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GSK CEO Sir Andrew Witty
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Good morning, everybody, and thank you for your time to listen to the GSK presentation. What I'd like to take you through is really an update on how we see the company's evolution since the R&D Day that we had back in New York in November, progress since then on some of the R&D side, and the general company evolution as we go into 2016.

Progress through 2015 positions GSK to respond to global changes and maximise opportunities

So, in terms of where we stand as we move into 2016, the integration between ourselves and the various assets that we swapped with Novartis is basically concluded. Most of the work is done and has left us with three businesses, all of which we expect to now move into a growth phase. We laid out a whole series of shape points, if I can put it that way for how we see the business performing over the next four years or five years through 2020. I'll refer to some of those.

So let me make just an introductory comment that none of the commentary that we gave last year has changed in anyway. So we continue to reiterate all of the various statements and comments that we made last year. I'll specifically call out one or two of them, but as a general rule, if I don't mention it, it hasn't changed, and overall, we're sticking to all of the various statements that we previously made. You can see now that really for the first time the consumer and the vaccine business really represents a very material part of the overall business with pharmaceuticals accounting for about 60%. Obviously within that pharmaceutical business, the HIV business has beefed up. Over the last eight years, we've been working hard to try and take what was a subscale consumer and a small vaccine business into much more global businesses. Both of those businesses now have global leadership positions, very substantial global distribution capabilities. We feel very good about what we've built through that period.

The overall business is represented very nicely across the world. Obviously that brings with it the good and the bad. So while emerging markets are going well, great, we've got good exposure. When it's a little bit more choppy, then obviously we pick up some of the flak that goes with it. But overall, the balance we think is a sensible approach as we go through the next five years or 10 years of general global macroeconomic evolution.

In terms of our expectations for this year, probably the most important thing is to restate our expectation that we will reach double-digit earnings per share growth at constant currencies. We laid that out last year. We continue to believe that's very much achievable.

I'm going to talk today about some of the various performance indicators, but obviously using Q3 actuals since we haven't yet issued our Q4 actuals. So I'll be referring to Q3, but in the sense of what we expect for 2016, no change. We'd expect to reach double-digit CER EPS growth. That's been driven through a number of things going well, obviously the new businesses, the performance of new products which I'll talk to, performance in the HIV and Respiratory business in particular, strong performance in vaccines, underpinned by some very substantial financial discipline, significant synergy being taken out already and continue through particularly this year and into next year from the transaction and continued focus on reducing fixed cost within R&D, a lot of that done during 2015 and continues into 2016.

In terms of the dividend, we made it very clear that we expect to pay a dividend of £0.80 a share for financial years 2015, 2016 and 2017. In fact, for financial year 2015, so the payment that comes just after the February full year results, will be £1 a share because we'll also be paying a £0.20 special dividend after the transaction.

Significant growth from new products

So think about just for a second, the overall effect of new products, this is looking at Q3 data. What you can on the left-hand side is probably the key story in terms of our overall pharmaceutical business, which is what's happening to Advair and then what's happening to new products. Advair has obviously been a giant product for the company, extraordinarily important over a period now approaching 20 years, but clearly now coming towards the end of its life, quite rapidly declining. About half of Advair has already gone more or less from the peak sales of the product. So we're well on the way through the genericization of Advair. Most of that genericization effect up until now though has come through price pressure. So we've retained the lion's share of the volumes, but the prices have come down substantially in Europe and here in the U.S.

And you can see on the slide on the left that the contribution from our new products, those products which have been launched over the last 3.5 years is now far exceeding what we're losing in terms of the Advair drag. Now, you also have to add on to that other losses from established products, products like Lovaza. But again much of that now is moving behind us. And as we look forward, what we're really focused on is making sure that that new product growth contribution continuously exceeds the decline rate from Advair as we just roll through the next couple of years.

On the right-hand side, this is a GSK analysis of new product contribution, simply looking at products launched since January 2012 as a fraction of total pharma. So this excludes vaccines and consumer for all companies involved. And you can see that actually the representation of GSK new products very, very strong. Interesting enough, if you go back and do this analysis another way, and instead of looking from January 2012, you look from January 2010, the data looks more or less the same, J&J would be ranked number one, with GSK ranked number two. It's a very interesting analysis, when you look at the companies that look the most like us in terms of new products.

