H. Lundbeck A/S

Transcript :: Q3 Conference Call :

Ulf Wiinberg

Thank you very much operator. And to all of you who have called in and followed us on web, thank you for being present at our Q3 conference call. Before we start, on page 2 we have the company disclaimer, which I trust that you are all aware of and I will not read to you.

So page 3. We are generally very, very pleased with the quarter, we are delivering financially good results and we are right where we want to be or maybe a little bit ahead after nine months. But more importantly, we are delivering on our strategic growth drivers, we have strong New Product sales and we have good progress in our geographic expansions in the US and in international markets and when we look at R&D obviously we are very pleased that Brintellix, which is named Trintellix, has been approved in Canada in addition to approvals in Mexico and South Africa and some other markets and then we feel we are making good progress getting Brexpiprazole approved in the US and that sort of prompts us to make everyone aware that we are planning to launch this maybe a year ahead of many people's expectations and launch it in 2015 and hence we are giving you a soft guidance for 2015, which will be a very busy year with many new product launches.

I just want to illustrate on page 4 the very positive momentum we have with New Products. So after nine months we have sold DKK 3 billion and we are up more than 40 %, and if you look at Q3 it is DKK 1.2 billion and up 56 % and obviously we made 25 launches this year in different products, different countries, and for next year we are planning more than 50 launches. So we are very busy making progress building the new Lundbeck.

I just want to give some highlights on our psychiatry portfolio. Abilify Maintena, I think market access in Europe has gone extremely well and we have now come out, as you could see earlier this week, with QUALIFY which will give us a very competitive position to promote from in Europe and the initial uptake has been very positive in Europe. So I feel we are off to a very good start here and I'm also encouraged with the progress that has been made in the US. When I look at Brintellix we have had more than 250.000 scripts and so far the feedback from prescribers has been very positive and we are having encouraging initial feedback in the EU. So our sales are only DKK 105 million so far, we feel that this will be an important growth driver for us. And lastly on Brexpiprazole, the US regulatory review is ongoing, clinical data will be presented later in 2014 but PDUFA date is mid-July 2015 and we are hoping for approval, both in depression and in schizophrenia.

0.03.50

So on page 6 you can see the Brintellix performance and obviously we have good gains and we are outperforming the competition, Viibryd and Fetzima and obviously for us very, very important is the launches we are going to make outside the US where we get 100 % of the revenue and here the approval in Canada is very important where we will launch in January, but obviously the other launches that we have with Mexico and the markets where we have launched, Chile, Denmark and South Africa, are also positive. So all in all, very encouraging.

More specifics on Abilify Maintena, we now have more than 9 % of the US long-acting market and in the US the dual-chamber syringe has been approved. We have submitted for approval of Deltoid administration and we are improving our access programs to ensure that it is as easy to get Abilify Maintena as any other depot product in the market. With respect to Europe, we have full reimbursement in 17 European countries and things are going as planned and we have launched in 11 countries with encouraging uptake.

Slide 8. Overall our US business is doing very well and a key driver for us is to strengthen our neurology franchise, which is up 36 % year-to-date. So all in all we are very pleased with the progress we have with Onfi and Xenazine and Sabril, but now the most important thing is obviously the launch of Northera and the launch took place here in early October. We believe there are significant unmet medical needs here and we are excited about this launch which we think has the potential to be the largest of the neurology products that we have in our portfolio.

Lastly Selincro. We have made great progress in getting market access, many of you know that we have been waiting and waiting and waiting, we said we were going to launch in Q2 but now we have made the launches here in September and October, we have got good payer endorsement with a very positive NICE recommendation and also ASMR IV classification in France. We have launched in France, Germany and Spain in addition to Belgium where we have launched previously. It is very early days, I will say, but everything is so far extremely positive.

