

GLAXOSMITHKLINE
INNOVATIVE PIPELINE

Tuesday, 3 November 2015

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Sir Andrew Witty (CEO): Welcome everybody to this R&D Investor Update from GSK here in New York. I would like to also say welcome to everybody who is watching this on the live webcast investors media around the world. I would particularly like to say a warm welcome to all of the GSK employees, particularly those in R&D and especially those who are working on the projects, which we are going to describe to you during the rest of the morning. I hope they take the great chance just to sit back and reflect on the work that they have done so diligently over the last five, 10, 15 years to get the company to where we are on this portfolio.

What we plan to do during the morning or so is to take you through a reasonably large number of projects in the six focused areas of research at GSK. You will hear really from just two presenters after me, Moncef and Patrick, but, as you may have noticed, we do have a number of GSK personnel in the front row or two here. These are all of the Discovery and Development leaders of all the various programmes which you are going to hear about today. While they are not going to present to you, they are certainly here for you to interact with, certainly in the coffee session, of course, but also if there are questions which Moncef or Patrick feel are better answered by the various individual leaders, you will be hearing from them in that context as well. So just so you understand that is how you are going to, hopefully, get to dive into some of the detail.

Cautionary statement regarding forward-looking statements.

Now before I go into the session and the rest of the session, I draw your attention to the slide in terms of the various warnings and safe harbours.

Innovation is critical to maximising the potential of GSK in the current environment

Moving to the real focus of what we want to talk about, I just want to make a few introductory comments, very straightforwardly, orientating us within the overall context of the Group. The company has been going through a very significant amount of change over the last few years in the face of some quite tough challenges, particularly in 2014, and particularly in the era of moving through *Advair*. Clearly, over the last year or two, we have had to start to deal with price competition on *Advair* at a significant level and more generic competition around the world for us.

That has, clearly, been a driver of some of the headwind for us but the reshaping of the Group has been (a) to try to ameliorate that pressure as much as possible in the short

run but, much more importantly, to set the company up for long-term, sustainable growth as we move through that pressure and whether or not there is a generic over the next few years. We need to make sure we have a company which is vibrant and in growth post-*Advair*.

We believe that the three businesses that comprise GSK really represent three individual platforms for that growth. The transaction with Novartis really was about delivering scale in Consumer and an opportunity to transform the margin structure of that business, alongside maintenance of a very competitive growth rate. Over the next five years, we believe we can build something very special there. The Vaccine integration, similarly, gave us a very significant opportunity to broaden out our therapeutic coverage and achieve a significant quantum of synergy in the short run. You have begun to see how the transaction in Q3 has begun to really change the momentum of those two businesses.

What we are focused on here today then is really the Pharmaceutical and the Vaccine R&D portfolio in the sense of the R&D organisations really being the drivers of growth for the Pharma business specifically and, of course, for the Vaccine business alongside the transaction that we did. So we see innovation being pivotal to drive forward this part of the company. I am more than on the record to describe my anxiety about the ongoing price environment that we face around the world.

The challenges in the markets generally are common but we are beginning to see, over the last two years, much more precise risk in the US as not just legislation but also market change, partly stimulated by the Affordable Care Act, starts to change buyer behaviour, payor behaviour and consumer behaviour in the US. We can't take price increases for granted for ever and we need a business which can withstand those sorts of shifts.

Our belief is that the way to withstand that is to have a business which, of course, tries to expose itself to the price opportunity that exists, but also makes sure it's exposed to the volume drivers which exist both in the developed and in the emerging markets, which is why we are focused on that part of the business.

It is also important that the products that we develop are as robust as possible to achieve the maximum price benefit they can and that is all about differentiation. I am very pleased that in the portfolio you are going to see today, up to 80% of the molecules that we are going to describe to you we think could be first in class. That is important but we also believe that they are going to be differentiated from competition either at the molecular level, the claim level, the trial design or the delivery system level, so various ways we are looking to build into our products that kind of differentiation. We believe that having a scaled

Consumer Healthcare business, global leadership in Vaccines and an R&D business driving the future growth of Pharma, particularly as the *Advair* drag starts to recede over the next three or four years represents a very long-term opportunity of growth for the company, a very sustained opportunity of growth.

