

GSK

Q2 2015 Results

Presentation to Analysts

Wednesday, 29 July 2015

At 2pm

Sir Andrew Witty: Good afternoon and welcome to this Q2 call, everybody. This is the first full quarter since the closure of our three-part transaction with Novartis and, so far, performance is quite encouraging and very much on track with our expectation.

Reported sales for the Group grew 7% on a CER basis of £5.9 billion, and that is up 2% on a proforma basis. Core earnings per share for the quarter are flat at 17.3 pence, again on a constant currency basis. We have also today reiterated our earnings guidance for 2015 and the outlook for a return to earnings growth in 2016. All of this represents early but positive signals of the benefits that the transaction is delivering for GSK in terms of performance and how it is reshaping the group and strengthening our Vaccines and Consumer Healthcare businesses.

Balanced business, driven by new products and R&D innovation

Following the transaction, today we have three world-leading businesses, which enable the Group to access the fast-growing global demand for healthcare and to balance our exposure to future changes in the industry pricing environment.

Turning first to our Pharmaceutical business, reported sales declined 6% but grew 2%, adjusting for the impact of the transaction. The growth was driven by impressive rates of growth for HIV products, partially offset by anticipated declines in Respiratory and Established Products.

In Vaccines, reported sales grew 11% but declined 5% on a proforma basis versus a strong Q2 last year. This business will inevitably see significant swings, quarter-to-quarter, not least due to the timing of tenders. We are very confident in the prospects, going forward, as we integrate post the transaction with Novartis and roll out new vaccines across multiple therapy areas.

In Consumer, sales grew 51% reported and 6% proforma. The switch of *Flonase* to OTC continues to be a great example of the combined strength of the company, combining our Pharma scientific leadership that included 40 clinical studies on this product, with Consumer FMCG excellence throughout the launch. Beyond *Flonase*, we have also seen a strong performance of Oral Health globally, but reductions of stock in trade have reduced some of the sales growth in International.

Stepping back, it is clear that two things are happening in the Pharma business. First, the continued successful implementation of the restructuring programme is underway and on track to deliver £1 billion of annual cost savings by 2017. Second, there is growing momentum in the new products. This represents contributions from a number of different therapy areas but most notably in our HIV medicines, *Tivicay* and *Triumeq*, which have combined sales of £294 million in the quarter.

Importantly, the growth of new pharmaceutical products is now more than offsetting sales declines of *Seretide* and *Advair*. Taken together, sales of new Pharmaceutical and Vaccines products were £446 million in the quarter and we remain on track to see contributions from these products of at least £6 billion by 2020, as we first set out in May.

A critical element of this new portfolio is of course Respiratory. During the quarter we received a positive FDA AdCom recommendation for *Nucala*, our IL-5 monoclonal antibody for severe asthma, which has also been filed for approval in Japan. That is just one example of our pipeline delivering for the business. More broadly, we now have around 40 NMEs, both drugs and vaccines, in advanced clinical development across six therapy areas including Respiratory, HIV, Oncology, Vaccines, Cardiovascular and Immuno-inflammation. These, among others, will be the programmes we talk about at our R&D investor event which we are today confirming will be held in New York City on 3 November.

With that, let me now hand over to Simon, to give you a few more of the details on the quarter, before we open up for Q&A. Simon.

Simon Dingemans: Thanks, Andrew. Although it is early days, overall we see the first full quarter since we acquired the Vaccines and Consumer businesses from Novartis as an encouraging start for the company in its new shape. In particular, performance from the acquired Vaccines and Consumer businesses has been in line with our original expectations: we are on track with delivery from both the Pharmaceuticals restructuring and the Novartis integration programmes. We have made further progress in the renewal of our Pharmaceutical portfolio, with particularly strong performances from our

newly launched HIV products. We are also continuing to build from other launches, including *Benlysta*, and our new Respiratory products.

Growth in new Pharmaceutical products, including HIV, is now starting to offset the declines we are seeing in *Advair*.

Pricing pressures continued to impact *Advair/Seretide* in the quarter, as contracting changes continue in the US and generic competition increases in Europe and International. We expect *Advair/Seretide* to continue to decline at similar rates in the second half, as we progress the transition of our Respiratory portfolio to newer products around the world.

The transition will inevitably be lumpy, quarter to quarter, but we remain on track with our plans and continue to expect to deliver our guidance for 2015 at a constant currency percentage decline in EPS in the high teens, reflecting also the dilution in the year of the Novartis transaction.

Following this transition year, we continue to expect to return the Group to growth in earnings per share at rates that, in 2016, should reach double-digit levels again on a constant currency basis.

Turning to the details of the quarter, before getting into that, on a CER basis, I should point out that currency has been a more significant headwind to the reported results this quarter than in Q1. Currency movements provided a 1% drag on sales, with a positive impact from a stronger US dollar more than offset by the strength of Sterling against most other currencies and particularly the Euro.

At the core EPS level, the currency drag was higher at 9% and this is primarily a result of the currency mix in our cost base. Also, exchange losses on the settlement of inter-company transactions were £34 million higher this quarter, reflecting the exceptional currency volatility that we have seen over the last several months.

Sales growth analysis

Pharmaceuticals

On the main divisions, in Pharmaceuticals, which includes both HIV and global Pharmaceutical sales, down 6%; proforma, Pharma sales grew 2%, as strong sales of our HIV products offset a 4% decline in global Pharmaceuticals which primarily reflected the decline in *Advair/Seretide* in US and Europe.

HIV (ViiV)

For HIV, Q2 sales grew 59%, with a very strong uptick of *Tivicay* and *Triumeq* continuing in every region. *Tivicay* is now launched in 43 markets and *Triumeq* is launched in 23.

