H. Lundbeck A/S 926447 Wednesday, 6th February 2013 13:00 Hrs UK time

Chaired by Ulf Wiinberg

Ulf Wiinberg

Thank you for joining us today on our fourth quarter and full year telephone conference. I am joined by Anders Götzsche and our Head of R&D, Anders Gersel Pedersen. On slide two you can see the Company disclaimer, which you've seen many times, so I will not read it now. I will go directly to slide three.

We will get more in-depth on the financials and the R&D, but overall if we exclude Lexapro US, Q4 we had a revenue increase of 18%, which includes the Takeda milestone, but excluding that we're still up by 10% in the quarter. What's very good is to see the very strong momentum we're enjoying with our new products. We also had a terrific quarter with respect to R&D where Selincro received a positive CHMP recommendation and we're now moving full speed ahead in preparing for launch. We have filed Brintellix in the US, Canada, and Europe, and we have filed Abilify Once Monthly in Europe, so a very busy quarter with respect to filing and regulatory work. From a financial point of view, the 2012 results, both top line and bottom line, are in line with what we have guided for the year, both at the beginning of the year and then when we updated the guidance in June with respect to our European restructuring.

With respect to 2013, we have an outlook that is 14.1 to 14.7 billion on revenue and 1.6 to 2.1 in EBIT.

You do know that our strategy has been one of differentiation both from the geographic point of view, moving from European to global, and from product point of view, moving from being very dependent on only Escitalopram to have many products, and what we are now seeing is great momentum with both of these strategies, so the US, excluding Lexapro, we saw a 33% increase in the quarter and 29% for the year. Onfi did more than 80 million in the quarter and a quarter of a billion Danish Krone for the whole fiscal year '12, and we have now divested the mature products portfolio.

Japan, we have seen a very good market share momentum and the sales in the quarter were 62 million and for the year we had DKK 195 million.

Europe, we initiated a significant reconstructing of our European business in the second quarter last year. The intent is to have a more flexible workforce, so that we can invest behind products where we have market access and pricing. This restructuring seems to have gone well and we expect to be fully completed by April, which is very good and very important that we are, so that we can start preparing for our new product launches.

We're also very pleased with the international market growth with 11% for Q4 and 9 for 2012, and again I want to highlight Canada's performance, more than 300 million a quarter a full year sales of 1.1 billion – outstanding performance.

With respect to new products, we have seen an increase of 71% for 2012. Selincro right now is about 14% of total revenue or around DKK 2 billion. We expect additional new products in '13 with Abilify Once Monthly in the US, with Selincro in Europe and with Brintellix towards the end of the year. At the same time, we expect to continue the momentum on the products we have launched in recent years, so we have high expectations that the positive platform for new products built in 2012 and the momentum we have will carry forward and, if anything, accelerate.

It's now a pleasure for me to hand over to Anders Gersel Pedersen

Anders Gersel Pedersen.

Thank you, on the next slide, slide six, you will see the portfolio presentation, the late stage pipeline, and, as you know, we have had a very busy year here with significant investments in this pipeline and that will also continue into 2013 where we are ramping up the investments in 58054 in particular, as it moves into phase III.

In the next slide I will go a little more into a couple of details on some of the late stage parts of this. First and foremost on slide seven we have had the filing of the depot anti-psychotic, Abilify Once Monthly, which we think is an important filing. We expect PDUFA date on 28th February, so quite soon, and we have submitted in Europe late last year for review during 2013. We do see this as a very attractive product in this area; given the side effect and efficacy profile of Abilify, we think that it has a very attractive profile as a depot. Lots of patients are non-compliant with the medication and therefore with the drug that has a good safety profile, as this one it is ideal for depot treatment in this population.

