GSK Q2 2018 Results and R&D Update

Wednesday, 25 July 2018

Part 1

Sarah Elton-Farr: Good morning and good afternoon everyone. Thank you for joining us today for our Q2 2018 Results which were issued earlier today. You should have received our Press release on those results and the 23 announcement, and can download our presentations from GSK's website. The presentations today are also being webcast. Before we begin, please refer to slide 2 of our presentation for our cautionary statement. With that, I will hand you over to our Chief Executive Officer, Emma Walmsley.

Emma Walmsley: Thank you and let me reiterate a very warm welcome to everybody.

Agenda

We are going to be splitting this afternoon into two sections. Firstly Simon and I are going to be covering our Q2 results and then, after a break, we will hear from our new Chief Scientific Officer Dr Hal Barron for the first of his updates on R&D and our pipeline.

Q&A Panel

For both sessions we have a full Q&A team in the room, and I know they are also very much looking forward to talking with you all at our reception at the end of the meeting.

3 long-term priorities for all 3 businesses

This time last year, I laid out my three long-term priorities for GSK: Innovation, Performance and Trust, all to be powered by a necessary change in culture. When I first laid this out, of course it was simply a framework, but I do hope you now have a better understanding of the changes we are starting to make.

Innovation was our first priority and is the very heart of GSK's purpose, which is to use our science to develop better medicines, vaccines and consumer healthcare products for patients so they can do more, feel better and live longer.

Hal is going to talk to you later about how we are taking our approach to innovation forward, but on this first priority we have already made some great progress over the past 12 months.

First, we have seen three major approvals, in *Shingrix*, *Trelegy* and *Juluca*, and the launches are going well. We have also taken some significant steps in advancing our early stage pipeline and have started our first pivotal study for BCMA in multiple myeloma.

On performance I have said very clearly that GSK has to deliver better results. We have taken a series of actions to do this, such as reallocating resources to key products in geographic areas that can best deliver profitable growth, the US and new product launches being at the very top of this priority list.

It is obviously people that drive performance, and building the right team has been key to the changes that we are making. Half of our top 125 leaders are new in role, with 75% of these being internal appointments, and we are all very focused on building a culture that is underpinned by purpose and values, but with greater performance edge, which means more focus, agility, accountability and, where appropriate, the courage to take smart risks. Culture change of course takes time and energy, and as well as having aligned leadership, we are also supporting the change we need with new metrics and incentives.

Trust is built first and foremost by the quality, differentiated innovation we bring, and the impact we have on millions of people's health and wellbeing, be it through our latest innovative launches or the access we provide globally to needed vaccines, medicines and consumer healthcare products.

I want us to build trust in the long-term by being a responsible company and a modern employer, and our new six-monthly check-ins on our global workforce engagement is showing good progress. We have also developed a new approach to global health that is going to be one that is more science-led and more sustainably funded, and our priority focus for global health is accelerating access to those in extreme need, to prevent and to treat infectious diseases that affect children and adolescents in the developing world, that is particularly HIV, TB and malaria. We were really thrilled last week with the FDA approval of *Krintafel*, the brand name for tafenoquine, the very first new medicine for the radical cure of P.vivax malaria in more than 60 years.

Overall, I am pleased with our progress over the last year on these three long-term priorities, but of course today our first agenda item is the immediate topic of our performance over the last three months, the Q2 results, so let me turn to them.

CER Sales growth in all 3 businesses;

Improved Group operating margin

We delivered Group sales growth of +4% in constant exchange rate terms in the second quarter. The Pharma business grew at 1% CER during the quarter, driven primarily

by the performance of our HIV business. Our new Respiratory portfolio grew at 37%, including a £26 million contribution in *Trelegy*. In HIV we also continued to deliver double digit growth, driven by sales of our dolutegravir portfolio, including *Juluca*, the first of our new two drug regimens.

Vaccine sales were up 16%, with a continued strong demand for *Shingrix*, and a good performance in our US business. Sales of our meningitis vaccines declined, primarily due to prior year vaccinations catch-ups in Europe, but we do continue to see meningitis growth demand over the longer term.

In Consumer Healthcare we delivered 3% growth, with good performances in Oral Health and Skin Health, partly offset by slower growth in Wellness and Nutrition.

Group operating margins this quarter were up 80 basis points, with lower spend in R&D reflecting the Priority Review Voucher last year, as well as the benefits of prioritisation of R&D expenditure.

Earnings were up 10% CER, reflecting a 7% increase in operating profits, as well as a reduced non-controlling interest allocation of Consumer Healthcare as a result of the Novartis buyout and the reduced adjusted tax rate. The improvement in operating profit was reflected in our free cash flow of £492 million.

We have today upgraded our guidance to 7% to 10% growth in adjusted earnings at constant exchange rates, if no generic *Advair* is approved this year. The upgrade reflects the positive momentum we are seeing from our new launches, the vaccine *Shingrix* and the buyout of the Novartis stake in our Consumer Health business, offset by the pricing pressure we continue to see in our inhaled Respiratory portfolio.

In the event of a generic *Advair* being available from October 1st, we would expect the adjusted earnings growth to be between 4% and 7%.

Respiratory: successfully transitioning to new portfolio

Turning to our Respiratory business in a bit more detail, we continue to see good update for our once-daily closed triple therapy for COPD *Trelegy*.

This quarter we had the landmark data from the IMPACT study presented at the ATS conference, and we received approval for a broader label for the product, and we are now able to promote it to this broader patient group beyond simply conversion from Ellipta, and we have prioritised our sales and marketing resources behind the product.

Nucala is continuing to build momentum too, with sales growth of over 100%, and we have increased our frontline investment in this growing market. Uptake in Europe is particularly strong, and we see further opportunity as we continue the launch rollout.

