H. Lundbeck A/S
Q3 2013 Financial Results
Wednesday 6th November 2013
13:00 Hrs UK time
Chaired by Ulf Wiinberg

Ulf Wiinberg

Welcome to our Q3 teleconference. Before I get into the presentation I assume that you are all aware of our company disclaimer and I will not talk more about that right now.
We are very pleased with the Third Quarter and all aspects of the Quarter; and the Quarter is helping us making 2013 a very good year both from a financial and a strategic point of view; from new product approvals point of view, and also in our efforts to address our cost phase which is a must for us in order to create headroom to launch the new products in 2014.

Looking specifically at the Quarter, the revenue was flat and we have addressed the impact of Ebixa going generic, so that in itself is a positive and we see strong new product sales at 29%. I think the most important event, at least we at Lundbeck, have waited for for many years is that we've finally achieved the FDA approval of Brintellix and the EU CHMP recommendations of Brintellix. We believe that the labelling has come through positively and we are now gearing up to commercialise these products with full force together with our partner Takeda in the US and also preparing for launches to get () and commercial launch in Europe and the rest of the world.

We are also very pleased that we have a positive CHMP recommendation for Abilify Maintena, so all in all, a very exciting quarter from an R&D perspective.

With respect to financial performance, I am very pleased with the tight cost focus that we have and obviously we have previously communicated on our European restructuring which was successfully concluded in the first half of this year and we're now working with project () and cost management will continue to be very important for us. All these things together means that we are able to revise guidance up to 1.5-1.7 billion for 2013.

So just commenting on the specific regions, obviously the US we have the FDA approval of Brintellix and now we are ensuring that we have access so that we can do a full commercial launch from January together with our partner Takeda, and we also have very good growth of our new product and particularly Onfi up 122%. In international markets we have found Azilect in China and we have continued strong development in Canada which is a most important international market.

With respect to Japan the Lexapro share is now 11% and we feel this is a strong market share two years into launch and our ambition is to become market leaders in Japan, together with our partners Mochida and Mitsubishi Tanabe. We have also partnered Selincro with Otsuka and the development programme will be initiated and we're hoping to conclude the programme and have the product launched in around 2018 timeframe. It's

important to say that we have given peak sales guidance of 2.5 billion for Selincro and Japan in included in that guidance.

With respect to Europe, obviously the positive opinions from Abilify Maintena and Brintellix have come through and we should see approval on Maintena hopefully before year end, Brintellix beginning of next year, and then obviously the work starts to get market access in Europe. We have also filed Selincro for approval in Russia. So with that, I want to hand over to Anders Gersel Pedersen.

Before I do I also want to comment specifically on Maintena sales on Page 5 where the sales are now close to 15 million in the Third Quarter according to IMS and we feel that although it's early we're confident that we will continue to do a strong uptake in the US and we're excited about the European launch and we believe this will become a leading product in the long-lasting markets for schizophrenia. With respect to Selincro we have previously said that obviously it takes time to get market access. It's important to emphasize that normally we don't launch products before we have market access. On Selincro we have seen private sale which we rarely do before we have investment and we have very small private sales of 2 million in the Quarter. That said, we are now starting to get market access. We are seeking a reimbursement in the Netherlands and Scotland and we have had the first full commercial launch in October in the Netherlands and obviously when we look in 2014 we hope that within the year or around a year's time we should start seeing approval of the major markets in Europe, France, Germany and the UK, Italy and Spain and so obviously material sales for Selincro should not be expected to be seen until the second half of next year. And lastly I want to say I'm very excited about the partnership deal we have with Otsuka on Selincro for Japan.

Maybe a product we don't talk very much about but we are very proud of the launch of Treanda we have done in Canada, in our 1,500 patients treatment with Treanda and year to date sales are a little bit above C$13million and obviously when we did the deal with Cephalon and later Teva, Treanda was part of the CNS deal but we are very pleased to say that we have become rated as the second oncology company by the blood cancer KOLs in Canada, so we think that's a terrific achievement.

With that, I would like to hand over to Anders Gersel Pedersen.

Anders Gersel Pedersen

Thank you. Let me first start by saying that we are in the R%D side and we are very pleased with the approvals and points of recommendation we have received this quarter, and that this is cornerstone in our ambition to remove from the original treatment strategies which basically were at getting remission in patients, then to get remissions with reduced side effects and now to treat not only to do this, but also try to tackle some of the symptoms that still bother patients with depression beyond just the core symptoms and thereby hopefully helping them also in having better lives.