Next slide please, slide 10. So just to comment, you know we said before we wanted to go from European to global and obviously we are very pleased with the strength of our European business but building a strong presence in the US has been a top priority and in that sense revenue is up 48 % in Q3 in the US, and the US in Q3 now is almost a third of the total Lundbeck business. And now with the important Northera launch and the ongoing launch is for Brintellix and Abilify Maintena and Brexpiprazole coming up we can see that we will be at or very close to USD 1 billion sales in 2015. International markets, we are very pleased with 16 % growth in the quarter and the international markets also now constitute roughly a third of our business. Very important for us is the progress we

have made in China and China is becoming one of our leading markets and Lexapro is now the number one brand in the Chinese depression market and again, as said before, we are pleased with the progress made with Abilify Maintena in Europe which has had a very good start. Selincro, it is early days but looking good and we are also making great progress with Brintellix. So with that I would like to hand over to Anders Götzsche to talk more about our financial performance.

0.08.44

Anders Götzsche

Thank you Ulf, and please turn to slide 11. As Ulf also mentioned in his opening remarks, we only saw a modest decline in revenue in the quarter and that is of course a combination of a decline due to generics for Cipralex and Ebixa but that is partly compensated for with a very strong uptake in New Products and we are actually taking market share and growing in all our products where we have exclusivity. Expenses continue to be under control and we have had a third quarter with flat development costs and that actually means that we have been managing our spending our costs for the first nine months so they are in par with last year. And if you take a closer look into the different cost lines you can see that SG&A, that sales and promotion costs have increased and that is of course due to the high investments in the high number of product launches and that is fully as expected. And the main launch is, of course, Brintellix, which will gain further traction in 2015 and of course the heavy lifting for Abilify Maintena and Selincro. Our admin has most of the year been flat but we see fluctuations between the quarters but in general it is flat or declining. The SG&A ratio for the second quarter was 48 % which is also around that level you should expect for SG&A for the full year and that is of course, as I said before, due to the additional costs this year for the global launch of Brintellix and Maintena and the uptake in launch cost for the European launch of Selincro in France, Spain and Germany. And then fourth quarter is impacted, of course, will be impacted by the launch of Northera in the US. The R&D trend there are some fluctuations between the quarters but you should still expect the R&D percentage to be around 20 % for the year. We think it has been a solid quarter from an earnings perspective and we delivered a core EBIT of close to DKK 300 million and of course the priorities for the upcoming year is of course securing that we are very cost conscious in all parts of the organisation including the project and utilizing on the project fit for the future and then reallocating the funding for securing a good uptake with the new products. To conclude on the quarter we can say that all in all we are actually very satisfied with the quarter, we think it is a strong quarter and with that please turn to slide 12.

0.11.54

We think that with the quarterly the first nine months' results we are well on our way to deliver on full year expectations. We still have a number of variables ahead of us, we have the sales uptake for the new products, we have the erosion on Cipralex from generics in Europe and Canada and then of course, as I just said, we will see significant investment in

the New Products launches in Q4, and traditionally Q4 is also a weak quarter. So based on that we stick to the guidance for 2014, DKK 13.5 billion in revenue, a range for core EBIT between DKK 0.9 to 1.4 billion and EBIT DKK 0.0 to 0.5 billion. And then we have also today announced a soft guidance for 2015. We saw that it was prudent to provide you kind of insight about our thinking for 2015 and the preliminary outlook indicates revenue at the level of or slightly below 2014 and the flat development will of course be a combination of loss of revenue for some of our key products but then compensated by revenue from new products. As we now expect to launch Brexpiprazole in the US in the second half of 2015, of course pending approval, and as we face more investments in product launches you should also expect that core EBIT in 2015 will be close to zero or might be slightly negative and that will of course be dependant on product uptakes, exchange rates and also the erosion trends for the mature portfolio. And we will give a hard guidance when we release the financial result for 2014 on 5 February2015. And with these concluding remarks I will turn over to Anders Gersel for a walk through the latest development in our pipeline.

0.14.10

Anders Gersel Pedersen

Thank you, Anders. If you turn to slide 13, first and foremost we are very pleased with the approval of Trintellix, as Brintellix is called in Canada, earlier this month, and we have with that as one of the largest anti-depressant markets and also one in which Lundbeck has a strong tradition, so we are very pleased with that. Brexpiprazole, we have had an acceptance of our file which is a file of both indications for depression as adjunct therapy in depression and for schizophrenia. We expect to present data on the depression filing package later on this year at ACNP. Desmoteplase, we had presentation of the DIAS 3 data at the World Stroke Conference a couple of weeks ago where we clearly could see results on the sub group with MRi scanner and I will come back to that later on here and we are still evaluating the next steps with this molecule. Abilify Maintena, we had some very positive data come out of the QUALIFY study in which we showed superiority over Paliperidon in terms of quality of life measurements.

