

AstraZeneca PLC Second quarter and half year results 2014

31 July 2014

Pascal Soriot - AstraZeneca PLC - CEO

Good afternoon, everybody. I'm Pascal Soriot, and I'm joined today by Briggs Morrison, our EVP of Global Medicines Development and our Chief Medical Officer. I also have with me Marc Dunoyer, our CFO; Mene Pangalos, our EVP of Research and Early Development at AstraZeneca; Luke Miels, our EVP of Global Product and Portfolio Strategy. I also have with me here a number of members of our investor relations and our finance teams.

Thank you for joining us today and giving us the opportunity to spend a short time updating you on the second quarter and the half year, and reiterating our commitment to achieving scientific leadership and returning to growth.

We have posted a set of slides on the investor page of our website and we'll follow along with this presentation. We'll try to give you the slide number as we go through.

If I move to slide 4, I will provide a brief overview of our financial performance to date, and as we promised, I'll provide the quarterly update on our strategic priorities. I will then hand over to Briggs, for an update on the progress we've made on our R&D pipeline, and finally to Marc to run through the financial performance in more details. And we'll also give you an overview of the deal we announced yesterday with Almirall. I'll then give my closing remarks before opening up for questions.

Moving on to slide 5, starting with our second-quarter result, it has been another quarter of significant progress. We've seen genuine momentum across our business. I'm particularly pleased to note this is our second consecutive quarter of revenue growth.

We had sales of \$6.5b in the quarter, which was up 4% at CER. We've also grown core EPS by 13% in the quarter. This reflects the good work by the teams across AstraZeneca in successfully executing on our strategy.

I would also like to highlight the second consecutive quarter of double-digit growth in the emerging markets, one of our key growth drivers, and over 23% growth in China, where we continue to outpace the market.

We've also seen strong progress from our younger brands this year, including the successful launch of Farxiga in the US, our treatment for adults with Type II diabetes which we launched in early February.

Yesterday, we announced a deal we are progressing with Almirall, which will be important to bolster the growth of our respiratory franchise. Marc will outline the key financial details and the new assets we'll benefit from in his presentation. I'm really looking forward to welcoming the new colleagues from Almirall who will join AstraZeneca.

Turning to scientific leadership, I'm pleased to report that this has been another productive quarter for AstraZeneca. We've had the opportunity to provide updates on our rapidly progressing pipeline at various congresses in May and June, including ATS, the ASCO and the ADA. We now have a total of 14 compounds in our late-stage pipeline, on which Briggs will give you a more detailed update. This has increased from last year, when we had eight compounds in Phase III or registration.

Significant advancement has been made in our immuno-oncology portfolio since we presented the pipeline update at Q1. As you know, this is one of our key scientific areas and one of the most exciting growth areas across our entire industry. During the quarter, we also had a positive advisory committee vote for Movantik and look forward to an FDA approval decision in September.

You will have seen the recent FDA vote on olaparib, which of course was a disappointment. However, our discussions with the FDA continue. The agency has now extended the review time by three months to early January, after we submitted a major amendment in July.

Let me turn to slide 6. You can see key data for the first half. We had revenue growth in all key regions except in Europe, where we're still facing price challenges and generic challenges. The emerging markets, however, grew in double digits, with China being the key driver at 23%. We also had good 26% growth in Russia.

In Europe, as I said, we continued to face the effects of loss of exclusivity on key drugs as well as pricing challenges.

In Japan, we've seen strong underlying demand for our recent launch brands, but overall growth is only marginally up over the half year. I will talk about that later.

Core EPS for the Group was marginally down over the first half of the year, with a 13% growth for the quarter.

Slide 7 is a reminder of the three key strategic priorities we've outlined for AstraZeneca. I will now review the return to growth platforms in more details before Briggs gives his R&D update.

If we move to slide 8, I'm pleased to say that our five growth platforms contributed \$6.8b of revenue during the first half of the year. That is an increase of 14% here. I will shortly review each one of these in more details.

If you look at slide 9, it's important to note that our revenue performance is helped not only by the growth platforms but also by the resilience of some of the mature products, like Pulmicort and Crestor, essentially driven by the emerging markets. This has helped us offset the effects of the loss of exclusivity of some of our off-patent products.