US Rx

In the global Pharmaceuticals business in the US sales were down 7% proforma, primarily driven by *Advair* again, which was down 17%. It is down 19% year-to-date, and we continue to expect a decline of around 20% for the full year, reflecting both lower price realisations but also the shift to the newer products.

On the positive side with sales of £90 million in the quarter and some recent share improvements, *Breo* is continuing to build, helped by the recent launch of the asthma indication and the commercial changes we have made.

Anoro's progress in the market continues to be more difficult. As we have explained before, *Anoro* represents a significant change in the treatment options available to physicians for COPD and it appears that it will take some time to move current approaches to treatment. That said, we remain confident in the benefits to patients from the product and continue to sharpen our commercial execution resourcing.

Overall performance in the US was significantly better than Q1 when it was down a pro forma 21%, primarily due to the headwind from *Lovaza* generics diminishing significantly, but also the multiple growth contributions we are now seeing from *Breo* and *Anoro*, but also *Tanzeum*, *Benlysta* and a *Relenza* stockpile shipment to CDC of £33 million. I shall remind you that we expect *Avodart* in the US, which contributed £66 million in the quarter, to begin to encounter generics during Q4 of this year.

Europe Rx

In Europe, sales were down 8% pro forma in the Pharma business primarily reflecting a 16% decline in *Seretide*, where we are seeing intensifying competition, as well as the continuing transition that we are managing to our newer products. We expect these pressures to continue but in Q2 total sales for *Relvar* and *Anoro* already offset almost 40% of *Seretide's* decline.

International Rx

In International, sales grew 1% pro forma, held back by the performance of our China business, which saw a 14% pro forma decline in the quarter, as we continue to reset this business for the future, including new pricing policies designed to drive volume. We are also disposing of a number of peripheral businesses to sharpen our focus in the country.

In the quarter, Pharma International was also impacted by disruption from the broader implementation of the global Pharma restructuring programme, as well as some limited capacity constraints while we debottleneck to meet growing volume demand. These factors should ease over the balance of the year.

Japan was up 13% pro forma with a strong performance from Respiratory, helped somewhat by the benefit of a weaker Q2 comparator last year.

Vaccines

Turning to Vaccines, overall Vaccines grew 11% but we are down 5% on a pro forma basis as strong growth in Europe was offset by declines in International and the US.

US Vx

US vaccines sales were down 5% pro forma mainly due to lower sales of *Infanrix/Pediarix*, which saw a key competitor return to the market during the course of last year. Encouragingly, sales of our meningitis portfolio Men B *Bexsero* totalled £27 million in the quarter.

We are pleased with the recent ACIP positive vote related to *Bexsero* which puts greater choice in the hands of physicians and should improve coverage for the vaccine. As a result, we expect improved momentum from *Bexsero* as the year progresses and awareness of the recommendation increases.

We also expect the US Vaccines business to benefit from higher flu sales in 2015. Early approval and shipment this year should see that benefit land mainly in the third quarter compared to last year when shipments were more weighted to Q4. All of the doses supplied to the US this year will be for our new quadrivalent vaccines, which attract better pricing. Last year, only 70% of our flu doses in the US were for quadrivalent.

Europe Vx

In Europe, Vaccine sales in the quarter grew 12% pro forma with the main drivers being *Boostrix* up 31%, benefiting from improved supply, as well as a competitor outage, and *Bexsero* which recorded sales of £24 million with tender sales in the UK and growing sales across Europe, particularly in Italy, Portugal and Germany.

International Vx

In International, as I flagged back in May, Q2 for the Vaccines business faced a tough comparator due to a large amount of tender shipments in the quarter last year. Overall, this resulted in a 16% pro forma decline, although this was exacerbated by some tender shipments moving to later quarters. Remember also that this part of the business is

particularly impacted by the supply chain investments we are making to improve overall reliability and expand capacity for the future. This will create some continuing constraints to supply over the next 18 months as the programme is completed.

Overall, though, we expect a better performance in International during H2 this year, although a fair amount of the shipments coming will be to lower margin customers including some significant GAVI tenders.

Consumer

On the Consumer front, Consumer Healthcare sales were up 6% pro forma with challenges in the International region partly offsetting very strong performances for the US and Europe.

The US business, as Andrew highlighted, was up 28% pro forma, continuing to benefit from the recent launch of *Flonase OTC*, as well as from some supply improvements in oral care. Those improvements also helped oral care in Europe which was up 7% pro forma, along with a number of important new product introductions in the *Sensodyne* range. *Sensodyne* globally was up 18% in the quarter.

In the International business, India continues to deliver strong growth and a number of sizeable markets saw a material impact in the quarter from reducing channel inventories in the Novartis-acquired businesses, most notably in China, Russia and the Middle East, with Russia and the Middle East also suffering from regional slowdowns.

Operating profit margin breakdown

Quarter 2 margin

Turning to operating profit, while there is a lot of work under way on the integration and getting costs out of the business, the quarter was heavily impacted, as expected, by the inherited costs of the Vaccines and Consumer businesses. The Consumer margin was also distorted by a one-off adjustment in the China business, resolving past sales tax disputes. This cost around 1.3% of the Consumer margin in the quarter.

To date across the acquired businesses, we have seen relatively limited impact from the integration programmes given their early stage. However, those programmes are firmly on track and we should start to see the benefits coming through to Vaccines and Consumer much more clearly in the second half, in line with the progression we discussed at the first quarter.

Overall, the Group margin in Q2 was down 2.4%, down 1% excluding currency. The impact of the Novartis transaction was around 350 basis points in the quarter, ahead of the

range I have indicated we expect for the full year of 200-300 basis points, mainly reflecting the phasing and timing of the transaction close. Remember, the impact in Q1 was much lower at 120 basis points. Excluding the transaction, the core margin for the Group improved 250 basis points on a pro forma basis, benefiting from a more favourable mix in the quarter and the initial benefits of the pharma restructuring programme, which we initiated last year, particularly in R&D costs.