In the next slide we will go to Brexpiprazole. I will just highlight you the profile as we see it with Brexpiprazole given the data package that we have submitted still confirms very much our expectations from a pre-clinical and early clinical perspective in terms of a very well-positioned molecule, both for treating patients with depression who have not responded well to classical antidepressants but also for patients with schizophrenia because it has a good balance between the intrinsic effects in terms of not agitating or elevating the mood level of these patients too much at the same time not sedating the patients and so it has a very good balancing profile which also leads to what many physicians describe to us as a more pure predictable outcome when they administer the compound because they are not surprised by individual sensitivities towards either of these two side-effects that are common with both for example Quetiapine and Abilify currently on the market. We believe the package that we have for the US filing is robust, is

a very large file, and we have good tolerability data that confirms the profile mechanistically and we will show these data at ACNP. We have also initiated programs for additional new indications that we potentially would file for later on over the next couple of years, one is Post-Traumatic Stress Syndrome and another one is agitation associated with dementia for Alzheimer patients. And these programs are both initiated and are running.

If you could turn to slide 15 I will explore a little more on what we are presenting at the World Stroke Congress. The sub-analysis of patients that we did was particularly interesting in terms of looking at individuals who had been entering the study with MRI scanning. There were two elements here, one was that it seemed that in itself the MRI scanning seemed to predict better for those patients who had a functional recoverable area of the brain than did CT scan, that is one part, and secondly it also showed that the assessment of the MRI scans was by far more predictable than that of CT scanning when it was done by independent blinded radars. So both from a predictability perspective but also from a prediction of patient outcome perspective MRI scans seemed to select a better patient population. This is clearly a population that is identifiable easily in the sense that if we take all incomers in the study that were assessed with MRI we clearly could see the effect here. From a regulatory perspective that does not solve the problem that this is a post-hoc analysis and this is basically the concern that we have in terms of discussing this in terms of what are the next steps going to be because as you are all aware, the development program for Desmoteplase has not been very fast because it is very difficult to enrol patients in placebo studies into this population as it is today. So we will consider what to do and we will let you know as soon as we have concluded on these, both based on input from key opinion leaders and various regulatory authorities.

If you turn to page 16 I will give you some update on Idalopirdine. We have strong support from both FDA and EMA in terms of the appropriateness of the program we have launched. It is a large phase III program with more than 2500 patients and it is enrolling as we speak. It is a competitive and hard market to get patients in so things are going a little bit slower than we had expected but still within time frames that we expect to have data read-out as outlined here in the turn between 2016 and 2017. Earlier on there was an article published with the phase II data in The Lancet Neurology. Clearly it is showing the statistical significant superiority of adding Idalopirdine to Aricept in a population similar to the one going into the phase III program. I know there has been some speculations also on the editorial side on the relevance of this, but just to keep in mind that first and foremost these data were known also by regulators when we discussed it with them in terms of the magnitude of the effect size here and secondly, if you compare the effect size seen in this study, it is as good as the effect size seen with Aricept as a single therapy in patients with Alzheimer's disease and that after all is what most patients receive today. So we do consider this as a very important addition to the current treatment opportunities there. With that I will pass it on to Ulf.

0.21.38

Ulf Wiinberg

So overall we are generally pleased with the progress we have made from a financial point of view but more importantly how well we are doing with our strategic growth driver, both with respect to New Products and in that context we are pleased to say we have a psychiatry infrastructure established in the US and we are expanding our neurology franchise with Northera. And of course the very good progress we have in international markets, particularly China. So with that we are ready to start Q&A.

0.22.21

Operator

Ladies and gentlemen, if you have a question for the speakers, please press 0 and then 1 on your telephone keypad. You have to press 0 and then 1. Our first question is coming from Mr James Gordon from JP Morgan, please go ahead sir.