On slide 10, if we now take each of these growth platforms in turn, I'll look first at Brilinta on slide 10, on this slide, which has continued to make good progress in Q2, with revenue up 77% globally. Brilinta has seen good uptake in Europe, in the emerging markets and the established rest of the world, and we continue to hold leadership positions in a number of our European markets and elsewhere. What is nice to see is that the US was the fastest growing area in the second quarter and we're making good, steady progress in the United States.

You can see on slide 11 that we continue to take market share in the US, and the new-to-brand market share was around 7%. We've always believed in the potential of this product, and we are pleased with the steady progress it continues to make with our ongoing investment.

And slide 12 gives you a little bit more of a granular view of the product. We can see improved momentum for Brilinta in hospital initiations as a share of the total anti-platelet market.

It's really pleasing to see the figure on the right, which shows the recent good share performance among STEMI ACS patients who are discharged from hospitals. During the last quarter, Brilinta has overtaken Prasugrel in this setting. So we have now renewed momentum, even though the DoJ investigation is not yet totally concluded, and we are looking forward to a conclusion of that investigation in the near term, hopefully.

Slide 13, looking now at diabetes, we've seen strong performance over the quarter. We focused on the successful integration of BMS' assets and the excellent US launch of Farxiga, which so far is one of the most successful launches in the overall non-insulin anti-diabetic market since Januvia. Onglyza, Byetta and Bydureon have also grown on last year, but Onglyza has seen a 0.3 point share decline in total prescription share in the quarter.

If we look at slide 14 now, which gives you a view of the Farxiga, you can see the launch aligned new prescriptions volume uptake of recent launches for Type II diabetes in the US. Farxiga is the blue line and is striking very nicely during the first five months of this launch.

If you look at the right-hand side of the slide, you can see the effect of the Farxiga launch on the monthly new prescription volume in the SGLT-2 class, and the figure shows the growth of the class since the launch of Farxiga. So we're not only taking share from our competition; we certainly are growing the class, which is a very exciting class of new oral agents.

Then you move to slide 15, to outline the strong performance of Symbicort in the first quarter -- in the quarter, which I'm pleased to report has continued from Q1, as seen on slide 15, and is up an impressive 30% in the US and 9% globally. In the quarter, the US price was broadly flat for Symbicort.

Symbicort sales in Europe are down 7%, due to competitive and pricing pressures in the market. We see now the introduction of analogs and the development of sales in Europe is as per our expectations. This is, however, somewhat offset by strong double-digit growth in the emerging markets, with revenues in China more than doubling, and the potential for Symbicort in China is very important.

If you look at slide 16, and we look more closely at the Symbicort performance in the US, you can see the new-to-combination therapy market share is up to 37.7% in the US, 3.8 share point increase in the first half. Total prescriptions in the US were up 32% for Symbicort in the quarter, compared to a mere 2% increase for the fixed combination market.

On the slide 17, I have already mentioned our strong performance in the emerging markets for the second consecutive quarter, but if you look at the slide you can see how our growth in China compares to the rest of the industry. We are outperforming our competitors.

We, as you know, are the second largest pharmaceutical -- international pharmaceutical company in China, just behind Pfizer, and we have the highest growth rate as of first half of this year. Actually, it's as of May. The purple bars show the growth in May and the green bars denote the growth in China year to date by the end of May.

On slide 18, if you look at the total moving annual total sales in China from the beginning of 2013, you can see how AstraZeneca, in purple, continues to outpace the rest of the market. We have a strong portfolio and strong team in China, and our investments in the country are bearing fruit.

I'm also pleased to say again that we had very strong growth in Russia as well; we grew in Brazil. So it's not only a success in China. We experience nice growth in a variety of emerging markets.

Slide 19, looking at Japan, we've seen positive underlying demand for our launch brands in Japan. Crestor, Symbicort, Nexium have shown good market share progression. We posted only 1% here growth in the first half. However, we saw 8.4% in market growth by the end of May year to date.

Our performance -- our in-market performance, however, has been impacted by the price reductions in April this year. We've also been impacted by the increased use of generic medicine in oncology, which has impacted our oncology brands.