Year to date margin

Year-to-date, excluding currency, the core margin is down 250 basis points with the transaction making up virtually all of that at a negative 240 basis points.

The impact of the transaction is expected to increase half-on-half, despite initial synergy contributions, mainly because we exit a much higher contribution from oncology profits, almost £200 million more in the second half than the £100 million of profit we lost in the first half.

Remember also the second half last year benefitted from the £219 million of structural benefits we recorded in SG&A in Q3, which boosted the full year 2014 operating margin by approximately 1%. We still expect the overall decline in the core margin for the full year to be in the order of 500 basis points on a constant currency basis.

Tax

In the bottom half of the P&L the core effective tax rate was 20% for both Q2 and H1 this year, a benefit versus the 22% for the same period last year. We continue to expect 20% is the effective rate for the full year.

Looking ahead the tax rate for the second half last year was just below 18% so while the EPS growth in H1 reflected a 2% tax benefit, the second half this year will have a 2% headwind from the effective tax rate.

Minority interest

Minority interests also significantly affected the quarter, reflecting the significant step-up we saw in ViiV and the new Consumer joint venture and we expect the charge for minority interests to increase further in the second half.

Cash generation and net debt

Turning to cash flow, the net cash inflow from operations for the quarter was £291 million, excluding £74 million of legal settlements. Adjusting for the tax payment of around £0.5 billion on the sale of oncology and approximately £250 million of cash paid out for restructuring and integration costs, both of which we are funding from the proceeds of the

Novartis transaction that we received in the first quarter, the cash generated from operations was £1.1 billion, broadly comparable with last year. Dividend payments to our shareholders in the quarter also totalled £1.1 billion.

We continue to manage the balance sheet to protect our credit ratings and maintain our financial flexibility and, as we highlighted at Q1, we continue to prioritise ordinary dividend payments and the funding of investments to accelerate the delivery of transaction synergies and other investment opportunities we have identified in the portfolio, including restructuring benefits.

Net debt at the end of the second quarter was £9.6 billion, £4.8 billion lower than the end of last year, again reflecting the net benefit of the proceeds of the Novartis transaction and the initial costs of accelerated integration spend.

Summary

Overall, with the integration of restructuring programmes on track, the business performing in line with our expectations, we are encouraged by the progress in Q2 in delivering the value we see in the new shape of the group and we remain confident in delivering our 2015 guidance and the outlook we have set out for 2016.

With that I hand the call back to Andrew.

Thank you

Sir Andrew Witty: Thank you very much, Simon. Now I am very happy to open up the call for Q&A.

Question & Answer Session

Graham Parry (Bank of America): Thanks for taking my questions. The first one is on ViiV and the 76.5% margin obviously driven by strong *Tivicay/Triumeq* performance in the US. Could you just give us a feel for the sustainability of that margin going forwards, any mix effects from launching in new countries, or *cabotegravir* R&D impact on that margin?

Secondly, on Consumer margin that was still only 8.5%, even after we add back in the one-off in China. Again, could you just talk through the moving parts on that margin and expectations for the remainder of the year?

Finally, if you could just help us understand the key challenges with *Anoro*? What is your long term strategy to overcome this? KOLs were always quite keen on *Anoro* and earlier, more aggressive treatment for COPD, so I am just trying to understand a little bit better where you are coming up with the strongest resistance?

Sir Andrew Witty: Thanks very much, Graham. Simon is going to pick up the HIV margin in a second. On *Anoro*, what is happening here is the market is very well entrenched into two groups of physicians: those who essentially start with a product like Spiriva and then progress and potentially add in other products, for example, like *Advair*, or those who start with *Advair*, or products like *Advair*, and then potentially add in a Spiriva.

What we are seeing is this new category of the double bronchodilator is not really opening up yet as a category. It is not simply an *Anoro* issue. What we need to work through with the physicians is a much clearer understanding of how they can insert the double bronchodilator in the pathway of care and really obviously it creates another alternative. From where we sit we think there is a very compelling argument, given the very strong head-to-head data we have for *Anoro* versus the market leader in the anti-cholinergic space. I think it could be quite interesting as Boehringer themselves start to move into this category how that will potentially also help develop the category.

There has been no doubt though we needed to tighten up some of our commercial promotional message, which we have done over the last three or four months and we also needed to up-weight our promotional share of voice, which we have also done, essentially effective as of about three weeks ago.

There are a number of things we needed to do tactically; we have done those, but the reality is it is about creating a new category where you feel pretty optimistic about how that plays out over the next couple of years, but it clearly isn't quite the same as just launching a product into a pre-existing category.

As far as the Cx margin is concerned a couple of things: first of all you would expect this quarter to be the worst margin. As you know that the Novartis margin was significantly below the GSK margin coming into the transaction. Obviously very little of the restructuring benefit has actually accrued yet, so some of the people who are leaving the organisation, some of the sites which are going to be closed, just beginning to happen. It obviously takes a couple of months to get that going. Actually we are slightly ahead of where we anticipated in that process, but it was never anticipated that it would hit Q2 in any meaningful way. So

you are essentially looking at the inherited depressed margin which came in from Novartis, number one.

Number two, as Simon said, there is a particular one-off in the quarter of about a point and a half of the tax catch-up settlement which obviously affects it.