0.22.36

James Gordon, JP Morgan

Hello, thanks for taking my questions. I have a question about Brexpiprazole and also a question on Selincro. On Brexpiprazole, actually I have two questions; one is the preliminary guidance for 2015 that reflects on Brexpiprazole launch costs. Will that be very much back-end weighted cost towards the end of 2015 or are you very confident of approval and will you actually be doing lots of pre-launch activity for Brexpiprazole? The other Brexpiprazole question I had was just in terms of assuming we do get approval what the launch for a product like this could look like? Is it going to be very much a phase launch where you get more data over time supporting the product or do you see a high level of differentiation from the beginning, meaning you would have a strong initial launch? And then just the third question on Selincro which was you mentioned there being some stock in this quarter, how much was the stocking and are you still as confident in this product reaching the DKK 2.5 billion or is this product a bit less of a focus than the other three innovative psychiatric products that you…

0.23.42

Ulf Wiinberg

James, let me start by saying on Selincro, this is a new treatment concept and as such we are in unchartered territory but when we look at the reactions we get from payers like NICE and CSMO4 that we have in France we are very encouraged, I think the feedback from the launch markets with full reimbursement has been very positive but again it is very, very early days so we should give you a better picture in the quarters that follow. As

regards the sales, roughly two thirds are stocking. And then Anders, do you want to comment on, I think on Brexpiprazole basically you tend to hire the people when you have the approval and do that and we are planning to go full speed at the time of launch and you want a comment on..

0.24.45

Anders Gersel Pedersen

In terms of the data package I think first and foremost it will have a differentiating profile from day one as one part we have been very pleasantly surprised by the ability of finding what we expected in the clinical trial section compared to what we expected pre-clinically from pharmacology and also in the very early data that we saw a couple of years ago. That is one part. The second part is that there will be further data coming beyond what is in the registration package, first and foremost there will be data that will be supporting the later European file which will come out but there will also be other studies that will materialise over the next couple of years.

0.25.42

Operator

The next question is coming from Mr Jo Walton from Credit Suisse, please go ahead sir.

0.25.48

Jo Walton, Credit Suisse

Yes hi good afternoon. A couple of questions. One was whether the R&D spend that you had in the third quarter of this year may be a representative run rate for next year, then I wanted to ask you whether you expect the FDA to hold an advisor committee I had of the FDUFA for Brexpiprazole. And finally comment on Brintellix label in Canada, I mean if you can give any more colour on that and maybe on the expected pricing in Canada for example compared to the US or any more colour on the label in Denmark or in other countries where you have it? Thank you.

0.26.40

A: Anders Götzsche

I can start with the R&D spend. You should not take the expenses in third quarter as the run rate going forward. What you should expect is that we will use around 20 % also going forward due to, of course, we have a lot of studies ongoing with the 58054 and other

products already on the market. So you should not expect that. And with respect to the Brexpiprazole advisory committee, Anders will take that.

0.27.15

A: Anders Gersel Pedersen

Yes. Technically we do not know if you will get an advisory committee until we have had the first interactions with the FDA. Normally they would guide you after in the PDUFA 5 program they would normally guide you at the first interactions which we expect to have within a couple of months from now and at that time we should know. In terms of our internal opinion about it, for what it is worth, I don't think we will, but I don't know, I mean it's entirely up to the FDA to decide that.

0.27.51

A: Ulf Wiinberg

With respect to pricing we don't comment on pricing before launch, which takes place in January, but you should expect a premium price for the Canadian market and the pricing in this market.

0.28.07

A: Anders Götzsche

Label-wise in Canada, we are very pleased with the label that we have received in Canada. I think the importance for us is that it recognises some of the features of Brintellix that are unique to the molecule and within the Canadian environment we think it allows us to tell a story as we see it with the molecule.

0.28.32

Q: Jo Walton, Credit Suisse

Anders, sorry, just to clarify if I understood correctly, when you say if premium pricing in Canada, do you mean a higher price than in the US or is that what you mean?

0.28.43

Ulf Wiinberg

A: Actually in the Canadian markets. I don't want to give you more colour than that because we normally don't.

0.28.50

Q: Jo Walton, Credit Suisse

Okay, thank you. Bye.

0.28.55

Operator

Next question is coming from Mr Peter Hugreffe from SEB, please go ahead sir.