R&D strategy: reliable fill & flow with greater novelty & improved return on investment

If we look at what we have done in R&D over the last several years, you see this in your slide pack, this just summarises some of the changes that we have made in the business. First of all, you can see the process of accelerating the number of programmes. You all know we implemented with Patrick and Moncef a new discovery approach back in 2008, the DPUs. We said at the time it would take seven or eight years before you would really see much of an impact from that, because discovery is a long cycle business, you are now seeing a very substantial amount of product coming forward from that portfolio of research teams. We are very keen to allow those teams to do their work, have their chance to succeed or fail, but we don't let them fail forever and about two-thirds of the teams we began are still operative, the rest have been recycled and renewed with new ideas, it is exactly the kind of vibrant challenge that we wanted to build into the business. Of the work you are going to see presented today about a third was discovered by Discovery Performance Units inside GSK and about two thirds are worked on by those Discovery Performance Units, obviously in collaboration with outsiders.

I have already described the potential novelty of this portfolio, it is worth noting you are going to hear a lot about large molecules, you are going to hear a lot more about biological molecules, monoclonals, an area where the company hasn't necessarily been the leader, at the beginning of that science field, it is an area where we have invested significantly over the last several years to develop, we think, some interesting products, obviously *Nucala* where we are already in receipt of the positive opinion in Europe, anticipate FDA action imminently, *Nucala* is really one of the most exciting near-term opportunities for us in that particular area.

A lot of what you are going to see today was discovered inside GSK, there is an easy rhetoric to talk about how big companies don't discover anything, actually that couldn't be further from the truth, big companies, scientists inside big companies, discover enormous amount of product and GSK is no exception, but equally it is wrong to say that big companies only discover things internally, we have a very active collaborative research culture in the organisation and actually the split is about 60:40 in terms of where the products come from, and in terms of how we think about our discovery versus development focus about 60:40, and over the last seven or eight years we have been very focused on

taking fixed cost out of our organisation to allow us to develop our products going forward, so to move fixed cost to project cost has been a priority. That is why, over the last five years, nobody else has developed or filed or gained registration approval by FDA for more products than GSK, so we have been able to deliver a very substantial amount of product, while we have been able to control our R&D cost, because we have been taking out fixed cost and dedicating the resources to flexibility project cost. We will continue to do that.

Earlier this year we made the decision to close our research facilities in North Carolina, that releases a very significant amount of fixed cost, it has allowed us to spend more on projects, without overall increasing our expenditure. The Novartis transaction gave us a chance to unwire some of our fixed development cost which had built up around Oncology and some of the platforms, similarly giving us more flexibility.

As we look forward, we have, over the last few weeks, gone through a process where we have made a variety of decisions to stop investing in some of the products which are already on the market, where we believe there is not much utility in doing more work which generates more information in 2020 or 2022. The consequence of that prioritisation decision is we have created an envelope within our forward R&D spend over the next three years to accommodate the bolus of products that we are now seeing. So we think at least for the next two or three years we can absorb the likely cost of all of the progressions you are going to hear about today without a material change in the R&D budget, because we have made the choice to prioritise our investment in this portfolio.

New product contribution increasing as generic exposure reduces

As we think then about what does the next 10 years look like, you see the various phases of assets coming through, the group which came through, up through the end of 2014, that obviously includes the Oncology products that were then sold at the end of 2014 to Novartis, the batch which we have talked about generating at least £6 billion by 2020, the products we have launched last year plus *Nucala* and *Shingrix*, and then the next batch which, essentially, flow through from everything you are going to hear today; a very substantial amount of product we expect to be able to drive through the organisation.

Importantly, the drag on the company's Pharmaceutical business really diminishes as we run through that cycle.

New product growth more than offsets Advair decline

So over the last seven or eight years, of course, our Pharmaceutical business hasn't grown very much during that period, mostly because it has been burning off an enormous amount of genericisation assets in particularly the US. It is often why predicting or

understanding what the exact margin of this business is so complex, because it is easy to underestimate how much profit was skewed into that North American older business, but that business has gone now, the *Advair* price is moving through, there may or may not be a generic in the future.

Assets profiled at R&D day by planned filing dates

As we look through all of that portfolio you can see that the balance of growth delivery from the new products on a sustainable basis looks very different from the balance of drag that you would expect from the older products dropping out. Really for the first time since the creation of GSK the pipeline will have the opportunity to essentially be the contributor to growth, rather than the neutraliser of the drag before it contributes to growth, and that is a big shift and I think it is going to be a very notable point over the next five to ten years.