We presented the long term safety data from the COLOMBA study at ATS, which demonstrated consistent reductions in exacerbations and improvements in asthma control in patients over an average treatment period of three-and-a-half years. The consistency and durability of the responses seen with *Nucala* are gaining good tractions with physicians. And, of course, we have the potential for some further upside in additional indications.

Overall, the performance of our New Respiratory portfolio remains strong, despite the continued pricing pressure we are seeing within the ICS/LABA category, and we are very focused on delivering competitive commercial execution.

Portfolio performance on track with GEMINI studies

building confidence in 2DR outlook

Moving now to HIV, our US market share for our leading products *Tivicay* and *Truimeq* is holding steady, despite the increased level of competition in the market. The first of our new two drug regimens, *Juluca*, which now has a 3.7% share of New to Brand prescriptions, generated sales of £24 million in the quarter. *Juluca* weekly TRx in the US is now over 1,000 prescriptions, with approximately 1,400 physicians having prescribed so far.

Yesterday we presented data to a packed venue at the IAS conference from our pivotal GEMINI studies. This is for the second of our important two-drug regimens for both naïve and switch patients. The studies showed that the two-drug regimen dolutegravir plus lamivudine led to a non-inferior virologic outcome compared to a triple regimen of dolutegravir plus two NRTIs at 48 weeks. The success rates we saw were high regardless of baseline viral load count and, very importantly, we did not see any treatment emergent resistance in either arm of the study.

With this data, we are confident in the potency and safety of the dolutegravir plus lamivudine combination, and we expect to make regulatory submissions before the end of the year. With more patients with HIV living normal life expectancies, we believe it is very important that they have the opportunity to reduce the number of medicines they are taking, to stay well while reducing the risk of side effects and drug-drug interactions.

Shingrix: continued strong demand

Moving to our new vaccine *Shingrix*, which was launched towards the end of 2017 in the US and Canada. Last year we received a preferential recommendation from ACIP,

giving a target universe of over 100 million patients in the US alone. In Q2 this year that was echoed by a strong recommendation in Canada.

As you know, *Shingrix* represents a new standard of prevention, with more than 90% efficacy in the prevention of Shingles. The demand for this vaccine is high, from both distributors and patients. More than three million doses have been administered in the US since launch to date, and we expect to vaccinate significantly more patients this year than were vaccinated in total by both us and our competitor in 2017.

We saw sales of £167 million in Q2, and now expect sales for the full year to be broadly in the range of between £600 and £650 million, this reflecting our growing levels of supply.

Driving our growth outlook beyond 2020

Today our growth is being driven by the medicines and vaccines I have talked about and the three key launches identified as critical for our 2018 to 2020 performance: *Shingrix*, *Trelegy* and *Juluca*. This growth is supported by the optimisation of our base business and the solid performance we are still seeing in Consumer Health.

In the period to 2020 a number of new growth drivers will come into focus, with launches in the near term – if successfully approved – the two drug regimens dolutegravir plus lamivudine and the long acting cabotegravir plus rilpivirine, and, of course, our most advanced oncology asset BCMA, and potentially further indications for our Respiratory products.

In the longer term, we anticipate seeing our earlier stage pipeline start to have an impact on our growth outlook from 2021, as illustrated here on this chart. This of course will evolve as the data reads out and we supplement with business development too, but we have a portfolio of assets with the potential to launch in the subsequent five years. Obviously Hal is going to talk to you a lot about that in more detail later.

It is also worth noting our limited exposure to patent expiries in this timeframe, once *Advair* has been genericised.

Capital allocation framework

Last summer I laid out our capital allocation priorities, which remain the same. The first is investing in the growth of our business, and within that Pharma and its R&D pipeline is the most important commitment.

During Q2 we completed the buyout of Novartis' stake in our Consumer Health JV, and this will allow GSK shareholders to capture the full value of a business we believe is well

positioned to deliver future sales growth and continued operating margin improvements, and bring certainty too to future capital allocation planning.

I am just going to take a moment here to comment on what I know will be a question later on the recent press speculation regarding our Consumer business. The board's position on the Group structure is unchanged. We believe that the three business structure of the Group offers significant opportunities in the current healthcare environment, and provides GSK with more stability in our earnings and helps in free cash flow generation. But, as we have also consistently said, this is subject to each business continuing to perform competitively and having access to capital.

For Consumer we continue to see very good potential for growth and performance, hence our decision to increase our margin target for the business to approach the mid-20s by 2022, at 2017 constant exchange rates. We're also investing in Vaccines capacity, and this is to support the rollout of *Shingrix* and our other vaccines, including our meningitis portfolio.

Then after investing in the business, our next priority for capital allocation is shareholder returns. We know the dividend is important to our shareholders, and we continue to expect to pay 80p in 2018, and focus on rebuilding cash flow over time before returning the dividend to growth.

Finally comes scale M&A beyond Pharma pipeline BD activity, where we will maintain a strict discipline on returns.

Funding future growth

How are we going to fund our future growth? With the recent new product launches, the development of the new R&D approach and a successful buyout of our Consumer business, we have evaluated the Group's cost base and determined what is required to deliver competitive long term growth and performance in each of the three businesses. Simon is going to give you a lot more detail in a moment, but today we are announcing a new major restructuring programme. Savings from the programme will be fully reinvested into the Group to help fund targeted increases in R&D and support commercialisation of new products. This will supplement the other ongoing changes we are already making in our business to increase cost and cash discipline and to allocate resources better, with more focus on growth and profit generation.

With that, I am now going to hand you over to Simon who is going to give you a lot more detail. Thank you.

Simon Dingemans: Thank you, Emma.

Q2 2018 financial results

Overall, today's second quarter results demonstrate encouraging progress towards our key strategic objectives. We continue to grow sales across the business and deliver operating margin improvements, while investing behind new product launches. Based on this momentum, we are confident in our delivery for the rest of the year, and have upgraded our guidance for constant currency adjusted earnings per share growth for 2018.