0.29.01

Q: Peter Hugreffe, SEB Enskilda

Thank you very much for taking my questions. A couple of them, first of all if we take Brintellix then it seems as a lot of positive wording from you in terms of the launch, but if I look at data then first of all it seems that psychiatry has a 60 % share which I assume comes from your sales force which is a bit a surprise as I think that your sales force is significantly smaller compared with the Takeda sales force. So what is going on there? And maybe some flavour as well on the launch in the sale because it seems that you continue to lose momentum. And then second, this one goes to Anders in terms of the Brexpiprazole data, back in Q2 I remember that you were extremely mute in terms of data, you would not comment at all, you just filed and that was it and now all of a sudden you have shown us at least significantly more colour on the data. What has changed this and is there anything we have not fully understood? I think I will stop there.

0.30.05

A: Ulf Wiinberg

First let me say that we are generally very pleased with the Brintellix performance. I am not sure I fully understand your comment. We have a quarter of a million scripts. We have good feedback on the products from the doctors. Market research shows increased prescribing and we are outperforming the competition. So I think that is a pretty good Northerastart myself. Secondly when you launch a new therapeutic modality it is normal that you are more successful in psychiatry but as people are getting more comfortable with the drug you will see an uptake in the GP area. So of course the GP area is a great growth opportunity for us and that is something that we will go after. So of course we

plan on increasing usage in psychiatry but I hope when we get towards the end of 2015 you will see a different split in that market. Anders, do you want to take the other..

0.31.21

A: Anders Götzsche

With respect to Brexpiprazole I don't know if I have given you much more colour today than you can actually see in the published data because I think if you read the data there you will clearly see that the profile that we show there is the profile that we had hoped for and I think basically that is what the composite of the package also shows.

0.31.54

Operator

Next question is coming from Mr Peter Welford from Jefferies. Please go ahead sir.

0.32.00

Q: Peter from Jefferies

Hi, yes, thanks for taking my questions. I have one question, I guess probably on the commercial side which is on Northera. Could you please outline the initial feedback if you can you have had from positions with the launch of Northera in the US, I appreciate it is early days, but any initial sort of anecdotes would be helpful. And then two quick financial ones. Firstly the DKK 1 billion you are anticipating in amortisation during 2015, does that include approval of Brexpiprazole and therefore the hike in amortisation from that? Because I guess I am finding it hard to get to a billion, given we are already a latent million and obviously increased later this year for Northera. And also on Xenazine, are you assuming in the initial 2015 outlook that there will be a new Xenazine generics or are they excluded from the 2015 preliminary outlook? Thank you.

0.32.56

A: Anders Götzsche

We will definitely not speculate in any generics entering the market at what point of time in the US market. We expect to have good Xenazine growth also in 2015. From an amortisation point of view for 2015 it includes amortisation for Brexpiprazole. But of course the increase you see is that we have amortisation of the existing US neurology portfolio and it is Northera and then it is the full impact of amortisations for Abilify Maintena, both in the US and Europe because we start amortisation for Europe also in 2015.

0.33.47

A: Ulf Wiinberg

And with respect to Northera it is very early days but what we hear is that there are many patients who because of orthostatic hypotension don't dare to go out and leave their house afraid they would faint in public places and they have tried everything and now with Northera there is hope for them. So we think there is significant unmet medical needs and that is kind of what we hear from the medical community and obviously in quarters to come we will be able to give more colour on how we are doing. The launch meeting we had was on October 4. So obviously we will have some ideas already when we report Q4 and also in quarters to follow next year, but so far so good.

0.34.51

Q: Peter from Jefferies

Sorry and just following up on the amortisation question. If we look at the nine months of this year amortisation was about DKK 530 million, so that would suggest that you did the last quarter is going to be at least … the DKK 250 million to get your 800 guidance. So I guess if I just take the fourth quarter alone, that suggests near DKK 1 billion, annualising it. So is this one of the products expected to come down during 2015? Thank you.

0.35.21

A: Anders Götzsche

There will be some amortisation costs for the old ovation products that will decline in 2015 and then we will have higher amortisations for the Otsuka portfolio.

0.35.42

Q: Peter from Jefferies

All right, thank you very much.

0.35.44

Operator

Next question is coming from Miss Eleanor Fung from Goldman Sachs, please go ahead.