Now of course, why you don't see that in the top line of GSK over the last several years? It's a) the divestment of our oncology business, and b) the effect of the Advair drag and the generics of Lovaza. But as those things start to move behind us, then this underlying growth performance of the new products is going to come through much more.

Select key 2015 milestones

In terms of what we managed to get done in 2015, most importantly was closing the Novartis transaction I've referred to a couple of times, I will do again.

We've rolled out our new commercial operating model globally, what does that mean? That means our commitment to the way in which we pay our representatives is now globally established, and also our commitment to not pay physicians to speak on behalf of the company.

We believe those are very important elements of a long-term sustainable, commercial competitiveness. We don't think some of those elements that are necessarily sustainable in the long run. As regulators become more and more focused, and we think the right thing to do is to establish a new way of operating. We feel very good about how that's worked. And I'll show you some of the new product performances which they've underpinned.

All of our integration activities and all of our cost programs are on or ahead of schedule. So in terms of the synergy, the total £3 billion, which comes from all of the various cost reduction programs operating in the company, all of them are on schedule or ahead of schedule, and very substantial amount done already in 2015. The rest of it will be more or less completed as we run through 2016 with only a tail left in 2017, so going well.

Our key 11 new products, which were introduced over the last 3.5 years, underpin a commitment that we've made that we expect to deliver new product sales in excess of £6 billion by 2020. Again, very good progress being made on that, I'm going to refer to some of that. I think probably it's fair to say that we'd expect to now hit that £6 billion number maybe a couple of years early.

So I think it's more likely that we'll hit the £6 billion in 2018 than in 2020. That's obviously very positive. We're very encouraged by the very rapid progression of the new products, both in the marketplace, but also our confidence in terms of bringing forward the most recent launch of Nucala and also the potential filing later in the year for Shingrix. An R&D progress I will refer to, but we showcased I think pretty fundamentally a very substantial degree of pipeline opportunity now progressing forward both in terms of pharma and vaccine R&D.

Pharma 2015: new Respiratory products gaining scale

If we focus now on some of the new product performances, these two slides show you how Breo and on the right-hand side Anoro and Incruse are performing. Both of these products are critical to us in terms of establishing further growth in our respiratory business. We expect this year our global respiratory business to grow over 2015. And that's going to be driven largely by the performance of Breo, Anoro and Incruse, and obviously now Nucala just introduced.

Now, we all know that Breo and Anoro in particular had relatively slow start at the beginning of their time as we struggled to get full coverage in all of the key plants across the U.S. You can see here on both slides that both products now are moving very substantially. So, the higher line is new to brand. So this is essentially the most dynamic part of the marketplace. You can then see TRx and NRx underneath. Roughly-roughly in respiratory market, the NBRx to NRx lag is about 18 months, so it takes about 18 months for the NRx, TRx curves to catch to where the NBRx curves sit.

And you can see that in particular as we went through last year as coverage expanded and then especially as we gained exclusive position on the CVS contracts, we were able to move very dramatically forward with Anoro and Incruse. Now, just draw your attention on the Anoro and Incruse slide, you can see that in the dynamic sector, we're now taking about 24% market share.

So about one in four of every dynamic scripts are now coming to GSK. Remember that this part of the respiratory market is one we have never played, and we've never really competed in the Spiriva market place. And on the left-hand side, you can see we're up to about 12%, 13% share, taken the dynamic sets of Breo.

So we'd expect both of these products, all three of these products, but both of these categories to move forward very substantially this year. Particularly, as more of the plans, which we've just won, are only really just turning on in January and the New Year.

So we feel good and positive about Breo, Anoro and Incruse. We're seeing the same pattern reflected globally. So across Europe after slow starts, we're now seeing Breo perform better than recent launched analogs within the ICS combination marketplace. And if we look at Japan, where the Ryotan, the restriction on four-week prescribed has just been lifted. We've seen our dynamic market share jump up in the last six weeks from 4% to 12%. So Japan is looking very promising. And by the way, in Japan, we're now running at about a 20% share for Breo, Relvar.

