, we have a substantial amount of product not in the Respiratory area, which allows us to be confident around our overall growth profile. So when you look at our overall contribution from new products versus the overall decline of *Seretide/Advair*, it's a very, very positive picture and, obviously, that's one we want to continue.

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.

Nucala has started very well. It started well in every country that we have launched. We have seen very good pick-up in Germany, for example, very good patient exposure already, quicker than we would have expected. US similarly. We have seen a significant number, more or less all the physicians we need to get to have now been seen. We have seen good initial throughput, about 3,500 patient enrolments through our corporate hub, which is a mechanism for people to understand their insurance position. We are seeing good translation now of that population into patients on prescription and feedback so far good, so I would say at this early stage launch is going better than we had – better than planned and we are very positive about that. Obviously a long way to go, but we feel good and we feel good about the profile of the drug versus the up-and-coming competition. We think the dosage and the specific claims we have stand us in very good stead and obviously the six-month head-start doesn't hurt either, and for a reimbursement point of view we are not seeing any major issues there at all.

Next question?

Richard Parks (Deutsche Bank): Hi, yes, thanks for taking my questions. Firstly, on the meningitis portfolio, I think you had guided to some near-term capacity constraints, but that doesn't seem to have affected pretty strong performance in the first quarter, so could you just guide us how limiting that is going to be in the near term and whether the first quarter performance is sustainable on a quarter-on-quarter basis for the rest of the year?

Then, secondly, just as you progress with plans for the management succession next year, I am just wondering how much of a focus there is on internal versus external candidates and are there any particular characteristics that the Board is maybe looking for, in terms of someone to take the company forward?

And then, third question was on the cost savings, I think you said you had delivered £400 million in the first quarter, that is making the £800 million that you are targeting for the full year starting to look conservative. I am just wondering whether any of the savings, in terms of manufacturing efficiencies that were planned for 2017, could be brought forward? Thanks.

Sir Andrew Witty: Okay, I will let Simon take that last question in a couple of minutes.

As far as management succession is concerned, as the Board have said, they are looking both inside and outside, as you would expect. They did that when I was appointed, they are going through that process again. Obviously, they are going to be looking for somebody who punches a lot of tickets, in terms of ideal candidate. One of those tickets is understanding the environment, the various businesses we are in and, of course, the company itself, and outside candidates will score strongly in some areas, inside candidates will score strongly in other areas. I am very pleased that we have some very, very good and qualified internal candidates and I am absolutely sure that there are also good candidates on the outside. So the Board is going to take the right amount of time to do that in a very thoughtful way. I think what is very clear is we are very aligned, as a Board, around what the strategy of the company is. That is one very key dimension of this equation, because when you know what the strategy of the company is for the foreseeable future then you can, essentially, look for somebody to execute that strategy and to build on it, and that is the process they are going through.

In terms of Meningitis capacity, we had some tightness at the end of last year. We will continue to see tightness on and off, there will be occasional quarters where you see capacity tight. We are still dealing with the capital base that we inherited from Novartis, we are going through the process of expanding that. As we go through this year our volumes start to step up quite quickly, we have got very substantial global demand for this vaccine and I am absolutely sure we are going to sell every single dose we can make, but the pace at which we can expand comes in – it is a slightly lumpy process, so as we go through the year we will see those, kind of, lumps play through, but by the end of the year we should be in a better position now. But I have to say even as you project forward to the end of the year while we might very well be manufacturing the supply in three or four times more volume than we had last year, my guess is that demand is still going to be outstripping that, so it is going to be an area where we need to continue to invest, to build up our capital base from what we took over.

And, Simon, do you want to just comment on whether or not you are low balling the full year restructuring savings?

Simon Dingemans: Thanks, Andrew, and as I commented in my remarks the first quarter was always likely to see the biggest step up, in terms of incremental demand, given the low base that we were coming from this time last year, when we had only just acquired the businesses and as we go forward the increment is up against tougher comparators. So we still feel very good about the £800 million, we have always said we are trying to accelerate the programme, so one quarter at a time, but a good start to the year.

If you look at where those savings have come from, most of them have fallen in the SG&A or R&D lines and we have always said we expect manufacturing to take a lot longer. We are working as hard as we can to try and bring some of that forward and maintain the momentum, but it is a bit early to comment more specifically on that, because there are external parties, regulators and other agencies involved in any change you make to the supply chains in particularly Vaccines, but across the company.