But finally, I'm pleased to report that Forxiga is off to a good start in Japan. It's still early days since the launch in May, but the early signs are quite positive.

So I will conclude my initial remarks and now hand over to Briggs to take you through our exciting pipeline, after which Marc will discuss the quarter's financial highlights. Briggs, over to you.

Briggs Morrison - AstraZeneca PLC - EVP Global Medicines Development & Chief Medical Officer

Great. Thank you very much, Pascal. I'm pleased to be able to report on our pipeline progress over the second quarter and the first half of the year, and to give you some guidance on items you want to track as the second half of the year unfolds.

If we go to slide 21, I'd like to first note that we continue to make really good progress in growing our late-stage pipeline. On the left side of the slide, I show new pivotal programs that have started in the second quarter.

Roxadustat has started Phase III trials both in chronic kidney disease and in patients with dialysis. We've decided to increase the sample size of our randomized Phase II trial with our CTLA-4 antibody tremelimumab in mesothelioma to support a possible registration. And we've started Phase III trials for both 9291, our third-generation EGFR inhibitor, and MEDI4736, our PD-L1 antibody in non-small-cell lung cancer.

We've also started additional indications for a Phase III program in COPD for our anti IL-5 receptor antibody benralizumab and an adjuvant trial in BRCA mutant breast cancer with our PARP inhibitor olaparib.

As Pascal noted, as a result of these progressions, you can see on the right-hand portion of the slide that we now have 14 new molecular entities in pivotal studies, up from eight at this time last year and up from 11 at the beginning of this year. We are of course extremely excited about this progress, and our colleagues all across MedImmune and AZ are working diligently to deliver these programs.

If we move to slide 22, we've had continued momentum in the late-stage pipeline as measured by regulatory milestones, a number of accomplishments. The approval of Epanova in the US. The favorable vote for Movantik, indicating that for this class of agents we do not -- the FDA is not going to require cardiovascular outcome trials. AZD0914, a drug for drug-resistant gonorrhea, gained fast-track status from the FDA.

Bydureon Dual Chamber Pen received a positive opinion from the CHMP. I'll note that's a little bit earlier than we thought. In the first quarter call, I told you I thought that would happen in the fourth quarter. It happened a bit earlier. And we filed for Bydureon in Japan.

As Pascal noted, we of course were disappointed in our negative AdCom vote for olaparib, but we have submitted additional data which the FDA is reviewing and they've extended the PDUFA date till the end of -- to early January of next year.

I use slide 23 simply to turn our attention to our immuno-oncology effort. This slide simply highlights that in a patient with cancer there may be one or more obstacles to an effective immune response, and we are seeking to understand and address as many of these obstacles as we can.

There are a number of ways to theoretically improve antigen presentation, on the far left of this slide, including a recent clinical collaboration we have announced in the second quarter with the Advaxis HPV vaccine. We are clearly fully exploring mechanisms that can enhance T-cell function and memory, on the upper right of this slide, with PD-1, PD-L1 and CTLA-4. And we've entered into two additional collaborations both with Incyte, KHK to explore blocking known mechanisms that exist in the microenvironment of tumors to inhibit immune activity.

I want to note here that our approach is to explore as many of these potential obstacles to an effective tumor response in small Phase I and II trials that are designed and conducted by our translational scientists at MedImmune. These clinical investigative trials allow a detailed analysis of pharmacokinetics, pharmacodynamics and, importantly, relevant tumor biology.

As the science is advanced in these early trials, we then move the programs into our late-stage group, which is really focused on designing and conducting registration trials. These registration programs could be single-arm, uncontrolled Phase II trials, or they could be larger randomized trials.

If we go on to slide 24, we show on the left side ongoing trials in our immuno-oncology portfolio. Now, some of these are these early translational trials that I just referred to. Some of them are Phase II or III registration trials. And the asterisks indicate new trials that have initiated since ASCO.

On the right side of the slide, we show trials that are currently in the planning stage, but could start in the second half of this year. And again, there's a mixture of these early translational trials as well as more advanced registration trials, again with the asterisks indicating new plans since we discussed the immuno-oncology portfolio with you at ASCO.