Go to slide number eight, we were very pleased to receive the positive recommendation by the CHMP and expect to get the final approval from the Commission probably sometime late this month or early next month within the normal timeframes. The indication that we have received is the one we truly would like to have in terms of attracting or focusing on the patients with the highest medical need, and treatment support, and also patients which have shown dramatic treatment effects of alcohol consumption reduction of more than 50%, which means a very dramatic risk reduction for these patients in terms of healthcare risk over a fairly short timeframe after they have reduced their alcohol consumption, so we were pleased with these results and we're looking forward to supporting the launch also in the coming years in Europe.

On slide number nine, focused on the highlights of the profile of Brintellix. I will remind you that this is the first molecule where such a receptive profile, as we have the most modal receptive profile, which allows an indirect effect on a number of the neurotransmitters that we know are key for helping patients with depression. In particular we have high expectations for the effects that we have already seen in ameliorating some of the cognitive deficits that these patients suffer from, particularly in the elderly group. We will have the review ongoing through most this year, with both the FDA, the Health Canada, and with the European Agency, and we will also start seeing some of the results

coming out during the year on some of the subsequent studies to the pivotal programme that's constituted in the file submitted.

With that, we expect to see a number of reports coming out from the pipeline during the year and with that I will hand over to Anders Götzsche, who will review the 2012 performance.

Anders Götzsche

Thank you Anders and please turn to slide 10 and this is actually the third quarter following the patent expiry in the US and soon we'll not talk a lot about Lexapro in the US anymore, and you can see that new products, as Ulf also alluded to, is actually exceeding the lost revenue from Lexapro and we have a continued business without Lexapro and the milestone actually growing with 10%.

The European environment obviously continues to be challenging with the impact from numerous healthcare reforms, but it's also important to say when you look into the Cipralex, because the most dramatic event, so to speak, is actually the loss of exclusivity in Spain and that is the major factor for the decline in Cipralex, but which is actually in line with what we expected.

What is positive is to see that we actually had a good fourth quarter with Cipralex, sales were actually up 1% in Europe, and we actually...maybe it's too early to say, but the negative pressure is easing a little up. We saw that in the fourth quarter and hopefully that could continue next year. It looks far better outside Europe. Revenue from Cipralex is now...from Cipralex in Canada grew more than 30% and we are very close to 1 billion in sales in Canada. To support our geographical expansion, we are very pleased to see that both China and Japan is showing nice growth and on Cipralex in the international markets is growing around 10% for the year as well as for the quarter.

Ebixa actually did really well in 2012, if you take into account that we saw this price cut of 18% in France, but in most markets we have taken the significant market shares in 2012 and we also know that we will see generics in 2013. The only generics we have seen so far is in Germany and, therefore, you should expect for 2013 that it, of course, will not be able to grow Ebixa and you should actually expect a decline; the ballpark figure is 30 to 40%.

If we turn to Azilect, it was up 6% for the quarter and, again, I am very pleased with the market share development we have seen and the single-digit growth is actually a result of that. You know that we changed the setup with Teva for Germany and from the beginning of this year, this effect, the change in setup will have no effect. We are pleased with the new launches in the international markets and we actually expect to see a good growth next year for Azilect.

When you look into our geographies, it is important to emphasise that the decreasing revenue in Europe was more than offset by a very continued strong growth in our US business, and we are pleased with the continued growth around 30% for Onfi, Xenazine, and Sabril in the US. Xenazine is now delivering sales of 1.2 billion for 2012 and we are fully on track to actually delivering peak sales above 1.5 billion for the Xenazine.

Turning into international markets, revenue was flat in the previous quarter in this region and we are now back on track with around 10% growth. As I said before, the Canadian business is continuing to be impressive and Lexapro in Japan, the revenue of 200 million is also very positive. However, you need to understand that this 10.6% in market share, we know that it is not a real sign of what is actually the underlying market share. We would be...a market share around 8% is more the size and there will be swings between the different months, so we are on the track that we have seen before, but 10.6 is in the high end.