So, so far so good, but very good momentum in all three businesses.

Sir Andrew Witty: Okay, next question?

Tim Anderson (Bernstein): Thank you, a couple of questions. On the dolutegravir franchise, consensus has sales across *Tivicay* and *Triumeq* reaching about £4.5 billion by 2020. I am wondering if you can give us some idea whether you think that is a doable number or too high or too low, just some directional commentary would be helpful?

And then a longer term modelling question unrelated to the quarter, you have talked about tax rate creep in the past over time, can you at all quantify this for us or are we looking, for example, at a few percentage points increase over a five year period or what exactly?

Sir Andrew Witty: Thanks, Tim. I'll ask Simon to comment on tax in a second. I am not going to give you an endorsement of a specific number, but obviously at £560 million in the quarter we are clearly annualising a run-rate north of £2 billion already. Provided we can continue this kind of momentum we have seen no real change in the growth profile since competition has intensified at the turn of the year. That is very encouraging; we continue to feel very good about the competitiveness of this molecule and its combinations. We obviously have more in the works. I think we feel like this is going to be a very substantial product and, as I have just mentioned on the introductory comments, it is already neck-and-neck with *Advair* as our biggest US product and it has only been two/two

and a half years in the marketplace. I think we are set well for this, we have to execute it well, we have to keep being very vigilant.

We are up against a very tough aggressive competitor; we need to make sure that we don't have any complacency and, as I think about the overall portfolio, because I do think Tim, over the next few years, the view has to broaden a bit from purely *dolutegravir* to the dolutegravir/cabotegravir and then the BMS programmes. I think we have given ourselves several angles to really drive this business forward, continuing delivering what we have now in the marketplace, further combinations here obviously, potentially the long acting strategy through cabotegravir combinations, potentially moving to dual regimens, very important opportunity and then playing in the BMS portfolio, both in monotherapy and potentially ultimately in combinations.

From an overall portfolio point of view we feel very optimistic about the HIV business and clearly the dolutegravir components look like they are going to be very substantial products and could certainly be one of the largest products we have ever had in the company.

Simon, do you want to talk about tax?

Simon Dingemans: Yes, thanks Tim. As you put it, it is probably something in the order of a few percentage points over the next three/four/five years. The rate at which it moves is partly driven by our own mix of business and the other, as we have flagged before, is the constantly changing regulatory environment we are dealing with, with many governments, including the US, changing their own particular tax codes and we are having to react to that. Depending on how that evolves I think that is a reasonable set of assumptions for you to build in.

Sir Andrew Witty: Thanks, Simon. Next question.

Jo Walton (Credit Suisse): Thank you. Three questions, please. I was intrigued by your comments that you are looking at some contracts out to 2017 for *Advair* in the US, I wonder if you could tell us how that might work, as you have also alluded to the fact that there could be generics around? Whilst on the subject of *Advair* and generics, I wonder if you could tell us a little bit more about what the practical impact of generics in the UK has been? Have you had to cut prices in the UK? Have you lost volume? How have generics been accepted in the UK market?

My second question is just a simple one: the corporate and other expenses were £150 million in the quarter, it was only £170 odd million for the whole of last year, so is there

anything unusual on that or can you give us some help on what that might be for the rest of the year?

My final question is a broader one. You are looking at 10 to 12% local currency growth this year and within that you have got a very big slug of incremental cost savings coming through. I wonder if you could give us some sort of sense of what you think is the underlying rather than cost-cutting driven growth rate will be because that is probably the guide that we need to look to as we start modelling 2017?

Sir Andrew Witty: Thanks Jo. I am not going to give you any insight into the 2017 contract shape for obvious reasons, so sorry to frustrate you about that. In terms of UK generics, basically impact on price, but volume relatively benign. If you look at the whole of Europe, all of Europe *Seretide* generics has about a 4% market share and *Relvar/Breo* has a 5% market share, just to put that all into context for you. When you think about the overall European position, inclusive of the UK, then that is more or less what is happening. From a volume perspective, the generics are pretty low, frankly, but it has a price effect because the negotiators clearly use the generic as an angle to try and pressurise price, and that is essentially the dynamic that is playing out.

In terms of the corporate expenses and the effect of the cost reductions, maybe Simon, do you want to comment on those?

Simon Dingemans: Yes. 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 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.

Sir Andrew Witty: The underlying cost reductions versus -?