I'd like to emphasize one set of new planned trials, and that is the registration program in squamous cell carcinoma of the head and neck region.

If you go on to slide 25, at the top of this slide is a before and after picture of an elderly patient who had a significant response to our PD-L1 antibody MEDI4736. We anticipate that a paper will be presented at ESMO that will summarize the safety and efficacy of MEDI4736 in a cohort of patients with squamous cell carcinoma of the head and neck region.

This data that will be presented at ESMO has encouraged us to plan a pivotal program in this tumor type. So we have plans for a pivotal program with both PDL-1 monotherapy and the combination of PDL-1 plus our CTLA-4 antibody tremelimumab. We will be exploring both PDL-1 positive patients as well as patients who have tumors who do not stain for PDL-1.

We are in ongoing discussions with regulators to inform the final set of designs, but I want to highlight to you that we believe that these trials will start in the second half of this year, and we'll give you further details on the head and neck program at ESMO.

If we move to slide 26, I wanted to spend a moment on highlighting our participation in what we think are really very exciting novel collaborative trial designs, one in the US and one in the UK. In both of these studies, we are really seeing the future of the practice of medicine, where patients' tumors are molecularly characterized and specific medicines offered based on the specific molecular defects identified.

On the top of the slide is the so-called lung-MAP trial, which is a very nice trial put together by FDA, NCI, Friends of Cancer Research, in which patients with squamous cell carcinoma of the lung are genotyped, and depending on the specific mutations that are found in their tumors, they are put into one of different treatment groups.

So, for example, if the patients have abnormality of the FGF receptor, they will be randomized in a Phase II portion of the study to our drug AZD4547 versus a standard of care docetaxel. If there's a signal in that Phase II portion, this is a seamless Phase II/III trial, the arm is then expanded into a Phase III registration trial. If there is no activity, then that arm of the trial can be stopped.

Similarly, you'll see on the bottom of this schematic, for patients who do not have one of the four currently identified abnormalities in their squamous cell carcinoma, those remaining patients will be randomized to our PDL-1 antibody versus docetaxel, again in the Phase II portion. If there is a signal seen in progression of free survival, that will extend out to a Phase III trial in squamous cell lung cancer.

So, again, we've used a very innovative design. We really applaud NCI, the FDA, Friends of Cancer Research, for putting this together. A very similar program has been put together in the UK, again where we have patients who are molecularly genotyped. We've contributed a number of molecules to the Cancer Research UK trial to do a similar type of thing in the UK.

So, again, we just want to highlight a great opportunity for very innovative trial designs, and we're eager and excited to participate.

Now, I'd like to move away from oncology just for a moment to talk about some other molecules in our pipeline that we're quite excited about. I'll talk about both Movantik and roxadustat.

So, on slide 27 is some information on Movantik, which potentially could be the first once-a-day oral peripherally acting mu-opioid receptor antagonist for treatment of opioid induced constipation.

On the upper right-hand side of this slide, you'll see some data on the frequency of opioid induced constipation amongst patients treated with opioids. So about 80% of people who get opioids will develop opioid induced constipation, and about half of them do not in fact achieve a desired treatment outcome. It's that half of patients that we believe that Movantik offers a new therapeutic option.

On the upper left-hand side, I've just summarized the primary efficacy end points. You will have seen the reporting of the pivotal Phase III trials in The New England Journal in June of this year. This is a quick summary of that, and so we are very excited about both the efficacy and the safety of this compound.

On the bottom of this slide are the anticipated key regulatory milestones. On the far left, you'll see that we -- how the Advisory Committee were again -- the Advisory Committee recommended to the FDA they do not need see the outcomes of trials prior to approval. In the third quarter, we anticipate a potential approval in Canada, and our PDUFA date is September 16 here in the US. We should potentially get EU approval as well before the end of the year.

Now, I'll highlight that the launch for the US is not until the end of the first quarter or early second quarter of next year, and the reason for that gap from the approval, we hope, anticipated approval in September until the launch has to do with the scheduling of this drug. Remember that Movantik structurally is related to opioid. It is an opioid antagonist, and as such must go through the DEA process on scheduling.