And then the third area which is a positive is we have had a very, very strong take off of *Flonase* in the US and we have continued to invest A&P behind that brand as we've gone through Q2, so actually although we don't show you this data, if you benchmark us to somebody like a Reckitt for example, we are spending more on A&P in this space than somebody like a Reckitt would be. Why? Because we have (a) *Flonase* which is a tremendous opportunity for us to build sustained switch volume, (b) we have *Voltaren*, another huge product which we can continue to move out around the world and obviously oral care where you can see again in *Sensodyne* in particular 18% up for the quarter. So some of it is A&P.

Now as we go through the year, you will start to see a whole number of things happen. First of all, we are getting good tailwind in terms of supply compared to last year so that helps quite a bit. We are seeing the gross margin look better as we move forward and you start to see the benefits of the synergy start to flow through, so I would anticipate that margin to strengthen quite materially as we progress through the next couple of quarters and we are absolutely on track to hit the medium-term outlook we gave you. I remind you that that was that we would deliver a margin of at least 20%, so we feel very, very solid and good about that.

On the HIV point, Simon please.

Simon Dingemans: Thanks, Graham. In terms of overall trend clearly the quarter is above trend at 74%. That's really reflecting the leverage from the top-line growth and the SG&A behind that.

What we haven't got in the P&L at the moment is some of the R&D that we expect to start putting back into the P&L as the pipeline progresses. Overall, and I know we've had a number of questions on this, if you think of a trend of around 70%, you are probably in the right place and clearly the margin quarter to quarter is going to move around that, depending on where we are in the development of current and future products.

Sir Andrew Witty: Thanks Simon and the next question, please.

James Gordon (JP Morgan): Hello, thanks for taking my questions. One question was on European *Advair*. I saw sales were down 16% this quarter; I am just

wondering how much of that is price versus volume? Is this a new run rate due to generic competition or are there some one-off factors we should think about?

The second question was on mepolizumab and the PDUFA date coming up, I think it's November. Assuming we do get a timely approval, is this a product that could have an *Anoro*-like launch or could this be a lot quicker and if you do get just an adult approval, would you do then an adolescent study and how long would that take?

And then the third question was just on the R&D Day. Should we think that we get Phase III go decisions announced at this event for products like cabotegravir and the HIF or do you need more work or more data before you can make that decision and announce it?

Sir Andrew Witty: Okay, James, just on the last part I won't prejudge what you are going to see. You are going to see a mix of data, but what you are going to see is data on the programmes which we (a) think are important and (b) the programmes which are going to potentially be fileable in the next five or six years. Of the 40 NMEs we would say roughly 20-25 of those are potentially fileable and approvable in the next five years or so.

Some of those you are going to see very advanced data, some of those you are going to see data which is about to trigger Phase III, some of those you are going to see earlier data but in programmes which go much more quickly, so for example oncology. There are some very interesting, very early stuff in oncology in some of the new targets. Obviously, as you know better than anybody, they can go very quickly once they start moving.

So at the R&D Day you are going to see a mix. It's not going to be a particularly one size fits all type of approach. I think if you look at the page we've put in here, you can see about 80% of the programmes we've listed in the book are first in class or potentially capable of being first in class¹ and of course there will be some more which we touch on at the R&D Day which is not in the list.

In terms of mepolizumab, you are right, the PDUFA date is November and in terms of launch, I think our expectation is that it will be a mixed experience because clearly there is already somewhat of a market definition and some overlap between the potential patient population for mepolizumab versus *Xolair*. There is already an established habit there. We have excellent data for this product, but having said that, mepolizumab has potential utility in a much broader and much larger population than *Xolair*, so there is going to be a bit of both. We are going to be launching in the period where we are going to be in the US payer environment dealing with the so-called miscellaneous reimbursement scheme because the J

¹ *80% relates to the NMEs in GSK's pipeline up to Phase II

Codes aren't going to be issued until January, so we are going to be in that slightly odd period.

For the physicians who are used to dealing with this kind of biologic, that shouldn't be a big issue but it will be a bit of an impediment for physicians who are not used to it. There is going to be a little bit of a mixed pattern.

We feel very optimistic about this product in terms of its material head start, so we think at least six, eight months ahead of the next, certainly years ahead of AZ and others and in terms of the data we have, we feel very, very competitive in that position.

Paeds will come later on and as far as we can see no sub-categorisation for adults. As far as European *Advair* as Simon indicated back in May and in fact going all the way back to the Q4 results in fact, we had anticipated more sporadic generic competition across Europe. We continue to see that, it's very patchy, so it's a different generic in a different country. Sometimes it's an aerosol, sometimes it's a kind of copy dry powder device, sometimes it's substitutable, sometimes it's not substitutable, so it's very, very much in line.

As we stand today, we have held onto the vast, vast – 90%-plus – of the volume. Obviously, there is a price that has come with that. The majority of what you are seeing in terms of the European *Advair* decline - and I think you should expect to continue to see decline as we continue to deal with these competitors - most of it is coming through price, but actually the volume is absolutely massively overwhelmingly in *Seretide*'s favour. That is not an unusual pattern. If you go back and look at *Ventolin*, even 20 or almost 30 years after the *Ventolin* patent expired, we still have very significant volume share. That has played out very much as we would have anticipated but, of course, there is a step down as you go through the price change and that is what we had indicated that we expected.

Thanks, James. Next question.

Keyur Parekh (Goldman Sachs): Good afternoon. I have two sets of questions, please. First, just looking at the Consumer margin, I realise that it is a tough quarter, but could you just help us think through how we should think about it, on a 2015 basis? What do you expect the exit rate for that margin to be, when you are exiting 2015, adjusting for cost savings versus the currency hit to the Consumer margins? That is my first question.

Secondly, Andrew, just in the sense of the broader healthcare environment around you, much has changed this year – even if you just look at what happened on the M&A side since May. There has been a great deal of reshaping of companies. Do any of those things

change your view on what Glaxo's strategy should be, going forward and, if so, how? Thank you.