Simon Dingemans: I am not sure, Jo, that is a meaningful breakout really. Cost reductions are a key part of developing a sustainable cost base going forward. Were you trying to identify some element of that in particular? Ultimately it is whether they are sustainable or not, which we believe they are.

Sir Andrew Witty: I think the key driver, really, on an ongoing basis is the top line sales growth, so the biggest driver of leverage in the company like ours is top line, and I think the most important thing about this quarter and what we saw, if it's been there all the way through last year, the underlying pro-forma sales growth rate has been picking up across all the different businesses and you see that really shine through in this quarter. That's going to be by far and away the biggest driver of earnings growth of the company and

obviously on an ongoing basis, continued pressure on cost remains a kicker to that but without the top line sales growth.

Simon Dingemans: A particular example might be the SG&A. If we were down 1.7 percentage points in reported terms as a percent of sales and yet we are backing all of these different launches and new products and promotions across each of the businesses which plays to the flexibility we've talked about for a while now where we are moving sales force around, we are moving A&P around, we are moving logistics costs around to put them behind the new products rather than the older products and that's why I think it's the sustainability of the cost base rather than the different elements of it that's important.

Sir Andrew Witty: Okay, next question.

Kerry Holford (Exane BNP Paribas): Thank you. Three questions, please. Firstly on the full year guidance, I wonder if you could just run us through what the key driver of the upgrade has been, given it's so early in the year. I wonder what in the business has changed or indeed surprised you in such a short period of time to prompt that upgrade at Q1.

Secondly on Vaccines going back to Graham's earlier question, could you please quantify the impact of the tenders in international regions and the CDC orders and give us some guide as to the impact on margins in Q1.

And then finally on the triple combo, could you also just run us through the rationale behind the decision to start a Phase II study in asthma. I am not aware that LAMAs are widely used in asthma – I may be wrong – but could you just run us through the reasons for your decision to start that study? Thank you.

Sir Andrew Witty: Sure. I mean, in terms of guidance, basically we have seen top line a bit ahead of where we expected at the beginning of the year and we have seen an acceleration of savings, essentially those two things. And I think if you look – you probably haven't had a chance to look at it completely yet, but if you look at the pro-forma operating profit numbers within the P&Ls that you are able to see, I think that gives you a sense of where, because it's quite important. You've got to remember, as Simon rightly said, this first quarter has the drag of the Oncology high margin business in it. When you back that out and you look at the pro-forma numbers, you can see why I think it makes a bit of sense for us to just indicate to you we think we're tracking a bit better than we anticipated originally.

Now I don't like anybody to get carried away either. It's early days, it's the first quarter, we are just signalling to you it's a little bit better than the 10% we had originally anticipated. Obviously as we go through the year as we get a firmer view, we will continue to communicate with you about it, but it's really driven by that insight of the pro-forma numbers which of course you can see.

I'm not going to go into the breakout of the detail of the tenders and the CDC order but other than to say the overall effect is relatively marginal; you are talking a few tens of millions, you are not talking gigantic numbers, but it is definitely a bit of an acceleration from Q2 to Q1.

As far as triple combo is concerned, actually anticholinergics, if you go back to the old days, Atrovent was widely used in asthma. It has been superseded a bit over the years but there remains at least a theoretical basis for it. It still is a significant amount of use in asthma, so that really explains it, and that's that.

Next question.

Steve Scala (Cowen): [*Inaudible*] – and note that the business has a lot of momentum. You suggested *Advair* is stabilising, you continue to have scepticism around *Advair* generics, the Oncology drag is behind you, you've now exceeded earnings estimates for a handful of quarters. Why shouldn't we be more optimistic than 10-12% earnings growth this year and look for something similar in 2017? So that's the first question.

Second, how does the failure of AstraZeneca's benralizumab change your thinking around *Nucala* in COPD? If you are still confident, then why and is the confidence module-specific or study design or something else?

And then lastly, how are you thinking about development of your OX40 versus the competition? How are you prioritising tumour types and why did you decide to combine it with a PD1 as opposed to a PDL1? Thank you.

Sir Andrew Witty: Okay, so if we look at the momentum of the business, again you can see for yourselves, you look at that pro-forma operating profit number you can see that there is some real strength in the underlying business.