0.35.49

Q: Eleanor Fung, Goldman Sachs

Hi. Three questions please on your 2015 preliminary guidance. Just to follow up on your revenue guidance, I am just curious on how confident you are on this number and also what you are assuming for Brintellix contribution? Secondly, in terms of supporting new launch products, just curious on whether or not you see 2015 to be the peak SG&A spend year or do you expect that some marketing costs will also spill into 2016 as in another investment year? And finally, now that you have guided for 2015 using core EBIT, how are you thinking about any potential dividend payments given that you have previously set this on reported earnings? Thank you.

0.36.36

A: Ulf Wiinberg

Just to comment, Eleanor, obviously 2015 is a dynamic year, we will continue to see generic erosion, that is not a surprise to all of you and we are replacing that with new products sales and we feel we have very good momentum here as described in this quarter and when we look at this year's performance and where we are with the various launches, so we think in 2015 new products sales will probably be at the range of 50 %, around 50 % of total revenue and we think revenue will be at or close to where we are this year. But of course there may be more variants in a year like 2015 than you see in a typical year when you don't have so many moving parts. And then, of course, you can add exchange to that. I think the way you should look at what we do in 2015 is that then we will largely have the resources we need to execute on the pipeline that we have at hand for now. We are not in a position or don't really have any interest in guiding on 2016 until we get closer to 2016.

0.38.03

A: Anders Götzsche

The dividend, we stick to the dividend policy we have for the time being and what is important is that, as you can see, the dividend related to the financial year 2014 and to the accounting year 2015 will of course be very limited. And that goes without saying, so that is what we are sticking to. We continue with the dividend policy we have so far.

0.38.40

Operator

Next question is coming from Mr Peter Sehested from Handelsbanken. Please go ahead sir.

0.38.46

Q: Peter Sehested, Handelsbanken

Thank you for taking my question and that also relates to the SG&A. To sort of make our own modelling of how it might look into the future, could you be so kind as to decompose the increment in SG&A costs, I mean how much of this is sales force, how much of this in promotion? If you also could give a flavour on how this is related to different products? That could be nice, so that we can make our own let's say more qualified assumptions going forward. A second question. You have previously been so kind as to give some point estimate guidance on the use or some of the sales for Brintellix. Could you give us a preliminary guidance for what to expect in Europe for 2015? Thank you very much.

0.39.40

A: Anders Götzsche

What you should expect from a Brintellix point of view is that the next region that is on the hook for getting decent revenue is International Markets. As you know, all pharma companies are facing in Europe, its market access will take some time and that will be the hard work we have to do in 2015 for Brintellix and as Ulf explained earlier, we are for the time being launching in the second largest market Canada so we will hopefully get good traction next year, we have Mexico, South Africa, other international markets will join in 2015. So that will definitely be the focus area and then continue to see uptake in the US markets. That is how it looks for 2015. With respect to SG&A costs it is very obvious that of course what will trigger the SG&A in 2015 is of course additional promotional spend for Maintena because we are launching in more countries, it is more launches for Selincro, it is launch of Brexpiprazole and then there will of course also be some additional sales costs depending on what kind of firepower we need behind how strong our market access is, and that is the concept we are running. When we have good market access we secure that we do a good launch and that is a reason also for coming with a soft guidance in 2015. And then I can promise you that we will of course try to keep the administration costs very stable and they are hopefully declining so that is one of our focus areas.

0.41.29

Q: Peter Sehested, Handelsbanken

I am sorry to keep dwelling on this one but could you just, the one billion, could you say how much of that is planned to be sales force expansion head count and how much of that is promotion and just to get a sort of practical feeling for what you actually spend on promotion and how…

0.41.52

A: Anders Götzsche

Peter, we are not willing to go into details with that because it will also, it can also change. So this is what is in the plans and this is a soft guidance, it is not a detailed guidance for 2015. So for now we are not willing to give more details on that.

0.42.11

Q: Peter Sehested, Handelsbanken

Okay, thank you.

0.42.14

Operator

I remind you, ladies and gentlemen, if you have a question for the speakers, you have to press 0 and then 1 on your telephone keypad. Next question is from Michael Novod from Nordea. Please go ahead sir.