All in all we are really satisfied with the revenue progression for the quarter, as well as for the year, and we think that we are doing the right thing by investing heavily in our products and, of course, we know it's a difficult business environment, but we think that the geographical expansion and our expansion of portfolio of new products is now starting to take off and we look very much forward to see that continue in '13.

Please flip to slide 11 and here again we have made a line called continuous operations and that is without the milestone from Takeda and without Lexapro, and we showed a nice growth of 10% in the quarter and 6%, so we are happy with that. It might seem as we are not fully under control with our costs, but I can assure you that most of the underlying cost lines are decreasing. The reason for seeing an increase is definitely that we invest in prelaunch activities and launch activities. Please bear in mind that we have pre-launch activities for Selincro. We are hiring in folks in the US to support our Abilify Maintainer launch, which will happen in Q1 this year.

Cost of sales are slightly down, but for the quarter it's up and that is, of course, due to the increased number of royalty streams for the new product mix.

R&D is in line with what we said when we started the year and EBIT is for the quarter 220 million and we are on track. We have delivered 2.1 billion in EBIT.

Please turn to the next slide, page 12. As you can see here, we had a good cash flow. Our net cash position is 1.9 and that is a combination of a cash position of 3.8 and a debt of 1.9, and we also...the Board of Directors will propose at the AGM to pay a dividend of 35% of the year's profit after tax to the shareholders and that will give approximately...or it will give DKK 2 per share. The dividend payout is to be approved by the AGM at the meeting on 21st March 2013.

Then we flip to slide 13, the financial guidance, and you can see that as we...we laid out our guidance in December and we art sticking to that guidance, so it's 14.1 to 14.7 in revenue (billion) and the EBIT is between 1.6 to 2.1, and as we said at that point of time the reason for the little less EBIT is, of course, the investment in new products and it is important to emphasise, as we have stated, it is including our expectations of a milestone from Takeda of \$30 million and it is including the gain from the divestiture of mature products in the US, as we announced just before the turn of this year.

Looking into the expected cost ratios for next year, the cost percentage for 2013 you should expect that to be in line with '12 and also if you look into the SG&A ratio, you should expect that to be around 45% next year. It's very volatile; it is our expectations for the time being. We will follow the launch activities during the year very closely and secure that we invest to secure the right uptake for the new products. The R&D

percentage will be more or less unchanged compared to this year and you should expect a tax rate around 30%. You need to be aware that the tax rate can vary a little and that's due to the fact when we have lower results before tax, slight changes will of course change the tax rate, but you should expect around 30% and financials you should expect a net loss of 50 to 100 million, and then please bear in mind that, as we have stated in the slide, that we might have to pay up to \$300 million to Otsuka in 2013 and that will lead to a Capex that should take into account between 2 to 2.5 billion when you make your cash flow statements.

With this presentation of the financials, I will now hand over to Ulf to make the concluding remarks for this 2012 presentation.

Ulf Wiinberg

2012 has been a great year from a financial point of view and with respect to strategic progress both geographically and with respect to new products. We're now looking at 2013 that will be an equally exciting year where we await many approvals from Selincro, Abilify Maintainer, and Brintellix. We are awaiting the pivotal data on Brexpiprazole and towards the end of the year, maybe the beginning of next year, we'll see the Desmoteplase data, so all in all a very exciting year ahead of us, so with that we'd like to close the call and now open up for questions. Thank you.

Questions and Answers

Michael Novod – Nordea Markets

Yes, hello, it's Michael Novod from Nordea Markets. Just a few questions. First of all, maybe you could try to explain a bit what is determining the high versus low end of your guidance ranges provided, not only in '13, but also in '14. You do mention that you see around 30%, 40% decrease to Ebixa. How much is this, say, actually playing into your guidance ranges if you don't see such a strong generic penetration for Ebixa in 2013? And then, secondly, could you try to comment on what kind of expected market share you actually expect to have in Lennox-Gastaut Syndrome with Onfi in the US? And then, lastly, to the Brintellix milestone, is that associated to approval or launch?