Now again as Simon said a couple of times, you are going to see a lot of – well, not a lot – you are going to see volatility quarter-to-quarter and it's a bit early I think for us to be too definitive about where that lies, but part of signalling the increase in expectation for this year, Steve, is to acknowledge that, right? We think it's a bit early to get too carried away

but it’s important to signal to you and others that we do feel more optimistic about the year than we thought originally.

So that’s an important thing to keep an eye on but I would ask you to just kind of indulge us or be with us dynamically on this, because it is early and it would be wrong to get too carried away. That's the first point.

As we look at next year, there is no doubt that, if you didn't have a generic *Advair* in next year at all, then obviously next year's earnings are going to be a lot better than if you do have a generic in next year, just to state the obvious, and it is just too early for us to know one way or the other. You can make a case to say there will be a generic *Advair*, you can make a case to say there won't be one, and you can make a case to say there will be something in the middle, a kind of partial genericisation. So that is just a question of time before those facts become true.

Now the reality from a value of the company point of view doesn't really - in a way, whether or not the generics come three months early, six months late - if they are going to come, it doesn't really matter. What really matters is what is the ongoing survival of *Advair* post the generics, so what is quantum of *Advair* prescriptions beyond the generic, and we are working hard to try and maximise that number, and also how strong is the non-*Advair* Respiratory business, which, of course, is what we are very much focused on right now. So those things are really the drivers of the long-term value of the company. In the year you get a generic, if there is going to be a generic, of course there is going to be a dent to earnings.

The reality, though, is it's going to be a lot less in 2017 than you would have thought it would have been three or four years ago, because we have probably taken half of the effect already through price; we can't take the price-cut twice. So you've seen that very significant effect, it hurt us a lot in 2014, it held us back a bit in 2015, but the reality is it's behind us and I think for GSK now, we are not so fixated and preoccupied with what may or may not happen with the generic because of all of that dynamic.

As far as the *Nucala* AZ competitor, obviously a different mechanism, IL13, you know we think there is a difference there. I'm not going to say that we are sat here banking on the COPD data either though, Steve, so we are not sat here thinking this is a home run, absolutely no question about it. We think it's worth the exploration and that is exactly what we are doing, but I don't want you or anybody else to sit here and think, GSK thinks that's an absolutely home run trial, it's not in that situation. We think it's well worthwhile exploring, we think there is a rationale for it but we also accept it's a high risk trial so I would just put that into that context. Between *Nucala* and AZ, there is clearly a mechanistic difference.

So in terms of the OX40, the reason we went with the PD1, we had very good animal data which allowed us to go more quickly. As you know, our OX40 is humanised, we have done some good work, we felt confident about going into PD1 first. You probably also know we have other combinations in development. Phase I has already started in eight different tumours: this is clearly going to be an area where we are going to be loading up a wide variety of potential combination strategies and we see it as one of the backbones coming forward. As you know, we have others including ICOS. Next question?

Jeff Holford (Jefferies): Thanks for taking my questions. There are many views from different stakeholders out there on what could and should be done with the Consumer business in the future. I just wonder if you are willing to provide more details on what you thought the levels of dis-synergy are in terms of operating profit margins that you think would occur if Consumer was separated to help the market evaluate that better as this is considered going forward? Thank you.

Sir Andrew Witty: Thanks, Jeff. We have looked at this pretty extensively one way or another, and I'll make a few general questions. First of all, as you can see, I think we are delivering good integration benefits, we are delivering good prioritisation focus into this business, and that is why we are driving this margin up. There's always talk about what the margins should or shouldn't be in Consumer. To my knowledge, there may be one, possibly two companies that have a sustained margin above 17% and, to my knowledge, there may be one which has a sustained margin above 20%. So if we are in that territory, we are in a very rarefied atmosphere of where Consumer Healthcare company profitability is.

When you look at the sustained mid single digit sales growth we deliver, again you see a very substantial, successful business and, if you just look at the overall scale of this company, we are right up there in terms of one or two, in terms of the overall scale of the company. So we are doing okay at that, right, we are delivering decent numbers and we are moving forward very quickly into a very, very peer-competitive position in terms of the economics of this business, and that is going to drive off - is driving off significant profitability and significant cash flow. First thing to say.

Second thing to say, to my knowledge there is no pure play Consumer Healthcare company of scale in the world. Every single Consumer Healthcare company that exists is part of a diversified group. It is either part of a pharmaceutical company or it's part of some other company that sells things like household cleaning goods, or razors or whatever but it is part of a diversified group.