Our earnings release provides an extensive amount of information, so I am going to focus on major points, our expectations for the rest of 2018 and important comparators to take note of within your modelling. I will also provide greater detail on the new major restructuring programme we are launching today.

As usual, my comments will be on a constant exchange rate basis, except where I specify otherwise, and I will cover both total and adjusted results.

Headline results

Starting with the headline results, Group sales up 4% to £7.3 billion, total EPS 9p, and adjusted EPS 28.1p, up 10%. Total operating profit was £0.8 billion, up over 100% compared to the small operating loss in Q2 2017. Adjusted operating profit grew at 7%, ahead of sales, with profit growth in all three businesses contributing, despite significant investment behind new products in Respiratory, HIV and Vaccines, especially *Shingrix*.

On currency, the strengthening of sterling compared with last year, particularly against the dollar, resulted in a headwind of 4% on sales and 7% to adjusted EPS. If exchange rates remain in line with the rates at the end of the second quarter, we would expect the full year headwind from currency to be approximately 6% to adjusted EPS.

Results reconciliation

Total results for the quarter show a significant improvement on Q2 2017, with reductions in a number of the more significant adjusting items.

Firstly, intangible impairments were materially lower this year, remembering that last year reflected our decision to withdraw *Tanzeum*. Secondly, major restructuring costs showed a further step down compared to last year as the existing programme nears completion. Finally, transaction related adjustments were lower, primarily due to the buying of Novartis' interest in the Consumer Healthcare joint venture during the quarter. Partly offsetting this was an increase in the charge for the re-measurement of the *ViiV* contingent consideration liabilities, driven by both exchange movements and changes to sales forecasts following the recently completed GEMINI study.

The rest of my comments will be on our adjusted results.

Sales growth

Turning to the top line, this quarter's growth of 4% was driven by a continued momentum in all three businesses, and by particularly strong contributions from HIV and Vaccines.

Sales within the Pharma business were up 1%, driven primarily by the HIV portfolio, which grew 11% in the quarter. Respiratory sales declined 2%, with growing momentum in Europe and international as the regions switched to the new products, offset by continued competitive and pricing pressures in the US. *Trelegy* and *Nucala* performed strongly, with *Trelegy* benefiting from share gains after an expanded US label. *Nucala* continued its global roll-out and also benefited in the US from market expansion, as well as some re-stocking after a de-stock in Q1.

Seretide/Advair continue to decline as we transition our Respiratory portfolio globally, but also impacted by the step up in US pricing pressures I highlighted in Q1. The pricing comparator for *Advair* should be slightly easier in the balance of the year as the increased pricing pressure really started in the second half of last year, before then again picking up in Q1. I still expect an overall decline in *Advair* for the year of around 30%, assuming no generic entry in 2018, although it might be a little worse, depending on how the anticipation of an imminent generic impacts year-end stocking positions. I will come back to our expectations for a generic *Advair* and its impact on our guidance shortly.

Breo grew 4% in the quarter, with strong growth outside the US being offset by a decline in the US. This reflects another quarter of the RAR catch-up that we flagged at Q1. Overall volume growth in the US was strong at around 30%. With the catch-up now largely done, we expect to be back to good new sales growth in the second half.

Established Pharmaceuticals declined by 5%, although the quarter benefited from favourable RAR adjustments for *Lamictal* and some post-divestment inventory sales. I anticipate that the decline will be steeper in the second half, and overall continue to expect the performance for Established Pharmaceuticals to be a decline in sales of mid to high single-digits over the full year, including the impact of divestments.

Despite the pricing pressures we are experiencing in our Pharmaceuticals business, the momentum we have from our new products and the recent investments we have made, we remain confident that we will deliver overall sales growth in the low single-digits, assuming we do not see a meaningful *Advair* generic before the start of Q4.

Turning to Vaccines, sales up 16%, primarily driven by further acceleration of *Shingrix*, as well as growth in hepatitis, which benefited from a competitor being out of stock.

Emma highlighted earlier the successful *Shingrix* launch, and we continue to work on increasing supply, but I can confirm that we have plans now in place to deliver sufficient doses to fulfil *Shingrix* sales in the range of £600 to £650 million for 2018 as a whole. Previous vaccination patterns for Shingles vaccines suggest we will see stronger seasonal demand in Q3 than Q4, and I expect to see this reflected in the phasing of sales in the second half.

The meningitis franchise remains an important growth driver for the business, even though this quarter saw a decline of 3%. *Bexsero* was particularly impacted by the completion of cohort catch-up vaccination programmes in Europe, while *Menveo* was impacted by minor supply constraints that have now been resolved. I expect a positive second half and we are well prepared as we head into the back to school season.

As I have said previously, Vaccines sales will continue to be lumpy, due to tenders and the impact of CDC stockpile movements, and this is demonstrated in the quarterly results for a number of vaccines, including *Synflorix* and *Rotarix*, as well as our overall international sales.

As a reminder, Q3 last year was very strong, driven by flu sales, and it is difficult to predict precise ordering patterns between Q3 and Q4, but current bookings suggest it might be a bit more weighted to Q4 than last year.

The momentum in the business continues to give us confidence in the mid to high single-digit outlook for sales CAGR over the medium term, though 2018 is likely to show higher growth than this as a result of the *Shingrix* performance.

Turning to Consumer, sales up 3%, despite a one percentage drag from the combined impact of the divestment of non-strategic brands GST in India and generic competition for TDS in the US. Quarter 3 is expected to be the last quarter impacted by GST, and although the decline in TDS may spread into next year, it will no longer be a material factor in 2019.

A strong performance from Oral Health was partly offset by a weaker quarter for Wellness, due to an abbreviated allergy season in the US, as well as tougher competitive

pressures in the pain category, particularly in Europe. Importantly, the business continued to achieve a good balance of growth between price and volume.