Just to comment first on the Lennox-Gastaut, we don't know the market share on that. We don't fully understand that yet and we are probably unlikely to have a complete understanding of this market and communicate on that, beyond that. Maybe we will learn more, but you should not expect us to have a full understanding of that going forward. I think for Anders, if you can comment on the guidance issues.

I think, Michael, it's very difficult to say what is the factor that will lead to a lower end result of the guidance or a higher end result. We have a lot of exciting activities in '13 and a lot of these activities will be depending on how fast are we getting the products into the different markets, how fast can we launch them, what's the resources we need to bring behind the products and, of course, you will also have an effect that is how fast is the generics coming into the market for Ebixa. What I would, of course, love to say that the good performance in Q4 would continue into 2013, because it was a very good performance and we are taking market share from most of the products, but I can't promise

you that for the full year '13. In respect of Brintellix, it's first commercial sales that is the trigger for that.

Okay. Maybe just a follow up to the guidance range. Can you say anything what kind of expectations you have in terms of sales, year two and three, for these products that you are launching Selincro and Abilify? Just some ballpark ranges, or...?

No, no, I think it's way too early. We need to take it step by step. We need to get that approval in the US and in Europe for our Abilify Maintainer and then let's see how...we hope we...you know, as we have seen with some of the products this year that we can make a stellar performance and then when we have, you know, hardcore data and we have seen a couple of data points then we can start to discuss what is the trend line. What we can say is that the peak sales estimates that we have laid out for these products, the 2.5 billion for Selincro, we have said around 2.5 billion for Abilify Maintainer. We have seen no signs whatsoever in our business and in the interactions with the markets, the label that Anders just described. We have seen no roadblocks in front of us that should actually get us in a position where we would like to change our peak sales estimates. That's where we are.

Thank you.

Tim Race – Deutsche Bank

Hi, there, it's Tim Race here from Deutsche Bank. Just a few questions, please. First of all, just on your sales and distribution costs ahead of the Abilify Maintena launch, how many sales reps have you got in place now? How many more do you need to build up? And then just in terms of the Brintellix launch in – particularly in the US, how many more sales reps will you need to put in place and when during 2013 would you start doing that? Then just moving on to the Otsuka milestones, you talk about \$300 million in 2013. Could you just be a bit more specific about timing and what they are actually for, and also maybe what other milestones are coming up in 2014 and what they are for? And then also maybe tedi – I can't say it. Tedatioxetine and Zicronapine, there is no active programs on those products yet. Will there be any active programs started in 2013? And what is the decision points or criteria to start those or not? Thanks.

I will start with your last question. We have had an unprecedented activity level from a regulatory and clinical trials activity point of view, and hence the two products that you talked about have sort of been a little bit on the back burner. My guess is that when we're after the summer we will revisit the programmes and decide a way forward and what we should do, and then as soon as we have done that we will share that with the market, but right now we are extremely occupied by delivering on the programmes that are ongoing, on the registrations that are ongoing, and also getting our Alzheimer's programme started in the summer, because we think if we can get that going then and execute that in a timely fashion, we have a chance to have the next new Alzheimer's drug on the market and we think that being fast with that programme has significant upside.

With respect to the sales force, we are short of 100 psychiatric reps in the US, we have fewer than that, and they are in place with respect to what we need for the Abilify Maintainer launch. When we get later in this year we need to put reps in place for Brintellix too, so if you see a significant increase, we haven't finalised the number yet, but

we expect to have a competitive share of voice together with Takeda. Anders, do you want to comment on the last point?

Yes, the milestones for...\$300 million first is important to say it's approval milestone in the US of 100 million and you should expect...hopefully, you would get...we should pay that in Q1/Q2, and then the \$200 million is a development milestone and from the top of my head I think it's mid this year, but I need to...

Towards the second half of the year.