So across the world, we're starting to see this move forward. Obviously, if I refer this back to that previous slide in terms of rate of gains versus rate of Advair losses, this bodes well for that potential ratio.

Pharma 2015: HIV growth acceleration

If I move to another part of the pharmaceutical business, the HIV business, this simply shows you the dynamic shares in the HIV marketplace, the solid red line is the dolutegravir products. So this is Tivicay, Triumeq, obviously a very strong performance last year. Dominique Limet and the team at ViiV have done an extraordinary job of rolling out dolutegravir worldwide, and we've seen extremely similar patterns in the majority of markets. There's obviously more data available in the U.S. and you can see on the right-hand side, just a little breakout of what's going on between the naïve patients.

The switch patients continue to have very high expectations for the continued performance of this product and there is no doubt that dolutegravir, Tivicay, Triumeq has played out as one of the most successful launches in HIV, and certainly one of the most successful specialist pharma launches over the last few years.

It's worth just mentioning, I did say earlier on that we were rolling out our new commercial model. The same rules, the same commercial model is used by the sales force in the organization that markets the HIV products, as well as the respiratory products. So all of those share gains I have just described to you have all been achieved using that new commercial model, which I think starts to dismiss some of the anxieties that some people have raised about whether that leads to a loss in competitiveness, I just don't think the evidence really supports that.

Pharma 2015: BMS transactions bolstering a leading pipeline with highly complementary assets

And in terms of some further business development, just before the holidays in the HIV area, we were able to close the transaction with BMS to bring over the BMS development assets and the discovery businesses into GSK. That integration obviously will start to go forward now once the regulatory clearances are all put in place, but that's an important step for us. So if you think about our HIV business, dolutegravir is obviously an absolutely key anchor to the success of that business.

Triumeq is the first development. There are whole series of combination products that are in development, there are moves towards dual therapies potentially. And by bringing in the BMS portfolio, that further extends our capacity to broaden our portfolio particularly into the refractory patients

initially with the attachment inhibitor. It also gives is a very strong bet now on the maturation inhibitor pathway, and then again on further combination products.

You then add to that the cabotegravir development programs, the opportunity to go to both oral and potentially parenteral long-acting treatment, both for treatment and potentially prevention. Those become very interesting drivers of value for our HIV business over the next several years. So if I think back to where we were five or six years ago with an older HIV business essentially beginning to genericize, clearly displaced by Gilead assets, and where we are today, I think there's been a very, very substantial turnaround in terms of the performance of this franchise. And I think what's very clear now, it's not just about one product, it's about a number of products in a number of different applications and we've got real opportunity here to drive a long-term business here.

Vaccines 2015: broad portfolio driving growth, realizing benefits from integration and ongoing investments

If I move briefly to vaccines, I just wanted to pull out a couple of very specific points. First of all, on the left hand side you can see the pick-up of the meningitis B vaccines; I think if ever there was a point of evidence to show that different assets can be managed and exploited in different ways by different owners, I think this business will prove out to be one of them. Our ability for example to win the UK mass vaccination tender within two weeks of taking control of the business was just an example of how GSK with its scale as a vaccine leader was able to get things done which previous owners had not been able to get closed. That alongside the general global rollout of the meningitis vaccines is really developing now, I think, into a very major vaccine opportunity for us.

On the right hand side you can see the data from the Shingrix program. We expect to file Shingrix later this year. We're very, very optimistic about this vaccine. As you know we've now got both of the big Phase III trials in, they essentially replicate each other. To show we have a vaccine here which gives tremendously high protection levels up in the 90% to 97% levels, essentially almost eliminating the fear of having shingles, almost eliminating the risk of having post-hepatic neuralgia, at an extremely significant promise versus what's out there today, builds on a vaccine which has large scale industrial manufacturing capability, no issues around live virus limits, all of those things which have limited other competitors. So we fully expect this to be a very significant product offer for patients. We think it's a very good bet for people to potentially be vaccinated relatively early in the age cohort because of its very high persistence and its ability to provide protection way into advanced years into 80 years plus as it appears not to see any waning in that later age population. All of that we think plays well.