Power brand growth dipped in the quarter due to stocking patterns and the phasing of some promotional activities. I anticipate that their growth will pick up in the second half, and they are expected to contribute strongly overall for the year. We remain confident in delivering low single-digit growth for Consumer for 2018.

Adjusted operating margin

Turning to our operating profit, our adjusted margin of 28.8% was up 30 basis points at actual rates and 80 basis points on a constant currency basis.

COGS as a percentage of sales increased primarily reflecting an adverse year-on-year comparison for Vaccines, which benefited from a £45 million settlement in Q2 2017 for lost third party supply volume. Aside from this, we saw a broadly flat COGS performance as favourable mix and continuing supply chain efficiencies offset US respiratory pricing pressures.

SG&A was up by 6% in the quarter as we invested significantly behind driving new products in Respiratory, HIV and Vaccines, particularly *Shingrix*. This was partly offset by reductions in back office and other non-customer facing resources, and I would expect SG&A growth to slow over the second half, although we need to continue to support key seasonable products in Q3.

R&D costs down 15%, down 6% excluding the impact of the PRV, and as I mentioned at Q1, the first half was expected to see reduced spend as the savings from last year's portfolio choices kicked in, but we also still expect to see those savings start going back into R&D over the second half, when we should see Pharma R&D spend start to grow again, accelerating into Q4.

Royalties down 23%, due to payment from the sales of Cialis, which ended in 2017 and we continue to expect around £200 million for the full year.

In the bottom half of the P&L we continue to manage our funding costs carefully. Net financing costs in the quarter included the additional costs of the Novartis buy-in, which came in from 1 June. With the additional debt funding for the buy-in, and some of our older debt now refinanced at lower rates, I except funding costs for the year as a whole to be around £725 million.

On tax, the adjusted rate was 20% in the quarter, and we continue to expect a rate of 19-20% for the full year.

The charge for minorities in the quarter was £170 million, compared to £174 million a year ago. The ViiV minority interest increased due to the share of the PRV costs that impacted the minority last year, and this was offset by 2 months' saving on the Consumer Healthcare minority interest, as we recognised 100% of the profits from when the agreement to acquire full ownership became unconditional on approval of shareholders on 3 May.

Improved cash generation

Moving to cash generation and net debt, we remain very focused on driving greater cash discipline across the group and improving cash conversion.

Free cash flow for the Group during the first half of the year was £0.8bn, up £0.4bn compared with last year. This increase was driven by improved operating profit, reduced restructuring spend and tighter control of capital expenditures, as well as the comparison with the cost of the PRV in Q2 2017. This progress was partly offset by the Vaccines milestone payment to Novartis at the beginning of this year, foreign currency movements and a greater increase in working capital than the first half last year.

The working capital increase reflected the usual seasonal build we see in the first half but also additional inventories going in behind new products in Respiratory, HIV and *Shingrix*, and the rapid take-up of *Shingrix* has also led to a step up in receivables which we would expect to collect during the balance of the year. Like last year, I expect cash flows overall to be weighted to the second half.

Net debt now stands at £23.9bn, after the £9.3bn impact of the Novartis buy-in, dividend payments of £2.1bn and adverse currency impacts of £0.4bn, partly offset by the increased free cash flow and some small disposals.

Our credit ratings have recently been confirmed unchanged and we remain comfortable with our balance sheet capacity to support future investment requirements in the business.

Continued cost and cash discipline to fund future growth

Our results demonstrate the benefits of having clear financial goals, as set out in our financial architecture. Rigorous benchmarking is used to target a competitive cost structure for each of our businesses, while ensuring that we prioritise the investments that will generate the most attractive long-term returns.

Ongoing efficiency improvements are particularly focused on streamlining back-office activities where we can take advantage of our recent systems improvements to automate and drive down costs.

We have also made significant changes in procurement, with a new global organisation driving top quartile savings. In the commercial space, advanced data and analytic tools are helping us target more precisely our product and market investments.

We have also unlocked deeper, larger-scale structural changes in our cost base through Major Restructuring, including the integrations around the Novartis Vaccines business and the formation of the Consumer Joint Venture, as well as the re-shaping of our pharmaceutical commercial footprint that we initiated last year.

Through these twin efforts we have re-sized our cost base to allow each of our businesses to be competitive in the markets in which they operate and fund the investments needed to deliver our key future growth drivers.

New Major Restructuring to fund future growth

This is clearly something we need to keep under review, and with the new product launches underway, the recent buy-in of Novartis's stake in the Consumer Joint Venture and a new approach to R&D in place, we have evaluated again the Group's cost base and the requirements of each of the 3 businesses to deliver competitive long-term growth.

As a result, we are today announcing a new major restructuring programme, which aims to deliver £0.4 billion of annual savings by 2021. The new programme is expected to cost a total of £1.7 billion, comprising cash costs of £0.8 billion and non-cash costs of £0.9 billion. This new programme aims to significantly improve the competitiveness and efficiency of the Group's cost base, with savings delivered primarily through supply chain optimisation and reductions in administrative costs.

Savings from the programme will be fully re-invested into the Group to help fund targeted increases in Pharma R&D and support commercialisation of new products. As you think about your models and future spend levels for R&D, adding most of the savings identified to the regular low single digit increases in R&D gives you a guide as to how we are thinking we will need to step up R&D spend.

The cash costs of the programme will be self-funded through improved cash conversion as well as disposals of fixed assets. The programme is not expected to have any impact on our dividend policy.

Upgraded 2018 guidance

Moving on to expectations for 2018, based on an encouraging first half, I am very pleased to be able to upgrade our guidance for the year. Assuming no generic *Advair*, I now expect adjusted EPS growth of 7-10% for the year on a constant currency basis, and in the event of a 1 October entry of generic competition, I expect adjusted EPS growth of 4-7%,

again on a constant currency basis, with US *Advair* sales of around £900m, again at constant exchange rates.