Oh, second half. Second half, sorry. It's the second half and then...but you also need to understand that for 2014 we don't expect any development milestones, so you should not see the 200 again in 2014. I hope that answers your question.

Yes it does, thanks. May I just jump in with another question rather than jumping back on the queue while I've got you on the line, Anders? In terms of the various cost lines, could you just do the usual guidance of up and down of the – or the percentage figures of the R&D sales and distribution and admin and COGS line of 2013 of what you're expecting, just to give us a better ballpark for the underlying business rather than including one-offs?

I think the SG&A margin this year you have a margin if I remember correctly around I think it is 46.7% and that is including our restructuring. Next year you should expect it to be around 45%, but of course we don't include a lot of one-offs in that, the one-offs you might have in that you could call it a one-off, it is the launch cost, so this year we have one-offs with approximately 500-600 million in SG&A. The R&D percentage will be pretty much in line with what we have seen this year and the ballpark of that is of course projects, the investment in the pipeline. the cost percentage will be the same level as this year, around 21-23%, it really depends on the product mix, so when we come down the line it could be that some of the products is taking better off and it really depends on how much royalty we have on these products, so is that pretty much covering your question or do you need more granularity.

Well you can give me the actual numbers if you want, but I think that's good enough for me thanks.

Martin Parkhoi - Danske Bank

Firstly, a question on Sycrest, which I don't think is going exactly according to plan. Could you tell me, I guess you are putting a quite high royalty on this product and you also have some dedicated sales reps attached to this product, so I guess there will be some time that you have to decide if it's actually worth continuing to launch this product. Is that something that you have in your mind already now? What kind of level of sales is actually worth for you to continue to promote the product?

then, coming back to Onfi, I can understand that you didn't want to talk about market share, but can you talk a little about what kind of patients that you are treating right now, at least the feeling of what kind of patients you are treating right now on this product?

Just on Onfi, I mean our understanding is that we were treating Lennox patients, but we don't fully understand the dynamics because we are quite pleased with the performance.

It has at least been said that it could also be used in other areas than, except for, outside Lennox-Gastaut and, for example, in anxiety.

We are promoting the drug for the approved indication Lennox-Gestaut, so we are not aware of any use outside Lennox-Gestaut and we are positive, we are encouraged by the sales but I have no more information to give you on that. The comment on Sycrest is obviously that we are not deliriously happy with the performance. Sycrest was a product that we said we could bring In to help us support our infrastructure between Escitalopram and Brintellix so obviously it is being used in a spare capacity position, also after Project Rico, as you know in Project Rico we said we would hold onto the specialist marketing competencies and that point of view Sycrest is the specialist product. We have actively reviewed the investment and we are doing that on an ongoing basis for the reasons that you have said. I am sure when we get later in the year we will have an idea of what the peak sales is going to be.

Let me just clarify, Project Rico is obviously the European restructuring we initiated in June to build a specialist sales organisation in Europe that is more flexible and agile so that we can act more decisively when we get marketing opportunities and pricing on new drugs in the countries where we get them and when we get them, and as part of that we took out some 600 of our headcount in order to create that headroom to have the flexibility.

What is important what is left is obviously much specialised, or a specialist sales force and Sycrest is used in a spare partition capacity within that sales force. We have a high royalty on it and Sycrest is not a contributor and so far is not meeting expectations.

Peter Hugreffe - ABG Sundal Collier

A couple of questions on the pipeline to begin with. First of all, on 58054, could you just give us a little bit more flavor on the status on your decisions in terms of partnership? Secondly, also what have you decided about the Phase III trial in terms of number of patients and so on? Then maybe also could you give us some kind of indication, or has there been any kind of showstoppers from the partnerships, maybe give us some flavour on that. Then secondly, in terms of Brintellix, you state that a number of clinical programs will be completed. I assume you expect to dispose the cognition and the sexual dysfunction programs. They are still ongoing; actually, they're from clinical trials. They are not in the overview of events for 2013. Should we understand it that way that they will not be presented, or how should we understand it? Then, finally, maybe you could give us a status on the launch of Treanda in Canada. Thank you.