It is worth noting that after *Advair*, if indeed there is a generic *Advair*, the next material patent expiration for any asset within any of the forward forecasts that is imputed on this slide does not occur until after 2025, so you have an extremely long period of very calm water in terms of intellectual property protection. That is going to be very different picture to the picture we have been dealing with for the last decade and is a consequence of the focus we have made on innovative medicines and vaccines which we believe will give us sustainable growth going forward.

Just to reflect back to last week in terms of the Q3 results and really a proof point if I can put it that way, this just puts that schematic that I've just shown you into actual delivery over the last quarter and the last three quarters in fact, you can see the accelerating contribution.

New product growth more than offsets Advair decline

This is growth year-on-year, this isn't the absolute sales delivered by these new products in Q3 was £591 million, the year-on-year growth was £412. You can see that the drag, the year-on-year drag from *Advair* was £182 – bear in mind most of that was price because we are actually holding pretty big chunks of our volumes – most of it is price. That's the drag that we are having to deal with, but you can see that already the new products are significantly moving ahead of the drag and we would like to see that trend continue. We think it can continue at a pretty material pace as we go forward.

Assets profiled at R&D day by planned filing date

In terms of what you are going to see and how these products lay out over the time periods going forward, this is essentially hopefully a reasonably helpful sort of segmentation of when we think the filing dates are likely to come.

You can see here a summary of all the key assets and we all know not all of these assets will make it. This is the drug development business. There is inevitably an attrition rate, but this is our anticipation. Some things may go quicker, some things may go slower, there may be failures along the way but we think this is a pretty good estimate and of course we are not describing to you absolutely everything in the pipeline today in any case. It's simply a focus on the major projects.

I just want to make one point here. You will see that the first column says 2014 to 2017. I am well aware we are in 2015. The reason why it says 2014 to 2017 is because *Nucala* is on there and as you know, *Nucala* is still a filed asset rather than an approved asset and given its potential very substantial scale of opportunity for the company, that's why I've used the slide that way, so I think that's pretty straightforward.

Focus on delivering innovative and sustainable presence in 6 key areas

In terms of how that portfolio is essentially represented in how we focus in the company, we are focussed in R&D on essentially six areas - HIV/Infectious Disease, Respiratory, Vaccines, Oncology, Immuno-inflammation and Rare Disease.

These are the six focus areas of GSK. We are focussed within those six areas on innovative science. We focus on discovery ourselves, where necessary in collaboration with academia or other companies.

We believe that that focus on innovation will deliver a sustainable growth capability for the company. It's important to recognise that when we think about business development partnerships we have seen over the 15 years or so of the life of the company that the greatest value added transactions we can do are early stage, often academic rather than biotech, often platform rather than molecule. That doesn't mean to say that there aren't great molecules to buy in or partner with and it doesn't mean to say there aren't great late stage molecules to partner or buy in.

But generally speaking, the evidence that we've seen through our own actions over the last 15 years and looking at the rest of the industry is that it's better to focus on the earlier collaborations than the late and that's where our focus of partnering is.

Right now we have about 1,500 partners like that. We believe that's very important. Of course you don't necessarily see the outcome of that partnership in the next quarter or the next year but it absolutely drives the future value creation.

Great examples of that would be the adjuvant technologies, the cell and gene therapy technologies, those are examples of extraordinary early partnerships. The epigenetic collaborations we have with academia are unsurpassed by anybody else in the world and that's how we think about R&D. It's focussed, it's all about innovation and it's all about delivering a sustainable growth for the company, not just for the next year but over the next ten or 15 years.

Focus for today: Innovation to deliver products of value

During the rest of the day you are going to be led through these various programmes by Patrick and Moncef, the heads of our Pharmaceutical and Vaccines R&D businesses, two people who have been involved really from the start of the new way of doing R&D at GSK from 2008. They have been all over every decision that we have ever taken inside this portfolio.

The projects which have been killed have been killed because they have approved them and the projects that have been green-lighted have been green-lighted because they have approved them.

In the case of Moncef, his name is on some of the patents. You are not going to meet a researcher who has got more credibility around understanding the science, particularly in the vaccines field and in the case of Patrick you have one of the most accomplished academic physicians in British medicine. Again, you are going to go a long way before you find somebody who is better qualified to think about how medicines can be developed to change people's lives.

I have been incredibly privileged to have these two men on my team over the last seven or eight years and I am extremely proud of the work that everybody who works for them across all of our R&D organisations has done to move the company's R&D portfolio so far forward.

It gives me great pleasure now to ask Patrick to come up to begin the rest of the presentation and to start the day in full. Thank you very much. Patrick.