The major moving parts enabling this upgrade include the positive momentum demonstrated by *Shingrix* and the benefit to earnings of the full ownership of the Consumer Healthcare business. These more than offset the continuing pricing pressures we are seeing in US Respiratory, which also leads us to continue to expect a steeper decline in *Advair* sales before generic competition of around 30% for 2018.

The eventual timing of the launch of a generic *Advair* will clearly impact the growth rates we can expect to see across 2018 and 2019.

Confident in delivery of 2020 outlook

So, in conclusion, it's been a positive first half. Our new product launches are going well, we are working hard to drive cost and cash discipline across the company and seeing the benefits within the results we have reported.

We have upgraded our 2018 guidance and we are increasingly confident in our financial outlook for the group of mid-to-high single digit EPS growth over the 5-year period to 2020, even with the new investments we are making in R&D and new products.

Our financial architecture and the new major restructuring programme we have announced will provide us with the flexibility to make the increased investments in the new approach to R&D which you will be hearing about from Hal shortly.

Q&A

And with that, we'd like to take your questions related to our Q2 results, and I'm going to invite Luke, David, Brian and Luc to join Emma and me on stage to take your questions. I'd just ask, any R&D related questions, please save that for Hal later. Thank you.

James Gordon (JP Morgan): It's a pipeline question, but a financial question, rather than a pipeline data question, or two questions: one was just, R&D was down this quarter, but how much might R&D grow over the next few years, and asking that both in terms of the P&L and also in terms of M&A. So for the P&L, I know you have some costs savings coming through, but if I benchmarked versus peers and the level of investment for the Pharma business, could you go up to high teens, as many of your large cap peers are? In terms of the R&D not going through the P&L but actually doing some business development, how aggressively might you do that? I think previously you said just bolt-ons,

but could it be quite a big bolt-on, what does a bolt-on count as, and as there's not a lot of very obvious imminent phase 3 go decisions, could a big chunk of the rebuild be external?

Emma Walmsley: I'll just answer both of those briefly. In terms of percentage of R&D, I'm not a big fan of saying there needs to be a percentage spend in R&D, and I know that Hal would take this position as well we will spend according to the data readouts that come, and we are minus six excluding the PRV, in part because we stopped a whole load of programmes, and as Simon has already said, we expect increases to accelerate through to the end of the year; and for the models you should assume that the savings programme that they have put in place, assuming that the data justifies it, is added to the spend that we have. I'm quite relaxed about having even a potentially quite lumpy R&D spend according to the assets that we are putting in place.

In terms of BD, I'm not going to set numeric criteria around what qualifies as a bolt-on. I would anchor us in, we're feeling good about some of the organic momentum that we have, whether it's the recent launches that we have or indeed, some potential – assuming they are approved – pending ones in that period 2018-20 for our outlook, whether it's the new dual therapies and HIV or indeed BCMA, which you're going to hear a lot more about. Then we have a whole new cohort that we will be looking at, and Hal will highlight some of that, later today.

We absolutely do expect to do more business development to strengthen that pipeline, it's the first priority in capital allocation. In the room we have Kevin Sin, who has been here for all of three weeks, so he won't be outlining his full and complete strategy for that yet, but you will hear from Hal on how he thinks about BD, and by the way, obviously focusing on the priorities that he is laying out in terms of assets, or technologies, partnerships, as well, but it's not just going to be in-licensing, we are also looking at out-licensing, and creating more flexibility for funding in that way.

We just announced *Tapinarof*, it may also be on other parts of the broader portfolio: as you know, we have our review ongoing with Horlicks; so we are quite comfortable that with the strategy that we are laying out today, organisationally we have the balance sheet and the capacity to pursue that, but a lot is going to depend on the data that reads out in the next couple of years, in terms of how much we need to accelerate that or not.

Simon Dingemans: Just to add to that, remember also when you look at R&D spend, the three businesses have very different characteristics, and looking at the group number is not very useful. If you look at Pharma R&D to Pharma spend, and the overall shape of that P&L, I think if you run your own models through the numbers we've just talked about, if that's a relevant benchmark, I think we are pretty competitive as to what we

expect, and we obviously have factored in some element of BD, because that's a central part of the strategy; clearly there is a degree of unpredictability around that, that we will have to deal with when we get there.

Graham Parry (Bank of America Merrill Lynch): You've upgraded 2018 guidance and I think consensus looks like it's running a little bit below the range at the moment, but next year you are still going to be facing slowing HIV, potential *Advair* generic coming, maybe possibly even at the turn of the year, the increasing in R&D that you have some savings to help, but when you put all that together, how comfortable are you with where consensus numbers are sitting for 2019, and in particular the current assumption of flat margins into next year?

Secondly, a question for David, on dolutegravir: NBRx absolute have now dropped around 28% since Biktarvy launched, and Biktarvy is equalling you roughly on NBRx, TRx look like they are flattening off in terms of absolute, so could you perhaps run us through the dynamics that you are seeing in the market, how long you think it takes for new to brand prescriptions to translate into total prescriptions, and if you are seeing any switching from dolutegravir regimens, or is this just all the new patient share gain at the moment?

Emma Walmsley: David, that one is coming to you in a second, but let me just answer the first one by saying, we don't comment on consensus, we're very pleased with the 2018 upgrade, and as Simon said, we are feeling increasingly confident about our 2020 outlooks, whether that's because of the momentum, *Shingrix*, the consumer buy-out, US tax reform, and we are absolutely expecting to digest the *Advair* genericisation; and I'd remind everyone our 2020 outlook is within a range, so we are feeling increasingly optimistic about that.

David, do you want to pick up for HIV?