Treanda in Canada, all we hear is very, very positive, we don't have any real specifics as of there and positive sentiment to share with you as of January, but there is a lot of activity as to our Canadian organisation, a very positive, very high upbeat and they have very high ambitions.

With respect to 58054, I had initially thought that we could do a preparation of a clinical programme and start that up and do a partnership deal in parallel, but what I realise and maybe I should have known this, someone would say, but I realised that by doing it that way we would delay the start of the programme, because if you do partnership deals that takes you six to nine months, then you agree on the development programme, then you get the advice from the FDA. My sense was the earliest we would get that probably and started if we followed that approach would have been by middle of 2014, so since we have

expertise in the area we decided to do the programme ourselves, design it, go to the FDA for advice, we did that last year, and as part of that we are now working towards starting a programme in the middle of the year and if we can do that and if we are successful and of course this is a risky programme, if we can do those two things we have a chance to be the next new Alzheimer's drug on the market, especially now after the setbacks for the vaccine. The decision we said, even if it is painful with the guidance discussions and all of that is that this is too good an opportunity not to go after, to be the next Alzheimer's drug and that was the decision. Now we have sort of done that, we are working on the partnership deals, and I would just say we have a high level of interest, we don't know how long time it takes before we do a deal and as always with any deal until you announce the deal it is sort of like being pregnant, you're either pregnant or you're not pregnant. You either have a deal that you can announce or you don't have one, but now where we are this is the top priority for us to work out here. Obviously what we are looking for is a deal that is good for Lundbeck and that ensures that we maximise this product to the benefit of Alzheimer's patients around the world.

Anders do you want to comment on the specifics around the programmes and Brintellix too.

Yes, I can tell you that currently our expectations that with Phase III studies and that we will initiate them not simultaneously simply because it is a lot of effort to do that, but do them somewhat staggered, with the first one mid this year. The size of this is not horrific which is one of the good things that have come out of the discussion we have had with the FDA in December which takes studies to be running with, I don't get the numbers exactly this moment but I think it is around 600 patients roughly per study that we are talking about, it is 900 patients per study, it is three treatment arms in the studies. There have been a number of discussions going on that and what we do have to do before we are completely final on the numbers is that we will as you know have a final sign off with the FDA until these actual studies and that might have some impact also on the final sample size numbers. That is where we are in terms of the concepts, the endpoints of what we want to do, how we want to construct them, we have the agreement on that.

Anders, just to clarify, so you mean you have three Phase III studies with 900 patients in each and you will go head on with one identified dose? How should I understand that?

No we will not go ahead with one identified dose; we will go ahead... that is why we have three treatment arms.

Sorry, but you will not do a Phase IIb study in order to find the optimal dose? You have been allowed to go ahead to Phase II by FDA?

Explaining the Phase III, so that is why we are running three programmes to cover a range of dosages yes.

And on Brintellix?

On Brintellix we have not put it on the announcement as to when we are going to declare these studies. Most likely they will be ()()() until they're being presented at scientific committees. I will say that may be changing depending on questions also we may get through the regulatory process. We will as you know get some of this data during the

regulatory filing process, both in the US and Europe, so that may have an impact on that position, but at this stage our plan is to publicise them at scientific meetings.

Jo Walton - Credit Suisse

Hello, just a couple of quick questions, please. Selincro is now pretty much at the starting blocks. Can you tell us a little bit about how your discussions are going in terms of pricing, whether you're becoming more confident that payers are going to reimburse this new approach going forwards? Secondly, I'm just looking at the timing of your launch costs. I'm surprised you've got a big bonus of spending that we saw in the fourth quarter of 2012. It seems to me that that should be the barest minimum and that we should be seeing your launch costs and your initial marketing costs, and the extra sales people, ramping up so that, sequentially, we're getting bigger and bigger SG&A, and yet your overall guidance for SG&A for this year doesn't seem to accommodate a really big upfront spend. Is that because your partner is going to be taking a large part of that and that's why we're not seeing it for you? Is there the possibility that, particularly as we come to the end of the year and we have Brintellix launch, we should see another step up in the marketing costs?