0.42.28

Q: Michael Novod, Nordea

Question to the SG&A. You don't want to give details but maybe you could just elaborate a bit on how you see a sales force size for successful launch of Brexpiprazole because I guess you are going to be building up a GP sales force. What has that to do to the tune of numbers? Because I guess that will be cost that will be recurring into 2016 and onwards. And then secondly on the QUALIFY study. How are you going to use that? I guess there is a very strong promotional power in such a study so maybe you could give a bit of flavour on how it is going to be used in the different regions for Abilify Maintena?

0.43.47

A: Ulf Wiinberg

I think with respect to QUALIFY, obviously first we have to get it published but the data will primarily be important in Europe where both physicians and payers are very interested in differentiating data. I think to leverage today then promotion in the US will be more difficult so this is particularly valuable in Europe and select international markets. I think the final sales force number that you need for Brexpiprazole is, we haven't agreed that number yet with our partner Otsuka but you have to remember that it is more fifty-fifty cooperation we have on Brexpiprazole in the US whilst with Takeda it is more twenty-

eighty on Brintellix. So clearly it is a more significant investment even if you require a smaller overall sales force for a product like Brexpiprazole compared to Brintellix so that is kind of the thinking, as regards to the other comments on sales force we follow the principle that when we have access we try to initiate the hiring so that we don't sit with people at risk and obviously the time lines for approval vary greatly around the world and we adjust the model accordingly with respect to sales force. But clearly what we are doing in 2015 is obviously the total of fifty launches and we are expecting a full launch for Brexpiprazole second half next year.

0.45.51

Q: Michael Novod, Nordea

Okay, thank you very much

0.45.55

Operator

Next question is coming from Peter Sehested from Handelsbanken, please go ahead.

0.45.58

Q: Peter Sehested, Handelsbanken

Yeah hi, I just have a couple of follow-up questions of less significant importance but nevertheless could you just elaborate a bit on Abilify Maintena US revenues, the slight weakness of Onfi in the quarter and also Japan's Cipralex revenues? Thank you.

0.46.17

A:

You know the Onfi, could you be more specific, what do you mean with Onfi in the quarter?

0.46.26

Q: Peter Sehested, Handelsbanken

I mean just sales appeared a bit weak compared to what they usually do.

0.46.31

A:

We expect Onfi to see growth around 50 % for the full year and if that is the fact then we think it will be a very nice growth trend and it is also important to say that we have seen quarters with three digit growth rates for Onfi and you know that will not continue forever, that is just a fact, the baseline is getting bigger and bigger so if we can have high double digit growth numbers also going forward we would be extremely pleased. You had a question about…

0.47.13

Q: Peter Sehested, Handelsbanken

Cipralex, Japan. And what was the other one? Abilify in the US.

0.47.20

A: Anders Götzsche

You know Abilify in the US, we think that we are doing our utmost together with our partner to secure that we get the right uptake and it is going better and better, and as Ulf also said, we are trying to improve all the services around the product and you could say based on the QUALIFY study and also that we also have seen good results in Acute we are coming with new devices, we see that 2015 will be very interesting because that could actually, we expect to see good uptake for Abilify Maintena in the US and we can also see that in most European countries we are ahead of plan with access and it is going really well with the launch activities. So we are really confident for Abilify Maintena in general for 2015.

0.48.23

Q: Peter Sehested, Handelsbanken

Okay, but Q3 revenues in the US of around DKK 80 million, would that be appropriate to plug in?

0.48.29

A: Alf Wiinberg

I think both with respect to Brintellix and Maintena and also Northera when you come in the early quarters you know it is more important to look at the script trend than the actual trading patterns because it varies with stocking and other things so you can see great

fluctuations between the quarters that can be very misleading. So I would focus on the script data as you are trying to get an idea of the trend for Maintena in the US.

0.49.08

A:

And when you look into the figures in the quarterly release you can see that under other pharmaceuticals we had DKK 80 million in Q3 and this is of course a combination of Abilify Maintena and then the stocking of Northera. So 80 % of that is Abilify Maintena.

0.49.30

Q:

Thank you.

0.49.35

Operator

Next question is from Peter Hugreffe from SEB again, please go ahead sir.