David Redfern: Thanks, Graham. As Emma said, first of all, globally, overall dolutegravir and dolutegravir-based regimes grew 18% in the quarter. I think if you go into the US, as we showed, TRx for DTG overall, up to around about 37,000, it clearly varies week-to-week, but 37,000 a week. Our market share the way we define it, of core and STR, has grown a little bit, is just above 28% or so. We're pretty pleased with that. I would say, when you drill down into it, *Tivicay* particularly looks absolutely rock solid, so we're seeing almost no switching from *Tivicay*, and indeed some prescribing of *Tivicay* still into new patients, quite a lot of *Tivicay*, as we said before, somewhere in the 40-45% ranges with Descovy, but that business looks very, very stable.

Triumeq is a bit more competitive, we are seeing some switching round the edges, some of that is undoubtedly going to the competitors. Some of it is actually going to *Juluca*, so there is some switching from *Triumeq*, perhaps not as much as some might have anticipated. As Emma showed, we're actually quite pleased with the way *Juluca* has launched, up to over 1000 scrips a week, we have about 1,400-1,500 physicians now in the US prescribing, and I think that paves the way very nicely for GEMINI and Dolutegravir and Lamivudine – there is clearly appetite for two-drug regimes. That's where we are. I don't think any of those trends are that different from Q1, it's really been very much a continuation, and I think we're pleased with that.

Michael Leuchten (UBS): Two questions on the financial side: the upfront costs for the restructuring programmes seem high relative to the savings, so what makes this programme different from what maybe you have done previously? Then on the free cash flow definition, I think you have now moved disposal gains from intangibles into free cash flow - just your thinking behind that, what that means?

Emma Walmsley: Simon, do you want to pick up those?

Simon Dingemans: I think what is different about this programme is the particular focus on the supply chain, and the moment you get anywhere near our fixed asset footprint you end up with reasonably sizeable non-cash write-offs. You can either take a view you never go near those, or if you want to confront them and address the overall complexity we have in our supply chain that's an issue I know we have debated with all of you a number of times. We felt that was justified.

The cash costs are £400 million against cash costs of £800 million, so very similar paybacks to what we've seen in the other programmes we've done, but it's really driven by that particular focus on the consumer supply chain post the Novartis buy-in, where we can really get after that business in a way that we couldn't with our partner, and now a year on with commercial focus being much clearer, R&D in place, we can look at the Pharma supply chain, see what do we really need to go forward and get at both of those in one programme. That's really why it's a bit different.

Then on the free cash flow, all we've done is a small tweak to the definition to bring in disposals of intangible assets - not businesses, intangible assets - because we add the costs in and not the disposal benefits, whereas on the fixed side we have both in, and I think that therefore it's just a question of balancing. There's about £18 million in the quarter and about £40 million last year, so it's not a big number.

Emmanuel Papadakis (Barclays): Maybe if I just take the inevitable *Shingrix* capacity question, you said you had enough to make to sell the 600-650 figure that you have kindly provided to us. Does that represent a ceiling on what you can make, and if not, where is the ceiling on what you can make this year, and what might be the additional flexibility between now and the end of the year on that?

Emma Walmsley: Thanks for that question, and it is picking up one that has come through from Danny from AXA as well, so I won't pick that up for a second time. Obviously we are delighted with the early start to *Shingrix*, obviously it is also in line with that preferential recommendation which was beyond initial expectations. We did significantly mobilise supply and continue to do so, and I'm not going to comment beyond that confirmed increased outlook of 600-650.

We do expect to continue growing this business through next year and for it to be a very material contributor to growth for the company. Supply is a bit bumpy, but we are working very tightly with CDC and with wholesalers, particularly focused on that second injection, and are very confident, considering we are also looking at the geographic rollout pacing, that we can maximise this launch in the US.

I don't know, Luc, if there is anything you would add to that?

Luc Debruyne: No, it's what you said, it's clear it's a key growth contributor also for the future and that's why Simon said we keep on investing, and we supply more, going forward.

Emmanuel Papadakis: Thank you, maybe if I could take a second question. The contingent consideration liability increase as a consequence of the positive GEMINI study, is there anything you can tell us about what we should think that might translate into, in terms of sales potential?

Simon Dingemans: I don't think we're going to give forecasts, but I think you can sense form the increase our degree of confidence improved.

David Redfern: And what we've really changed is the probability of success, because clearly that has gone up a lot.

Steve Scala (Cowen) (by telephone): Two questions: in the past a number of guidance elements have been provided for 2016-20 beyond earnings, but they have not been reiterated so far today, so these include for Respiratory, Vaccines, Pharma, Consumer

and total turnover, should we assume that all of those elements are intact or not intact, since they haven't been reiterated; and secondly, is Horlicks still likely to be divested in 2018, and what impact would that have on earnings if it is divested? Thank you.

Emma Walmsley: I'll let you take the earnings;, but the short answer to the question whether all the other guidance elements are intact is yes.

Simon Dingemans: And on Horlicks, I think it depends when it happens. The plan is still to get it to a conclusion during the course of 2018, but obviously we need to balance that with making sure we get the right price, so I think when we conclude that we can give you some more specific help on that.

Keyur Parekh (Goldman Sachs): Apologies if you addressed this in your opening remarks, Emma, but there has been some recent press speculation about the broader structure of the group. As you go through the *Shingrix* launch, rest of the world, just help us think about, conceptually would this be a good time for you to think about something different or is this kind of a good place in for the next couple of years?

Emma Walmsley: Thanks very much, Keyur, but I'm not going to repeat what I did say in my introductory remarks, which is, the Board's position on this is unchanged, we like the structure of the group for its continuity and balance of cash flow, as long as all three businesses continue to perform competitively and have sufficient access to capital, and on that basis we are unchanged for now. Thank you.

Andrew Baum (Citi): I was going to ask this question to the Chairman, but in his absence it's going to go to you. He's clearly indicated an understandable willingness to reassess the group structure in light of the context which you alluded to. Does the Board's open-mindedness also relate to reassessment of the Physician Engagement Policy which GSK is currently running with? You recently hired a new General Council, there are several of us who think it's uncompetitive versus your peers, and I suspect the same may be true of your own internal staff, so whether there is any intention to renew that, and what it would take to renew that.