Third, the majority of growth of high margin products of these companies comes from switch products: 90% of the switch products that have taken place in the last 10 years have gone from the parent to the child Consumer company. It is very rare to see switches go outside of family. When they do, they go from Pharma to a Consumer company owned by a Pharma company, probably because the Pharma companies are doing a different deal on the side, like an Rx collaboration or something like that. When you look at the fundamentals of the business, actually the position we have, I think, works in the industry, I think it supports the long term switch dynamics, which will be a gigantic dis-synergy if you locked yourself out of switches. It is interesting to note that the companies which are not owned by pharma have had no switches in the last 10 years, so that is a real dis-synergy.

When we have gone through the analysis of separating out the companies there is clearly a dis-synergy probably of the order of two, maybe more, points of margin for the consumer business and there is probably also a dis-synergy for the parent pharma business also, so you end up with two companies with dis-synergy. That is not uncommon when you look at breakups of other companies in other sectors and also in this sector you almost always see a dis-synergy.

Interestingly enough those dis-synergies are usually compensated over the next three years by a reduction in A&P spend, not by an economy of the thing that is driving the dis-synergy, because if the dis-synergy is being driven, for example, by the fact you need a new tax department, well, you can't just get rid of the new tax department, so to compensate for that extra cost these companies strip out cost from their A&P budgets; it doesn't feel like the right thing to do either.

From our perspective we see this as an industrially sound logic, provided we are competitive. The reason we did the deal with Novartis was to give us the scale and the opportunity to compete and structure to be competitive and I think Q1, and in fact all the way through last year if you look through the pro-forma numbers, what you are seeing is a continued progression and if you look at the success of *Flonase* OTC, nobody is switching products better than GSK.

For all those reasons that is why the Board remains unanimous around the structure of the company for the foreseeable future. Next question?

Nicolas Guyon-Gellin (Morgan Stanley): Hi here, good afternoon and thanks for taking my questions. I have three. The first one is on OTC, but talking about M&A this time and not break-ups. Do you identify any gaps to fill in your portfolio in terms of

brand, of geographies and, if so, would you be interested in some pieces, or the entire Pfizer OTC portfolio should they decide to divest it?

Secondly on *Anoro*. Despite a good quarter for *Breo* we still see no particular inflection for *Anoro*. You regularly mention challenges with opening up the dual bronchodilator class and positioning *Anoro* between Spiriva and the open triple. That would be a new inference in the LABA/LAMA field, you are supposed to have Phase III results for your triple combo later on this year, how committed are you to *Anoro* and to what extent would you consider deprioritising it.

The third question on ViiV. I appreciate it is early days and you briefly touched on increased competition, but I am just curious to hear your thoughts about any potential impact of newly launched Gilead Odefsey product on both *Tivicay* and *Triumeq*? Many thanks.

Sir Andrew Witty: Thank you very much, Nicolas. As far as the last question is concerned, no, we are not seeing very much impact at all. We are seeing the same trajectory as we saw previously and the vast majority of the Genvoya business, for example, is coming from within the family. Clearly a very dynamic entrant into the market, but it is not affecting the dolutegravir business, first thing to say.

Anoro, no, we remain committed to *Anoro*, but it is a harder build. There is no question, when you look in all the markets, even when you have got multiple dual bronchodilators in the marketplace already we are not seeing a very dramatic change. It is has taken a long time for physicians to change habit. The good news for GSK is, of course, we have a position not just in that marketplace, we have a position in the mono-anticholinergic market, we have the *Breo* position, of course we have the *Nucala* position and then we will have the triple, hopefully, relatively soon. That gives us a very strong opportunity to keep on developing these markets, but clearly we want to see *Anoro* continue to develop, we remain very committed to it as such.

As far as OTC M&A is concerned, might we occasionally buy the odd brand? Maybe, but I think at the scale we have now created if we are going to do M&A it needs to be serious M&A and not little bolt-on things, and obviously those things only come round every now and again and you need to have a structure which is helpful to create solutions that work. Actually, I think the business we built with Novartis not only gives us scale, it gives us a very unique platform to potentially strike different sorts of transactions, but we are more interested in bigger things than smaller things, but we completely recognise those things come round very rarely and we are pleased that we were able to pull one off last year and we will have to wait and see if another one comes along.

With that we are out of questions. Thanks very much for all of your attention. Obviously if you have any follow-up please don't hesitate to contact the IR team at GSK. Thank you very much.

[*Conference call concluded*]