0.49.39

Q: Peter Hugreffe, SEB

Yeah hi, just a follow-up on Brintellix because I am still at little bit puzzled, Ulf, so you might be able to help me because at one hand you compare yourself with Fetzima and Viibryd which are, in my world you are doing very good against these two products and that is fair. But on the other hand you have a target of generating revenues in your own books of USD 1-2 billion or is it DKK 5-10 billion, so I am just trying to understand because you can say that Fetzima and Viibryd are relatively small products so what are the dynamics you are looking into? Because I thought that those two benchmarks were quite easy to beat, at least if you shoot it up to your longer term guidance of the DKK 5-10 billion. So could you help me understanding what is actually the target you are looking at?

0.50.29

A: Ulf Wiinberg

I think, Peter, in the initial launch when we are setting up a sales force and Takeda is starting to sell in this area, if we are benchmarking against a company with the most

resource and the most competitive sales force to see whether we have the organisational fitness to execute on in the marketplace and from that point of view I think we have done pretty okay. I think we are targeting if we are going to get to USD 1-2 billion sales for Lundbeck we need to probably get to USD 1-2 billion in the US and clearly the journey to do that is to continue executing on the plan we have, accelerate uptake in psychiatry, accelerate uptake even more in GPs and then eventually bring in the cognitive benefits, we have three great studies showing cognitive benefits, nobody in the US knows anything about cognitive benefits yet because we cannot promote on that and clearly that will be a very important differentiator. But I think so far we have been able to show that Brintellix is a very good drug, people are prescribing it, they like it, they intend to increase their prescribing and we have a quarter of a million scripts in the market and that is pretty good, we think.

0.52.06

A: Anders Götzsche

And Peter, please remember that what we have said is that we expect that at peak sales that one third of revenue, this is ballpark numbers, one third of revenue should come from the US, one third should come from international markets, maybe a little more from international markets, and the rest should come from Europe. So that is still our aim and we still see no reason for not believing that we will be in the DKK 5-10 billion peak sales range. So that is our expectations for the time being.

0.52.49

A: Ulf Wiinberg

Okay, thank you Peter. Next question.

0.52.56

Operator

Next question is coming from Peter Sehested from Handelsbanken. Here you go sir.

0.53.00

Q: Peter Sehested, Handelsbanken

Thank you. Too many Peters on the conference call today, I am afraid, but… I think this question is for you, Ulf. I know it is not on your mind right now but I know it is on many investors' minds and that is sort of, let's say the longer term outlook, I mean if you have these high growth peak sales ambitions for your products they also will present a

headache for you when they go off pattern, let's say mid-2020 going forward, I mean could you just shed, I know it is very far away but nevertheless on the investors' minds, could you shed a little bit of light on your thoughts?

0.53.33

A: Ulf Wiinberg

You know, Peter, when I started in Lundbeck in 2008 the only thing I knew was that by the time where we are now we would basically have lost all the patents on products. And the way it looks like in 2015 if we execute we will have, if you exclude Lexapro that we had, we will have almost created a new Lundbeck in these six years with the new products that we have. But much more important, we have five significant growth engines with Brintellix, Brexpiprazole, Selincro, Abilify Maintena and Northera. Then at the same time we have a pipeline going forward where we have the chance to be the next new Alzheimer's drug on the market, we have several new indications in the works for Brexpiprazole and we may also have new indications for Brintellix coming. And then if I look at our research stage, we presented very exciting schizophrenia data with gene copy number variations which we could link with epidemiology making it potential albeit a long journey to have a biological target in this disease and we have done similar things in Parkinson's and we are pursuing most of the, we have a very broad Alzheimer's program in research and we are working with the best institutions around the world who increasingly come to us as we are by our own performance and other companies' lowered interest becoming more and more of a leader in the field. So I think when you look at brain diseases, the medical need is very, very high, higher than diabetes and other areas and we are establishing a good platform with the products we are launching and with the products we have in late development and the promise of what we are doing in research. So I hope we can be a company that can make a difference for millions of patients in years to come and lead science in this very, very important area.

0.56.01

Q: Peter Sehested, Handelsbanken

Okay, thanks.

Ulf Wiinberg

Thank you all for calling in and for following Lundbeck. Thank you.