Sir Andrew Witty: Great, thanks, Keyur. Let me ask Simon to answer the first question.

Simon Dingemans: Thanks, Keyur. As we touched on a little at Q1, Q2 and Q3 will have a great deal of disruption from the transaction but, overall, for the year as a whole, if you took the sort of levels that you were seeing in Q1, with a little improvement, you would probably be in broadly the right place.

Sir Andrew Witty: Thanks, Simon. As far as the broader healthcare environment is concerned, it is not just in the last three months but, over the last two to two and a half years we have seen a building dynamic within the environment. Frankly, what we are seeing at the moment is a re-emergence of government anxiety around pricing and affordability in Europe. I wouldn't say that it is a new behaviour but it is a re-emergence of noise that has been quiet for the last few years.

With the Affordable Care Act, and other market activity, which has happened coincidentally to the Affordable Care Act, we are seeing very dramatic changes in the way the US market operates in terms of the vertical consolidation from payer through to provider, and through the horizontal consolidation of sectors, most notably with the insurance sector. That is having very significant but admittedly patchy impacts on the procurement environment that we deal with in the United States. Obviously, that hit us last year in diabetes, and you know better than I what some of the big payers are saying about where there next target areas to go are. It is not obvious to me that there is any safe haven and, frankly, it would be overly optimistic to believe that there is a safe haven in terms of areas coming under pricing pressure.

That analysis has very much driven the long-term strategy, and the strategy over the last seven or eight years of GSK, first of all to renew its innovation and pharmaceutical portfolio. Notwithstanding everything I have just said, we still believe that the Pharma business is a higher margin opportunity than any of the other businesses. It is a great business to be in but, perhaps, not as great as it used to be. We therefore need to renew that and we need to make sure that, within that renewal, we are a business with multiple products and not simply one product. We need a lower cost environment to make that happen, and we need the cost per product to come down in R&D – all of which we have delivered.

In addition to that, we conclude that there are other very, very important profit pools, sales opportunity pools, in a European, American and, more importantly, global theatre,

where we can access significant returns at much lower average price points per pack – obviously in the Consumer and the Vaccine businesses. Those businesses have very strong links to the Pharma business but they offer an opportunity to create value and to create returns at an average lower price than the Pharmaceutical business. We think that is a sensible place to go, given the macro-pressure in the system.

That is why we are where we are today but how we see the future, going forward, depends a little. The reality is – and I have made no secret of this fact at all – that it is only post the transaction that I believe that our three businesses of Vaccines, Consumer and Pharmaceuticals are capable of building the scale to have potential optionality in the way you think about the business. That, of course, only happens once we have completed the integration and created the right high-margin Consumer business, the right high-margin Vaccines and the right high-margin Pharmaceutical business.

Once we have done that, it creates a great deal of optionality for the Group and frankly, right now, with the amount of dynamic that is at play in the healthcare marketplace, it would be unwise to make a call exactly on what your long-term deployment is. It depends a great deal on how the rest of this environmental story plays out and, of course, it depends very much on how our R&D pipeline plays out, because that will have a very significant impact on how we view the Pharma business, going forward.

As we stand today on Pharma, it feels more and more encouraging and it looks more and more likely that we will deliver at least that £6 billion from the products we launched in the last couple of years. What you are seeing in the Phase II and III pipeline is that we have a very strong portfolio of assets which could then give us the next class of assets to drive that business on, post 2018/19/20 and beyond. All of that needs to start to play through, to inform exactly what the right next step, strategic move of the company should be. In the short run, this year, we should be hyper-fixated on delivering the benefits of the integrations of Consumer and Vaccines, exiting as fast as possible the transitional service agreements with Novartis so that we can minimise our cost structure, maximise the speed and quality of the R&D delivery and maximise the delivery of the supply chain benefits to our Vaccine, Pharmaceutical and Consumer businesses. Those are the big focus points for us this year. So far so good, which is why you are seeing an on-track performance here but with some quite encouraging signals of the organic strength of the business. Next question?

Andrew Baum (Citi): I have three questions please. First, we have heard you speak before about GSK asking itself constantly what are the best owners for any individual asset. You have done that with ViiV and with your former Oncology business.

Has the Novartis transaction opened the doors further to drive that process across the pipeline? You have mentioned your plans to externalise your pre-term labour drug, there are other orphan drugs up for alternative monetisation through spin or licensing.

Secondly, perhaps you could talk about your new Oncology business: is GSK committed to taking all these products to market themselves through clinical development, or should we assume licensing at an earlier stage with a cash inflow? To what extent can this alleviate some of the balance sheet pressure and increase optionality?

Finally, you cite some issues in manufacturing in Derms and there are still some issues in Consumer. Could you give me a summary of where you are at as far as resolution of the manufacturing supply chain issues in both those two areas? Many thanks.

Sir Andrew Witty: Thanks, Andrew. Our supply issues are broadly behind us. We have a small number of Derm SKUs which are out of stock but they account for almost no sales. It is a minimal amount of sales, on the margin in the Emerging Markets. Those will be fully back to health by the end of this year but, frankly, it is not a material number in the company. Supply is a tailwind for the company this year rather than a headwind. Our Consumer business has never had higher OTIF (on time in full) deliveries in either the Novartis or the GSK legacy businesses, so both businesses had significant supply issues last year and both businesses have very material increases. To give you a sense, in Q2 supply was a 3% tailwind for the Consumer business², which gives you a sense of the energy that is flowing through there.

Where we do have some issues, as Simon rightly highlights, is we have a number of products where we are maxing out our current capacity. It is not a supply issue as far as disruption, it is a maximum capacity and we are waiting for new capacity to come on stream. Those tend to be in areas like antibiotics, they tend to be in one or two areas like *Ventolin* where we have enormous capacity.