Then a second question, for Simon, that relates to business development. You ceased R&D in your dermatologic creams area, I noticed recently, given your in-market sales are substantial, and there are now some private equity players coming in for picking up some of these established brands, are there potential opportunities to generate capital to re-invest elsewhere in the business, particularly within Derms?

Emma Walmsley: Thanks very much, Andrew – I will take the first question: it's an important one. We have been investing heavily, as you know, internally, in terms of our medical engagement capability, and we do continue to look at this. We look at it through the lens of very much what is in the interest of the patient, in terms of new data coming through, and also what's going to help the HCPs that we work with, especially as the innovative pipeline develops. What matters to us is patient interest and transparency, and on that principle we continue to look at it, but no new news today.

Simon Dingemans: On the assets side, I think as we've said a number of times, we continue to review the established pharmaceutical business, to see whether there are better opportunities in disposing of those assets. Generally the portfolio is a very strong cash and margin contributor, we have a number of disposals that are washing through the numbers this year, and some genericisation, which as we go into 2019 and beyond, reduce the drag significantly, but I think we are very open-minded where there is real value.

We are now managing that business much more discreetly, as a distinct entity to deliver margin and cash into funding some of the other objectives that we've described today. Typically when we benchmark those alternative proposals, that don't stack up very well, but occasionally they do, and some of the disposals we've made to Aspen would be a good example of that; we keep looking, and if a good value opportunity comes up we are very open-minded.

Luke Miels: I would just add, Andrew, the bulk of the value we can create is won through a more efficient and focused supply chain, better forecasting, and then overlaying that, a greater concentration of commercial effort on a smaller number of products, because we are quite dispersed in markets such as China and India, and I think there's a fair amount of work that is advanced, that should yield benefit over the next couple of years.

Sarah Elton-Farr: We're going to take a question online now from Danny at AXA on 2020 guidance.

Emma Walmsley: Simon, perhaps you can answer this. The question is related to what the levers and drivers are to get earnings to the upper end of the range in 2020, in terms of 2020 outlook.

Simon Dingemans: I think that we've highlighted a couple in particular in the upgrade that we gave for 2018, and those we certainly expect to continue to play

significantly as we go through to the 2020 period and complete that outlook that we gave back at the time when we closed the Novartis transaction.

Alongside that continued growth in our new respiratory products, there is growth in the meningitis franchise and – as I have just touched on – very different contributions from some of the established portfolios as well, coupled with continued cost drivers and operating leverage, and a good focus on the bottom half of the P&L. Put all of that together, along with improved cash conversion, and I think you can see how we get to the 2020 outlooks we have previously given and fund a very significant step-up in R&D spend that we are planning to put behind the new approach to R&D, as well as supporting some of the commercial priorities that we have identified.

"More of the same" is probably the one-line answer to that.

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Kerry Holford (Exane): I have two questions, please, firstly on *Shingrix.* Can you confirm whether you have started your DTC campaign on that yet? And, given the speed of the ramp, do you think this vaccine could now be more profitable earlier than you have previously anticipated? Also, can you just remind us which ex-US regions you have now launched the vaccines in?

Trelegy is my second question, and more broadly into respiratory. So, you have spoken, Luke,previously about commercial prioritisation - Can you detail what that actually entails? Have you increased the number of reps? Can you talk about the relative positioning in that promotional process of *Trelegy, Anoro, Breo*, and how you are now promoting each of those products to doctors? Thank you.

Emma Walmsley: Since Luke is also leading the execution of *Shingrix* around the world, why don't you pick up both of those questions, please?

Luke Miels: The good news is that we have not actually had to commence any DTC. We originally had quite a significant investment assigned for DTC but, as you are no doubt aware, the press coverage in the *New York Times*, the *Washington Post,* etc. has meant that we have not needed to engage in that at this point. This has meant that we have been able to deploy that effort to products like *Bexsero*.

Outside of the US, we have launched in Canada. It is very interesting, so, the NACI recommendation in Canada is not as strong as the US recommendation but what is striking – and it has only just come in – is that we have seen a nine-fold increase in the number of GPs who are regularly writing *Shingrix*. We've got a market that was declining at about 30%

for the last three years with Zostavax, is now more than 100% growth so the demand is there and I think that is encouraging as we look into Europe and other places.

The other place where we have a very narrow launch is in Germany. That is very deliberate because we want to establish a pattern of use in a subset of patients. Germany, of course, is really influenced by the presence of STIKO, and the recommendation with STIKO, so that build will be longer. Then we have a small allocation going to Japan for the same type of reason there.

In terms of *Trelegy*, and I think this is a key shift in the culture. Simon has made the point in terms of reduction in resources in areas. Historically, if we adjusted sales forces, that is where the cost tended to come out, because those people are very visible and you could do that. What we have tried to do to fund *Trelegy,* and really be quite bold in terms of our investment on *Trelegy*, is to reduce the back office and reallocate those resources. For the positioning of *Trelegy*, we are going after people who have had one or more exacerbations in line with the label. With *Anoro*, we position it for COPD patients who are symptomatic and, if you are exacerbating, there is *Trelegy.* That is essentially the strategy, in a very simple way.

We split the teams. Historically, in some markets, we'ld have people selling two or three products. The net result, when we looked at market research, was physician confusion, which is not the objective, and so we have split that and we try to avoid that at all costs. We have split that and then, consistently, when markets launch, I want almost the entire sales force on *Trelegy* at launch, so that we really inject energy around that. You can see those uptakes, whether you look at the UK, or you look at Germany, or you look at Australia. In Canada, it is not fully reimbursed yet but, if we look at the patient programme, again these trends are very strong and we now just need to keep that going.