Hi Jo, with respect to Selincro and 2013 obviously there will be staggered launches where we initially get market access and pricing established and once we have that we will spend more money. For this year the initial launches are likely to be smaller countries and then the big countries will come fully on stream in 2014. Consequently you will see a step up in expenses in 2014. With respect to pricing, we don't want to talk about pricing publicly until we have made decisions and engaged with payers, but that said your comment is astute in the sense that we like the recommendations we have received () and we hope to leverage that in the pricing discussion, but we have.

I would like to add that be careful not using the cost levels from quarter to quarter, but we are guiding on is the overall level for the year. There will be swings between quarters. We are not managing Lundbeck by delivering cost ratios quarter by quarter but actually managing the full year and actually investing at the right time of the year.

But 45% of sales doesn't seem to be enough when you're really launching, so should we assume it may be less than that at the beginning? When you get into the full launch then you'd be spending more than that?

Let me just make one comment, Lundbeck is on the journey where the old products are being replaced by the new products. We are sort of shifting spending from old products, so we are still promoting Cipralex. We are to some extent still promoting Ebixa. Obviously in a couple of year's time we will not be promoting those, certainly not within Europe, so obviously we are shifting these resources to the new products. I cannot be specific on exactly how you do that by quarter and by country but that is the journey we are on. Just be very careful with the additive elements, because a country might be promoting Ebixa still and then they get pricing and access on Selincro and decide they shift all of that resource into Selincro, or they may shift the Cipralex and the Ebixa resource to Selincro when they get that and spend all the effort on that and then when they get Brintellix they change the mix and decide what they do there. It is very hard to do it on just saying we're now adding this mass of expense, we have worked very hard on making sure it is not a fixed mass of expense we have and we want to be very aggressive

in shifting from the old to the new, but first when the opportunity really is there, and that is when we have market access.

Thank you, and one brief additional question. Could you give us some comfort that by somewhere like APA this year we'll actually see some of the cognition data in the elderly studies? Just looking for how much additional data will be published for investors ahead of the FDA AdCom, which presumably we'll get, I don't know, September time.

This is Anders, the elderly data on cognition has already been published on APA last year, so they're fully in the public.

Sorry, I was thinking of the additional data, the ongoing ones you have.

They will not be ready, you cannot submit anything to APA at this moment, so there is no data that will be presented at APA in this respect.

I am not sure I understood the tail end of your comment, but we are not aware of any advisory committee meeting for Brintellix in the US. Maybe I misunderstood you.

The process that is going on with the () is that we will be notified if an AdCom is expected and we will be notified of that I think sometime this spring here already, that is part of the new process, so at that time we will know if there is going be one or not. We have no indications at all and we wouldn't expect any knowledge from the FDA at this stage whether they want that or not.

Carsten Madsen - Carnegie Bank

Thank you very much. A couple of questions. First of all, on Ebixa we have recently seen the first centralized approval of a generic version and I think it was from a Slovenian company. In your guidance when do you assume that you will see a real generic competition in Europe? I guess they'll have some price discussions and maybe local discussions as well now. Also how many local approvals have you seen of a generic Ebixa? Then finally, on this 200 million-development milestone you'll have to pay to Otsuka, what type of event triggered this payment? Thank you.

This is Anders, we don't want to speculate. You have the same information we have around the decentralised procedures and approvals and so forth for generics in this area. You are as good as informed as we are. What we can see is when we see generics in the market we will quarter by quarter of course inform you around about the impact. It is too early to speculate. Based on what we expect, the knowledge we have, the historic knowledge around the different countries, we have calculated that we expect to see an impact of 30-40%, but as we go we will of course update you on that.