We have a very high production capacity which we think will allow us to roll this now onto a much broader global platform from the current market which is essentially in about only four countries. We've also had a good year last year with our flu business. We've spent a lot of time to try and bring forward our flu manufacturing capabilities. What that allowed us to do as you have seen is ship most of our flu vaccine in Q3 that proved to be a very fortunate thing to do given that the flu season this year has not been quite so dramatic as in prior years. And therefore, we wouldn't expect necessarily the Q4 flu market to be so robust. Having got in there earlier allowed us to good prices; good volumes and we had a good year there from a flu perspective.

Consumer 2015: innovation and geographic position driving growth, focus on accelerating integration

And the consumer business, obviously a central piece of the Novartis transaction, working very well with our partners in Novartis, I think we've really been able to build a business where we brought the best of both organizations' people together. The leader of that business comes from GSK, although five years ago she was running the big piece of L'Oreal. And the number two person in that business comes from Novartis, although his career started at Procter & Gamble. So we've got really strong, really true consumer leadership at the top of that organization and that reflects all the way down through that business, very substantial business. This is a business where we expect to see the margin more or less double over the next five years. We fully expect to get to a margin of at least 20%. I know a lot of people in the world say, why don't you say 22% or 23%? I would just remind you of the words at least 20%. So we're very committed to drive this margin as aggressively as we can. We think this is a mid-single-digit sales growth business on a very big number. So this is a big business, £6 billion, £7 billion business, growing mid-single-digits with a margin potentially expanding from where we started around 11%, 12% to at least 20%. We think that's going to be an important growth driver for the organization.

If we look this year, most successful OTC switch with Flonase here in the U.S. You'll have seen in the numbers during the first three quarters, very strong performance. It was an extraordinarily successful switch. To give you an example of what we were able to pull off and execute which by the way was being done just at the moment that we were integrating with Novartis. There was something like 25 miles of Flonase-branded shelving installed into U.S. pharmacies for the launch of that product. So, it just gives you a little bit of a sense of the scale of what actually goes on. And let me just reassure you not all 25 miles were in the same shop, that they were spread broadly across the United States and that what's really driven that business. Overall, this business again has a very nice geographic exposure. We are significantly tracking ahead of where we hoped in terms of integration speed, and so far so good.

R&D strategy: focus on long term sustainable innovation

In terms of R&D, we updated people back in November on the R&D organization. There’s a real focus on acceleration of moving products forward in the organization. Our DPU structure we believe works very well. About 60% of the DPUs that were set up at the beginning in 2008 still exist. We have a rotation every three or four years where we clean out those who we think are failing. I've seen many of the people stay. So just because the team gets or the project gets closed, doesn't mean the people lose their job. Sometimes it does, but that's not necessarily the case. It's often the case that a good person happens to be on a failing project and they can learn a lot from that. So this is not about necessarily losing the people, but there's always a rotation and discipline to clean up the quality of the projects. Overall, about 20% get turned over every three years. About 65% of everything we now have in the clinic came from those DPUs and it's about 60:40 in terms of a split between inside and outside origination.

The DPUs are completely free to collaborate externally. They don't have to do it all themselves. So sometimes the starting material will come from outside of the company. Nonetheless, we're seeing about a 60:40 split between the inside and the outside of the organization. And as we look our pipeline today, about 80% of what we have in the clinic we think is capable of being about first-in-class, whether we're actually first or not, we'll see but we're going to be there or thereabout. So it's a more innovative pipeline, substantial pipeline and it's been driven off a lower cost base.

In 2008, we had five global R&D – let's call it R&D centers of the 1990s; big, massive, fixed-cost infrastructure. Today we have two. We worked very hard to try and make our investment into R&D much more flexible, it's allowed us to put much more pressure behind the projects and move things through more quickly. We've seen a drop in the speed – sorry we've seen an acceleration in the speed, a drop in the time it takes to bring products to market. And I think one of the key metrics for us over the last wave of 11 products is every single product was approved first pass by the FDA. So that says something about the quality of the dossiers and the quality of the science which is going into the assets.

Our R&D is focused in six key areas, vaccines and then the five R&D therapeutic areas you can see on the slide here.