To give you an idea, in 2003 when *Augmentin* went off patent, we sold 400 tonnes of *Augmentin*. Last year, we sold 1,200! It is a similar story in Vaccines where the step increases in capacity take a long time to come on stream. We have a number of vaccines where we are selling every dose we can.

Over the last year or so, we more aggressively allocate those products to try to maximise the margin, which is one of the reasons why you have seen a more robust performance than you might expect inside the Established Product Portfolio where much of that is.

² For clarification: 3% tailwind to US Consumer business

Overall, notwithstanding the fact that we have some products where we are waiting for new capacity to come on stream, supply as an issue has gone up. Last year it was an issue; this year it is not an issue.

Secondly, regarding the choice of ownership of businesses, we shall continue to consider that but I would say there is nothing on the front burner at the moment as far as blocks of business, Andrew, in the sense of the way we looked last year at Established Products and ViiV.

I would say that it is certainly possible that there will be sporadic R&D assets which we conclude are better held by other people and, if we can strike the right value proposition, they may very well end up in somebody else's hands and, if we can bring forward the value to GSK shareholders more quickly, we will do that. That is not being driven by any anxiety about the balance sheet, because I am not sitting here dreaming that I could acquire something. If I look at what we are doing, we have a great deal within our own company perimeter to be able to drive growth going forward as we laid out at the Strategy Day. We have shown you that, even if there is a generic *Advair*, we believe we can deliver CAGA sales growth and a mid-to-high single digit earnings per share growth over that five-year period. If the pipeline does better, all of those things, that will end up being a number which we can exceed over time. However, it is very clear that we believe that within our portfolio, even if we have a generic *Advair*, we could still deliver that kind of performance. That makes it less tempting for us to go and pay very high valuations for assets which, inevitably, will have some risk attached to them.

We do not feel that pressure from a balance sheet perspective but we certainly feel it in that, if you have a product that sits somewhere outside of your established organisational structure and it is a one-off, with a large to go R&D cost, and if there is someone else who is prepared to buy it out for a substantial price, of course we would look at that. From time to time, I am sure you will see that.

As far as the Oncology assets are concerned, you will see a lot about Oncology assets on 3 November. Some of them are in the report today and you will see more in November. There are some extremely exciting programmes here in the immuno-oncology space, as well as in the epigenetic space. The work we have partnered with Adaptimmune is very interesting, the OncoMed partnership is also very interesting, so there is a lot going on in that space.

What are we going to do with those? The beauty is that we have every option in the world. We can go forward on our own if they are sufficiently strong and robust and we have enough of them, first of all, and we did that before, of course, that is a scenario. We could

choose to divest them, we could choose to partner with Novartis. We are not bound to do anything, but we have all the options and I think we will take whichever option we believe generates the absolutely maximum value for the company.

The good news is we have a lot; you will see a very interesting portfolio of oncology assets coming through and, having missed the current wave, I am very pleased that we are going to be able to participate in the next wave. Next question?

Alexandra Hauber (UBS): Good afternoon, thank you for taking my questions. Two simple questions on the cost lines. The COGS of 30.2% were better than in the first quarter at 30.7% despite the negative mix effect you had from the transaction. I was just wondering whether there were any specialist facts that really benefitted COGS this quarter or whether this is thought of, the below 31% rate is really the run-rate for the company?

Also on R&D, that extra decline sequentially, is that just phasing of studies or is R&D spend of the newco lower than what you had previously?

Then another last question on *Advair*. You have reported now for the first half a 2% volume decline in the US, but IMS scripts is suggesting that number is going to be 5 or 6%; can you perhaps explain the discrepancy between your number of the IMS numbers? Also do you have any feel whether you will be able to retain the exclusive status with CVS Caremark? Are you in a position to give us any idea whether next year's *Advair* price decline will be again double-digit or more like single-digit, more normalising?

Sir Andrew Witty: Okay, Alexandra, I am going to ask Simon to cover off the COGS. You should expect R&D to be lower and that is a consequence of the exit of the oncology R&D cost base and you will see, as we roll through the rest of the year, the benefit of further restructuring of the R&D organisation. I have indicated that numerous times that people are underestimating our ability to deliver. Frankly, we are delivering more experiments than we have ever done in the history of the company, we have more products in the clinic than we have ever had and we can do it by spending less and you will continue to see that flow through. That is absolutely right.

In terms of *Advair* pricing, I am not going to make a specific comment on a specific contract, but suffice to say our visibility for next year is pretty good. We feel pretty robust around our plans for next year. I would expect to see some continued *Advair* price fall next year, but I wouldn't expect it to be the same rate as we have seen this year and more importantly I do expect both US respiratory total and global respiratory total to grow again

next year, not least because of a less price pressure in the US than we saw this year and because of the new products flowing through.

In the IMS data a couple of things to say: first of all, you may or may not know but IMS have just re-stated their NBRx database, which bumped *Advair* up quite a lot. I am not quite sure why they have to do that but they did. Secondly, the IMS TRx data that you are looking at excludes the Department of Defence contract which GSK holds and it represents about 3% of the scrips. I am guessing that the delta – it sounds exactly like the delta – is between your number and the rest.

With that I will hand over to Simon on the COGS.

Simon Dingemans: Thanks, Alexandra. On COGS the quarter did benefit from a favourable mix, as I highlighted in my comments earlier, with ViiV accelerating very rapidly during the course of the quarter and some phasing of some of the lower margin parts of the business to the second half. That basically neutralised itself leaving the benefits from the pharma restructuring programme to flow through in the SG&A and R&D lines. That is why COGS is broadly flat quarter on last year.