I was just wondering if maybe in Q1 -- if we didn't see anything throughout the entire Q1 if that could be an incremental upside.

I would love to give you more granularity but I think to give a 30-40% range of decline is a lot of granularity and we will not go down to more detailed figures.

I agree.

As with Brintellix and the milestones we have not in earlier said what are the criteria for releasing the ()()(), sorry for that, we are not giving any kind of guidance what is actually the trigger for that, that is with Otsuka and that is also the fact of this milestone.

Lars Hevreng - SEB Enskilda

Can I just ask about Brintellix and the regulatory time lines in some important international markets, including Brazil, what's the status there? The second question, regarding Cipralex, if you could say something similar in Europe, expectations this year, something similar to what you mentioned for Ebixa this year. Then finally, on the tax rate, it's 30%. It seems that's a significantly higher rate than you have domestically. Is that something we should have in our models going forward as well?

What do you mean with the 30%

Yes, the tax rate indication you said for 30% for this year, since it's much higher than you have domestically. Is 30% what we should assume for the years ahead as well?

Sorry for that, the reason for the 30% is of course that we see every nice traction in the US and that the mix of taxation has changed, and it will really much depend on what kind of geographies, how successful we are in different geographies and what is the different tax regime in these geographies, but you should expect for the next couple of years around 30%.

With respect to Brazil, there are some markets where we want to have one approval before we file, so that they have a reference and it tends up to speed after the approval process, and Brazil is still one of those countries. When we get the FDA approval, I hope it will be the first approval, then we will immediately file this for Brazil.

With respect to Cipralex, the trend that we have seen in 2012 in Europe will continue in 2013, and with respect to generics, we will see generics in Europe by Q3 in 2014, and then start to see generic erosion after that.

Peter Welford - Jefferies International Ltd.

Hi, thanks, just a couple left over, please. Firstly, just on Sabril, the drop we saw in the fourth quarter on rebates, is this something we should be factoring in on an ongoing basis in the fourth quarter as we've seen with a couple of other products? Is this, say, a one-off effect for a catch-up phenomenon? then, secondly, on the \$30 million milestone to Takeda, are there any other pre-commercial milestones that are due either for other regions or other indications, or is this the last pre-development, if you like, approval milestone we should anticipate in this collaboration for Brintellix? Thank you.

If I start with Sabril, you are fully right, it is a catch up from 2010 until 2012, so you should not expect us to have a one-off like that every fourth quarter going forward. It is a part of the Obama cure that has been enforced and implemented and so we have made a provision for that and that is impacting the revenue for Sabril, the underlying growth for Sabril is the same as we have seen in the previous quarters, so in that respect there is nothing to be concerned on.

The milestone just to make sure, I wasn't quite clear the milestone that we received from Takeda on Brintellix is not one that we give, just so that was clear.

We received that for the launch.

It is first commercial... it is good that you clarified that Anders, it is from Takeda to Lundbeck, it is 100 million and it is first commercial sales in the US. I hope then if I mixed it up before then...

Sorry, it's 30 million, sorry, you said 100 million.

It is \$30 million corresponding to approximately 175 million Danish and then we have the \$100 million which is the approval milestone for Abilify Maintena and that goes out of our pockets.

The question was, are there any other milestones, sorry I think I got it wrong. Are there any other milestones that Takeda pays to you on approvals either in other geographies or anything? Is there anything else we should anticipate on Brintellix, aside from now, once the US is launched, milestones on when certain commercial levels are achieved? Is there anything else before those milestones that we should anticipate in the accounts?

No major milestones. A couple of small ones, but no major.

Closing Comments

Thank you again for calling in to our conference call. our Investor Relations are ready to answer more questions if there and otherwise we look forward to Q1 updating on our progress, thank you so much again, bye-bye.