Potential to file up to 20 assets by 2020

Those are the areas where we have the majority of our activity and I'll just touch on some of that very briefly, gives you a snapshot of everything that's coming forward. We've said we expect to file about 20 products between now and 2020. If I pick a couple of particular areas in oncology and the team are here today and in the Q&A session next if anybody wants to talk to or either Axel or Chris or Patrick Vallance, people who are leading all of these projects.

Progress in Oncology

We've seen continued very strong progress in our immuno-oncology epigenetic field as well as the cancer stem cell, where you can see here the number of novel targets. Obviously we divested our marketed kinase inhibitor small molecule business to Novartis in the transaction. We got full value for that and we think that that business was better managed by Novartis, but we continue to retain full ownership of all of our novel discovery areas. That's an area where we believe having not been a participant in the initial checkpoint inhibitor discoveries, we think we can play a significant role in bringing forward some of these more novel targets, and you can see here an almost unparalleled portfolio of novel targets. What you've seen during the last few months is some significant partnering activities with companies like Merck to make sure that we get the right partnership programs in place to get the right proven of each of these molecules.

Having divested that marketed oncology asset, we see ourselves very much like a biotech company in this space. So, we're not stuck having to justify our products against existing GSK products. We don't feel obliged to spend money defending the old products. We don't feel obliged to do clinical trials with our molecules just because we own them. We feel completely able to be promiscuous in terms of how we think about how we partner these assets to get the absolute best definition through the clinical trial phase and then we're completely free to how we commercialize and whether we do it on our own, whether we do it with Novartis or whether we do it with anybody else. There are steps we have to go through of course, but we are essentially fully unencumbered to be able to do what we want to maximize the value of these assets.

2016 return to growth

In terms of then the overall outlook for the company in 2016 from a business performance, we expect to, as I've said already, deliver an EPS growth reaching double digits at CER level. New products continue to be very important to us. As I've said already, I'd expect us to hit the £6 billion new product milestone

a couple of years earlier than we've previously indicated. So, probably more like 2018 rather than 2020 as we've seen the continued ramp-up of those products go very well.

The launch of Nucala is going to be an important opportunity for us this year, introduced in the U.S. just in the last few weeks of 2015, so really too early to say. But I would say, given that most patients that come in through the GSK portal to get their reimbursement sorted out while the product's on a [indiscernible] (24:26) allocation, we've seen a very strong engagement. We've had a lot of patients come through. I think in the first three weeks we had something like 1,000 patients already come through the system. We've seen already something like 60%-plus of the initial inventory load has already been shipped to patients. So we're expecting Nucala to have a very good start here in the U.S. All the signs look very, very promising. And of course, we're going to be rolling out worldwide as we go through the rest of the year.

We have a very important, although relatively small commercial milestone heading our year which is the potential approval for ADA-SCID as the first gene therapy replacement program. It's not a big financial thing but it's the first of a whole series of gene therapy programs that we have in the company. Initially, that will represent itself through other rare diseases as we move through into 2018-2019 window, but it is also, as you know, being deployed very substantially in oncology as well for us through a series of technologies not least with our Adaptimmune partner. So I think we will see some very significant progress this year. And getting that first approval of this type will be at a major milestone for us in terms of signaling where the future goes.

R&D is going to be another busy year, a lot going on, cabotegravir in terms of long-acting HIV is going to be important. The IL6 program, great data came in just before the holidays continue to see that, concluding during the year, the filing of Shingrix, a lot happening, data coming in from SALFORD on Breo; and as you saw from R&D, there are a lot of other programs coming through but those are just a few of the highlights, and awful lot happening in immuno-oncology and epigenetics with a whole series of programs either going for the first time to the clinical or progressing through the phases during the year.

And then from a financial point of view, guidance remains exactly as we previously stated it. Everything in terms of our cost controls feel like they're on track or ahead. The integration is on track or ahead. And our new product performances look like they're moving into the phase. We want them to be after an admittedly slow start in 2014 and the beginning of 2015, and I reiterate our expectation of the dividend is going to be paid in 2015, 2016 and 2017 at a rate of 80 pence a share, with an additional 20 pence a share to be paid in the upcoming 2015 dividend.

With that, I'd like to thank you all for your attention and look forward to any questions you might have in the next room. Thank you very much.

Cautionary statement regarding forward-looking statements