Sir Andrew Witty: Great, thank you Simon. Next question?

Tim Anderson (Sanford Bernstein): Thank you. I have one simple question and a little more complex question. The simple one is on the SUMMIT trial, I think we are supposed to see results; are we likely to see that as a top-line release first and can you narrow down the timing of seeing a potential top-line release? Do you think that realistically makes a big difference with the *Breo* outlook?

My second question is going back to the commentary when you describe optionality and the future for Glaxo. Investors occasionally raise the theoretical possibility that Glaxo could be combined with another big company; you also continue to paint a picture of difficult fundamentals, at least on the drug side, which could be a reason to join forces. I am hoping you can give us your perspective here. Would Glaxo ever realistically consider pairing up with another company in a major way or are you happy with the current structure and the long term outlook, especially if you are highly likely to remain an independent company?

Sir Andrew Witty: Tim, thank you very much. As far as SUMMIT is concerned, there will be a release on SUMMIT and, if I were you, I would expect it somewhere in the September/October timeframe. I can't give you anything more precise than that, but you should anticipate it somewhere in that kind of timeframe.

I personally believe it would be inappropriate for people to view this as anything other than a *Breo* phenomenon. It may well be that other drugs could demonstrate the same thing, but nobody else has been able to do that so far. The trial has been designed in a very thoughtful way in terms of thinking about patients with COPD and cardiovascular risk and certainly when you talk to physicians who are involved in the space, particularly the cardio physicians in the space, they would not take the view that there is a reason to believe a class effect.

Of course if it is positive, and I don't know yet whether it is or it is not positive, but if it is positive we will be moving forward to gain a claim on our file and we will be making it a very central part of the profile of *Breo*. It will be a very defining point and the reality is, let's be honest, if we get this claim only we can promote it. Anybody else who wants to say their product has the same attribute (a) has no data, and (b) it would be illegal for them to promote and make that claim. Also from the payer physician point of view if you want to then give your patient a product with the claim, you have to give them *Breo*.

I don't buy this story that this isn't worth anything. I think the pharmaceutical industry is absolutely full of examples of products which are in a class which have been able to generate claims which are differentiated. They may or may not have been copyable but they weren't and as a consequence, they really differentiated the product.

In terms of the company, obviously we are a product of mergers and we have been through these things before and we are in the middle of a significant integration in two of our biggest divisions.

We feel very, very good about the capability of the company to deal with the environment that we were engaged in. I completely accept that I have a different view or at least I have elucidated a different view to perhaps some other people. We saw even last week that the pure play strategies aren't necessarily immune from their own setbacks and R&D is a risky business in the pharmaceutical business. Sooner or later things do go wrong in R&D and therefore having businesses which are totally reliant on that we've seen over years to be quite challenging.

We also think that having exposure to the broad drivers of returns which means good price but not wholly dependent on price and good exposure to volume is a great way to drive returns over the long run and we think very much in step with where the direction of the environment is moving us.

The extent to which then you want to complicate or to create even greater company scale than the scale we have today is a big question. That is a big issue to cross and I would say it has a very high pain threshold, not because you can't read a banker's book and

imagine all sorts of synergies and everything else, but just the scale of the company, the complexity of the company, all of those very practical realities of how you actually run a business of that kind of scale when you are already dealing with corporations which are very, very large.

I think the threshold of that next step is very big. I would hypothesise, Tim, that at least to some extent what we are seeing at the moment is M&A in this sector, largely driven I think for the same analysis that we have elucidated, which everybody can feel the pressure in the system. People are trying to acquire assets or they are trying to acquire businesses to give themselves synergy pools or growth opportunities to ready themselves for the threats which are emerging around us, but they are doing it in, let's call it, the easy M&A space. As long as you have a cheque book you can buy the small companies, you can buy the biotechs, you can buy the mid-caps and you can leverage the cheap money to acquire it.

What we haven't seen so far is the big-to-big transactions for some of the reasons I've just outlined which is that they are the very high pain threshold, they are not easy to pull off and they bring with them a fair amount of risk.

Where we net out on all of this is at least for now we have just done one of the biggest transactions, one of the most complicated transactions to pull off, it gives us a tremendous chance to build up global leadership in Vaccines and Consumer without massively distracting our Pharma business which focuses on R&D launches. We think we should be really fixated and focussed on that.

Next question.

Richard Park (Deutsche Bank): Great, thanks for taking my questions. I just have a couple. Firstly I just wondered ahead of the mepolizumab launch whether you've had much interaction with payers, obviously payer restrictions limit the use of XOLAIR in many markets and I'm thinking Europe in particular. I wondered if you felt you could be more successful and how you might be thinking around factoring in eosinophil cut-off levels into pricing discussions and your decisions there.

And then secondly I know that you talked about at the Investor Day changes in the salesforce structure supporting *Anoro* and *Breo*. I think you are moving to two separate salesforces there and I'm just wondering what the reception for that has been. I don't know whether it's too early yet, but just if there's any feedback there.

Sir Andrew Witty: Thanks a lot, Richard. As far as mepo is concerned, yes, we have had engagement with pricing authorities where we are able to. I think we feel pretty

good here because the profile of the drug is very strong. We have quite a lot of room for manoeuvre because as you probably know, XOLAIR is dosed on a per kg basis and so actually, and this is particularly true in the US, some of the prices per patient are very significant because of the varying weights of the patients involved. Mepo is not, mepo is a same dose for everybody. That gives us very significant opportunity to capture a great value proposition against the backdrop of what already exists, first of all.

Secondly, I would encourage you to look at the success we've had in getting *Breo* and increasingly *Anoro* covered in Europe, and we are really seeing some tremendous rapid access for *Breo* in places like Italy and Spain, normally very difficult. We have also just got it in France, normally very, very difficult and that shows that we are able to crack that problem pretty well, so I'm not super anxious about that.