Laura Sutcliffe (Berenberg): I have another *Shingrix* question, please. Clearly *Shingrix* is going very well: it is more expensive than some of the other more commoditised vaccines products. We have not seen any DTCs spend for the reasons you have just mentioned. So, what are you thinking about in terms of margin in the Vaccines division, going forward, and when we might see some of the benefits of that?

Simon Dingemans: We are not going to get into a breakdown of margin by product but I think we have very clearly and consistently had a target of +30%. There is also the caveat that we would move the margin around, quarter-to-quarter, depending on when the investment requirements were most acute, and we have seen that this quarter.

But, if you look at the shape of the business, with the growth drivers that we've got, with meningitis, *Shingrix* and the established Vaccines business, there is nothing to say that we couldn't deliver a sustained performance in the 30- 35% range that we have typically had for our own business, pre the acquisition of the Novartis assets, historically. That is probably the right sort of guide.

Luke Miels: Just flagging it - it's in the results – there is quite a bit of pressure for the DTPA in Europe, as well as *Synflorix* in emerging markets through GAVI. I am sorry I didn't answer that in your question.

Jo Walton (Credit Suisse): I have two questions, please. If we look at the gross to net in the US, you can see that Respiratory is one of the biggest areas of rebating. I am intrigued as to what you think might happen if rebates were rolled back and you had to move to some sort of net pricing. Effectively, what is your speculation or your war-gaming or whatever it might be, and how do you think that might impact you? Because rebates are a big part of the Respiratory business.

Emma Walmsley: They are. I'm going toask Luke to comment. We are not going to be in the business of speculating – certainly not speculating publicly – on what's going tohappen in terms of the follow-up from Blueprint, but you are right. If you look at our net pricing in Pharma, already we have had a CAGR over five years of -1, and last year -5, and in fact this quarter it is a little more than that. It is a therapy area that is under a degree of pressure but that is why we are so focused on the *new* respiratory, because it is quite focused on ICS-LABA.

In terms of our policy, we obviously have responded ourselves to the request. We are very supportive of anything that will still encourage innovation but actually help with the out-of-pocket for patients and bringing more transparency to that huge differential between gross and net is actually a good thing. We wouldn't necessarily support rebates being removed completely but we do think that greater transparency in the value chain is a positive move.

Luke, would you like to add anything?

Luke Miels: Yes. I would just add that the discussions are comprehensive. There are some clear markers from the administration out there, in terms of rebates and a safe harbour. We have been involved through PhRMA in giving our views and you can actually read our submission on the AHS website. To Emma's point, it is too early to say, but I would expect that there will be some changes in the structure.

Jo Walton: My second question is a Consumer question, but in a different way. I wonder if you could just reprise for us what synergies you think there are between Pharma and Consumer: are we moving to a more Consumer-led prescription market, where some of your Consumer insights are valuable? I understand that you want to keep businesses that perform well in their own right, but the debate is about how much synergy there is between any of the individual businesses that adds more.

Emma Walmsley: I will let Brian talk about the synergies that he sees from the Consumer end of it, but I will just make a couple of points on the reverse side of it. First of all, the *Shingrix* launch is a Consumer launch. Most of its distribution is through the retail environment in the US, where we are very familiar operators. I think it is 65% of the distribution.

Much of the planning initially, around how to launch this – and, most would agree, it has been a good start – was actually in partnership with the Consumer teams. Effectively, you are asking an adult to self-present, to go and protect themselves: it is not a baby that is literally carried in, whether they like it or not. We see that as being a relevant capability.

And a second thing that has been very interesting to me – and I think you would agree that this is a long-term view – is that when you think about the deal we announced today with 23andMe, which is potentially extremely exciting in terms of identifying these genetically validated targets and therefore addressing this fundamental challenge in the industry about probability of success, it is also very interesting from a consumer empowerment point of view.

Whether you have 5 million people who are signed up now, that will be 10 million very shortly, who are massively motivated around their personal health, and 80% of whom – at the moment, I think that is correct – are voting *for* being able to participate in research. So, I think over the long-term, and we shouldn't overstate this, we will start to see patient power emerging a bit more strongly. It is one of the only industries where the end beneficiary is neither in charge of the paying or the choice that is involved. Over time, with the transparency of information and more value demonstration, I think this will be relevant.

Now, that does not mean that we don't need to prove the other criteria we have laid out as being critical to a group structure right now, that the whole Board is supportive of.

Brian, perhaps you could talk about that.

Brian McNamara: Maybe just quickly on *Shingrix*, both Luke and I engage a quite a bit on that and our teams actually work quite closely on the *Shingrix* plan. We actually transferred some folks from the Consumer marketing group into Luke's group.

I think the classic advantages we have had so far is, that we have talked about *Flonase*, which was a $5 million product in the US, we switched it to OTC and it was £200 million in 12 months and now we are actually launching that around the world and we are seeing good growth on that.

Most recently, the Pharma business did a quite a bit work on a CRM programme and their engagement with HCPs is obviously their expertise. We do a great deal of that with dental professionals and doctors around the world. We were able to take that off the shelf and launch it in 80 countries around the world last year – something we could never do if we were not part of the Group structure. We continually look for those opportunities to take advantage of being part of GSK, and they are there.

Luke Miels: Yes, and the next one is *Bexsero*. The upside of having a delay in the *Shingrix* availability ex-US is that I think we can do much more on *Bexsero*, particularly in Europe, where initially we had supply constraints. Then, of course, we started to think, is this a UMV market. I think the conclusion we have reached now is that it will be a private market and that, again, lends itself to the skill-set that is in Brian's team and we have another exchange going on in that dimension.

Emma Walmsley: Thank you very much. I will bring an end to the Q&A around Q2. I know that Q2 is very exciting, but wait to see what is coming next. Let's take a 12-minute break and return at 3.30 sharp please. Thank you very much.

[*Break*]

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