Now, our assumption, of course, is that it will not be scheduled, but it must go through that process in addition to the actual FDA approval. That process will take a little bit of time, and that's why we're anticipating -- and that process must be completed before we can launch the product. And that's why there's a gap between the actual planned anticipated approval in September and the launch at the end of the first quarter or second quarter.

If we move to the slide 28, I just want to again remind you about roxadustat, a compound we're developing in collaboration with FibroGen.

On the left-hand side is a diagrammatic slide to emphasize that this molecule, although it does induce local production of EPO, it has a number of other mechanisms that allow in a very coordinated way the treatment of anemia of chronic renal disease. And therefore we believe that the levels of EPO that are induced by this molecule are considerably lower than they are with recombinant EPO, which we believe could be of aid both as oral agent and a better safety profile than recombinant EPO.

On the right-hand side of the slide, just to highlight the number of patients with chronic kidney disease in some of the major markets and the percent of patients with various stages of chronic kidney disease who will develop anemia. It is a very important unserved medical need.

And we're excited, if we go on to slide 29, that we have now begun some of the -- our components of the Phase III program. The Phase III program is a very large program conducted by us and Astellas and FibroGen, characterizing both the safety and efficacy of the compound.

Two key programs that we have undertaken have started in the second quarter. One is in patients who are not on dialysis but have chronic kidney disease. Those patients are randomized to placebo versus roxadustat, and the primary end point here is major adverse cardiovascular event, cardiovascular death, stroke or MI. And the intent here is to show that roxadustat has an event rate comparable to placebo.

And the second trial is in patients who are already undergoing dialysis, where the standard of care is EPO. And there the patients are randomized to roxadustat versus EPO. Again, the primary end point is MACE and the anticipation is that roxadustat will have a lower incidence of MACE than EPO.

As you can see on the far right of the slide, it will be a couple of years until we have the results from these trials, but we are very excited and encouraged to be getting these trials underway.

If we move to slide 30, this is the slide that I showed you, a version of this slide, in the first-quarter call. On the far left are the pivotal study starts. This is now a summary for the first half of 2014. I think I've talked about all those pivotal study starts at this point.

In the middle are pivotal study decisions that we have made in the first half, and I'll just highlight here the Forxiga Type I diabetes indication, where we've decided to progress that into a pivotal program. And as I've mentioned earlier, 9291 -- no, I did not mention it. 9291 in first line non-small-cell lung cancer, we've made that decision to undertake that study and the study should start the end of this year. And then the two bottom ones, the PDL-1 plus or minus tremelimumab program in squamous cell carcinoma of the head and neck, and PDL-1 and tremelimumab in non-small-cell lung cancer.

I'll also note that on the far right we still have additional molecules that are completing their Phase II programs which we may be able to make additional investment decisions to progress yet additional molecules into Phase III before the year is over.

Moving on now to slide 31, I just want to highlight a couple of congresses that are coming up. The European Society of Cardiology Congress in Barcelona at the end of August, beginning of September; I'll highlight this one trial from Brilinta which you may want to take a look at when it's reported out.

This was an investigator initiated trial in which they asked the question if you start Brilinta earlier in the ambulance, could you improve TIMI flow and ST-segment resolution, so the patients are randomized to get either Brilinta or Brilinta at the normal time. And we encourage you to take a look at that. That will be at ESC Hotline Session in September. We have a number of other abstracts that have been accepted, and we think for those of you who are attending, we ask you to look forward to those.

On slide 32, I'll also highlight ESMO, which will be held in Madrid in September for immuno-oncology. We'll be presenting abstracts on additional monotherapy data, both in non-small-cell lung cancer and, as I alluded to earlier, in head and neck cancer.

You'll remember at ASCO we did not actually present at the scientific session our PDL-1/CTLA-4 combination data in non-small-cell lung cancer. We presented a very high-level summary at the investors' meeting. But this will now be presented at the scientific session, with abstracts there. There will be more patients, further dosing cohorts, some information on the biomarker status and some additional information on tremelimumab CTLA-4 inhibitor in mesothelioma.

There'll also be updates on 9291 in non-small-cell lung cancer, including with the duration of response -- of data on duration of response in the T790M second line population, and some data on patients who've been treated with 9291 in a first line setting and patients with brain metastases.