As far as the shift in salesforce, yes we have seen some early benefit. First of all our salesforce is telling us things are much better, they are much more motivated. We have seen a very substantial step up in the NBRx shares of *Breo* since we made the change, so it's gone up by about 30-35% in the last eight to ten weeks. We are now seeing NBRx shares up in the 9-10% territory. For pulmonologists we are up in nearly 20%. You would expect that the NBRx shares would translate to NRx and then TRx shares over about an 18 month period. Remember NBRx focuses just on the dynamic segment. It takes about 14 to 18 months in respiratory for the dynamic segment to reflect in the NRx shares, so we have seen a big jump in NBRx for *Breo*.

Anoro less so, but we have only just deployed the increase in Share of Voice and that as I said earlier on the call has just happened, so we would like to see a bit more there.

In Europe, we are seeing very strong performance of *Breo*, a slow start for *Anoro*, but for exactly the same reasons that I think I addressed when I answered Graham's question at the beginning of the call.

Next question.

Matthew Weston (Credit Suisse): I have two questions left, please. The first is on your experience with *Anoro* and the fact that you have been struggling to persuade clinicians to take patients off Spiriva. Doesn't that raise a significant risk when you move to the closed triple, that you will experience a similar reticence and therefore very low adoption of that project?

Secondly, I have seen it reported that you'll move rilpivirine plus cabotegravir in a long-acting formulation into Phase III. Can you confirm that? And can you confirm what the commercial relationship is between ViiV and J&J with that development programme.

Actually, I will sneak in a third question, with a follow-on to the reference to the US selling infrastructure. Can you let us know whether now, with the change in leadership in the US, there has been any re-evaluation of the actual selling strategy, rather than just redirecting headcount, and whether or not you were perhaps over-zealous in interpreting the CIA previously and now have relaxed your approaches?

Sir Andrew Witty: On the last point, we haven't relaxed our approaches but we have simplified the way we measure the salesforce. Honestly, I think there is a great deal of ill-informed amateur comment on what we do or do not do in the US, if I may say so, Matthew. We have seen no evidence that the fundamental shift in what we did in the US which, I will remind you, we volunteered to do before the CIA and which we would sustain even when the CIA finishes – we do not believe that that has caused us any problems. The salesforce give us very strong feedback that they appreciate that, and we have tremendous feedback from physicians on it, as we are doing as we roll out the same culture across the rest of the world.

Where we did have an issue in the US, Matthew, is that around that there was a supplementary measurement system put in place to try to ensure that we had good measurement of sales representatives and that we were monitoring the right things. That was cumbersome, frankly, and it was getting in the way, so we have streamlined that and it has made a big difference. It has nothing to do with what you think it is to do with, but it is to do with the unnecessary 'clunkiness'.

I will tell you a couple of things. First of all, we are seeing a very, very dramatic and positive jump up in the morale of our US salesforce – really substantial. We are seeing a great level of commitment from that team and we are seeing the shares start to move, as I just said, with *Breo* most notably. I don't think it is worth missing that we are generating a *Tanzeum* share close to Trulicity, when in fact you have Lilly as one of the two diabetes powerhouses – and yet here we are with *Tanzeum* basically going neck-to-neck with them in terms of performance. On that one, I am really not too concerned about that.

In terms of the dolutegravir/rilpivirine, that is in Phase III, but not cabotegravir. It is a dolutegravir combination programme that is already in Phase III: the cabotegravir programme is in Phase II. Of course, we have a relationship with J&J, but I will not go into the details of that.

Next question, please.

Nicolas Guyon-Gellin (Morgan Stanley): Good afternoon, and thank you for taking my questions. I have two quick ones, please. The first one is on US *Advair* generics. The latest update on the clinical trials that Simon you mentioned, June 2015 for the completion for the bio-equivalence trials conducted by Mylan. Based on your competitive intelligence, do you have any reason to believe that it may or may not be delayed? Any thoughts on this would be great.

The second is just a currency-related question. I think you mentioned that you expect 6% negative FX impact on EPS for the full year. Is that correct and does that mean that your guidance of high-teens EPS decline then translate into a low-20s EPS decline rate? Thank you.

Simon Dingemans: On the currency, yes, the release does say that 6% is our current estimate if rates at the end of the quarter are maintained for the balance of the year. Clearly, we cannot predict currencies and how they will actually perform and so that is why we give our guidance in constant currency terms. I will leave you to take a view as to what adjustment we make over the period but that is the current assumption.

Sir Andrew Witty: I have no special insight, other than what some of the generic companies have been saying at conferences. I think the most recent one I saw was a 'may' comment, where the company involved was talking about a potential filing at the end of this year or the beginning of 2016. What we know is that, typically, generic files take 18 months or so to review, depending on how complex or simple they are: the complex ones take longer than that and the simple ones sometimes go a little more quickly. I don't know whether you would take a view on this being a simple or a complex one. We also know that every other generic so far has failed. That is what we know.

We can't guarantee that this will fail, and we cannot guarantee that there won't be a generic, and that is why we have given you guidance for the medium term shape of the business, incorporating an assumption for a generic *Advair* in the US. Even with a generic *Advair* in the US, we believe that the business as currently configured, post- the transaction with the pipeline that we have launched, can deliver the numbers in the shape we showed you on the 6 May day, and Q2 shows that we are absolutely on track for the delivery of that.

I am afraid that we are out of time. With that, I would like to thank everybody for their questions and, of course, the IR team is available at GSK for you to follow-up. For those of you who could not put your question, I apologise: please give the team here a call. Thank you very much.

[Meeting concluded]