Now, as the year unfolds, on slide 33, there are some significant data readouts. The first three lines here are lesinurad, CAZ AVI, brodalumab. The data readouts here will define for us the actual profile of these exciting molecules.

For lesinurad, you'll remember that we talked with you about the monotherapy data that came out end of last year, where we did see an increase in renal adverse effects from lesinurad. We've talked about the scientific reasons why lesinurad in combination, which was the additional trials coming out now with febuxostat or allopurinol, potentially will have a lower incidence of adverse renal effects. Obviously, what we don't know until the data reads out is whether those adverse renal effects will be the same as placebo.

And so we're still -- we don't know what the profile will be here for lesinurad. I will just note that we do have a second generation molecule against the same target, 3170, which we've talked a little bit about with you previously, which at least in preliminary studies looks to have an even better renal safety profile than lesinurad. So we'll know very soon what the profile of lesinurad is in treatment of gout.

The CAZ trial, the initial trial in complicated intra-abdominal infections, should read out in the third quarter. And in the fourth quarter, the data -- the additional Phase III data from brodalumab, these are the head-to-head trials against Stelara.

The other molecules on the slide I think we've talked about previously, and I've highlighted for you congresses where there'll be more information on the molecules.

On slide 34, we have some additional key regulatory milestones. The filing of Iressa for non-small-cell lung cancer in the US. Hopefully the approval of Movantik, PDUFA date is September 16, and signs are looking positive with our interactions with the FDA that that will be a successful approval. We're also on track, as I noted earlier, for the approval of Movantik in Europe.

We are still under review in Japan for the potential approval for the ACS indication for Brilinta. I've talked already about the olaparib delay to the PDUFA date until early next year. We are on track for an approval of -- for Xigduo XR, the combination of metformin plus dapagliflozin in the US.

And then the three lines -- I'm sorry. The saxagliptin fixed dose combination filing at the end of the year. And then both lesinurad and CAZ AVI, depending on the data readouts, we would be on track to file both in the EU and US for lesinurad and in the EU for CAZ AVI.

And slide 35 is a slide I've shown you a number of times of the potential new molecular entity and lifecycle extension submissions. The only thing I want to point out here are the things that have changed since we showed this to you at the end of the first quarter.

One is AZD9291, where we now believe we will be able to file that in 2015. Our base assumption right now is that it will be in the second half of 2015. And based upon the work that we've been doing in our non-small-cell lung cancer program with MEDI4736, if the data reads out as we anticipate, we will be on track to file that in 2016.

So I'll stop there and turn things over to Marc.

Marc Dunoyer - AstraZeneca PLC - CFO

Thank you, Briggs, and good afternoon, everyone.

Today I will provide a little more detail on the drivers of the headline result for the second quarter and investment we are making in our growth platforms and rapidly progressing pipeline as we work towards returning AstraZeneca to growth. I will also discuss the key drivers of operating profit and margin, and briefly comment on the impact of exchange rate movements against the prior-year period. As Pascal said, I will give you an overview of the key aspects of the deal we announced yesterday with Almirall.

Turning to slide 37, we can see that revenue for the second quarter grew by 4% at constant exchange rates to \$6.5b, our second consecutive quarter of growth. The currency impact on second-quarter revenues was negligible. It was more of an impact at the bottom line. Core EPS for the quarter was \$1.30, growing by 13% at constant exchange rates. The impact of foreign exchange lowered core EPS by 5 percentage points.

I will now turn to the P&L for the quarter, and I will focus here on core margin and profit. The press release contained the statutory numbers and a detailed reconciliation to the core measures. As a reminder, when I refer to growth rates they will all be at constant exchange rates.

Core gross margin was 82.1% of revenue. There are a number of moving parts in the quarter, but as was the case in the previous quarter, the benefit from lower Crestor royalties was more than offset by the inclusion of diabetes related costs.

Core R&D expenditures were up 12% to \$1.2b in the second quarter. Having nearly doubled our late-stage portfolio over the last 12 months, together with the strong progression across all stages of development of oncology portfolio, there is pressure on our cost base. We are focused on delivering the pipeline to drive long-term value and are continuing to seek ways to contain costs.

Core SG&A expense was up 13% compared with last year. The increase in SG&A was driven by the inclusion of all the costs associated with the diabetes portfolio, as well as the investment behind the launch of Forxiga in the United States and continued investment in the emerging markets, and in particular China. This increase in sales and marketing investment is not mirrored in the G&A, which declined in the quarter.

Core other operating income for the quarter increased by 120%. This growth was driven by milestones related to the launch of Nexium OTC in the United States and Forxiga in Japan, without which other income would have declined.

Core operating profit was \$2b, 2% higher than last year. Core operating margin was 31.5% of revenue.

I don't intend to go in detail on this slide for the first half, since many of the drivers are the same as those discussed for the quarterly margin, in particular the growth rate of R&D or that of SG&A. However, I would like just to highlight the strong performance year to date and note that the revenue would still have grown if original assumption for generic Nexium in the US had transpired.

The impact of the acquisitions of the other 50% of the diabetes franchise corresponds to more than 3% of growth. Currency movements, most notably the appreciation of sterling and depreciation of the yen, negatively impacted operating profit by around \$200m.

As you have seen, yesterday we announced a strategic transaction with Almirall. I would now like to take you through the key aspects of this deal, starting on page 41.

This is a great deal for AstraZeneca. It strengthens our inhaled portfolio in asthma and COPD. In the short term, it brings greater device choice for patients and adds DPI option to complement Symbicort and the Pearl asset.

In the medium term, this deal brings novel MABA and LABA bronchodilators, which will offer once-daily treatment options and novel combination for severe patients. The innovative assets of both companies are going to be pooled, and potential revenues will flow to Almirall regardless of the origin of the molecule.

The deal is structured to reduce risk and enhance returns. It immediately brings revenue and is neutral to core earnings in 2015 and accretive from 2016.

As shown on slide 42, with this deal we acquire the Acridinium franchise, assuming all Almirall rights, an excellent pipeline assets, most notably the MABA platform, as well as option to in-license further preclinical assets. Importantly, also, we will gain the rights to the Almirall Sofotec subsidiary with its device expertise and employees, subject to relevant consultations.

We will pay an initial consideration of \$875m upon completion of the transaction, followed by up to \$1.22b in development, launch and sales related milestones. There are also some sales related payments, but these are less than 10% of the total consideration.

The scope of the transaction includes assets as well as people, and this means the deal will be accounted for as a business combination. We will give you more details on the contingent considerations and the total value of the asset on the balance sheet once the deal closes.

Slide 43 summarizes the benefit to the AstraZeneca respiratory franchise. It brings an on-market portfolio and accelerates their entrance into the LAMA/LABA market, as well as bringing us an option for patients who prefer the DPI device. It strengthens our pipeline with once-daily MABA and LABA, as well as access to interesting preclinical assets. And finally, it strengthens our device portfolio and brings a highly regarded team with a track record of technical and regulatory expertise.

As a result of the strong performance highlighted in the earlier slides, we now anticipate revenue to be in line with 2013 on a constant currency basis. You may want to know that this guidance is based on the business planning assumption of the entry of generic Nexium in the United States from October 1.

With continued investment in the pipeline and growth platforms, we now anticipate core EPS to decline in the low double digits at CER.

The Company continues to pursue multiple productivity initiatives and redeploy resources to fund its pipeline and growth platform, whilst managing its cost base.

Today we have announced a first interim dividend of \$0.90, and again reaffirm our commitment to a progressive dividend policy.

In conclusion, AstraZeneca has made further significant progress this quarter, and we're investing in the business to drive continued momentum over the course of the year.

With that, I will now hand back to Pascal.

Pascal Soriot - AstraZeneca PLC - CEO

Thank you, Marc. So let me just close by saying that, as you can see, it's been a very busy and important quarter for us. We're making good progress, not only rebuilding our pipeline and progressing our important projects, but also through achieving a second consecutive quarter of revenue growth. Our underlying performance gives us confidence in our strategy for returning to growth by 2017 and it underpins our long-term prospects.

I hope to see you all at our Investor Day. We will be holding it in London in November. And I hope you enjoy the rest of the summer. So with that, I'd like to open for questions. Over to you, operator.