We have with the approvals that we have received had recognition of both the full does range in Europe and United States, recognition of the novel mode of action and we have because of the slight difference in the filing opportunities in the two regions, six positive short terms that is a flexible dosing, long term () that is in the US, and for the European scenario we have obviously also the full dose range and the multimodality mode of action

acknowledged, also the cognitive findings in the animal data acknowledged, and we have 9 out of 12 positives that is as part of the filing here, and also the flexible dosing. We have () that a positive head-to-head study in the European label which is quite a unique feature for an antidepressant to have in the label.

If we look at the continued review that we have had in general, we have apart from the Brintellix approval I just mentioned, we have also had the Abilify approval which has been a discussion a bit for the US FDA,. We have had approval of the adult treatment for children to a younger age before for Sabril and then we have expectations still of the filing of IV carbamezapine later on this year.

In the clinical trials area we have had the first patient in the new programme on 58054 for Alzheimer's disease and we have initiated several studies in brexpiprazole. Just for those of you who follow closely, I would highlight that we will present data at the ISPOR EU conference later on this month and also at ACNP at the beginning of December so you can see it there.

With that I will hand on to Anders Götzsche to take us through the financial. Thanks Anders, please turn to slide 11.

Anders Götzsche

Thanks Anders, please turn to slide 11. First of all our continuous operations shows very satisfying growth with 11% in the Quarter which is driven by all regions and across products. We are pleased to see that the Cipralex continues according to the Third Quarter, from the previous quarters both in local currency and reported currency. And then you can also see from the figures that our US product portfolio is continuing to grow, and of course the growth in the Third Quarter was not as strong as you saw in the first half but you should remember that there will be swings between the Quarters and that the underlying growth of these products is actually excellent. We continue from a market point of view to have a difficult business environment in some of the countries but you know our product transition and our geographical expansion is on track and you can see that we have growth in the international market, we have growth in the US and we also actually show pretty strong growth in Europe with the existing product and next year new product growth will be accelerated by the extension or the extended portfolio including Brintellix and Abilify Maintena in Europe.

When we look into our sales figures, we have earlier been guiding decline of 30-40% for the year and we now expect it to be in a range between 25-30%, so the generic erosion has been a little less. You shouldn't take that into the 2014 numbers because we don't know how the erosion will happen in 2014. I would say from a revenue point of view all-in-all we are very satisfied with the revenue progression in the Quarter and that is also a part of the foundation as Ulf mentioned, the upgrade of our EBIT from 1.3-1.7 to now a revised guidance of 1.5-1.7.

Please flip to the next slide. The earnings in the Quarter, 511 million, and we also think that's an excellent result taking into account that we have provided, or we have recognised a provision for the future of 200 million. So the good result is a combination of seeing the impact from the costs projects we have driven over the years, the reorganisation in Europe,

actually seeing extremely good sales figures, and at the same time taking out 100-150 million a quarter.

So we think that the cost development is under tight control and we are as said, not investing in the new product launches before we have the market access and that will also be the concept that we are using in the period 2014 and 2015. And it is also important to say that 2014 and 2015 will be an investment period, we will invest in the product launches, we will invest in R&D so it will be a tough period.

If we go back to the Quarter, cost of sales is down 2% for the Quarter and this corresponds to 26% of our revenue, which is on par with the same period last year. You should expect a cost of sales to have an increasing sales revenue, and that will be caused primarily by the decrease and () revenue, and then we will increase our revenue from Zenazine and Azilect which is carrying high royalty costs. This is fully in line with our expectations and you should expect that our cost percentage for the full year will be slightly higher than you saw in 2012. You should expect the costs to be around 20% of revenue for the full year. SG&A for the full year you should expect it to be around 40% excluding one off and including the one off usually expected to be around 45%.

Our cash flow is in the Quarter negatively impacted by the payment to the EU Commission. If you adjust for that we think that the cash flow is actually excellent for the Quarter and that's also meaning that we have approximately a little less than 5 billion in cash and a net cash position of 2.9 million.

Please flip to the next slide. As I said, I hope that we have given the impression that we think that the business is running really well and you have seen the revised guidance and you also need to bear in mind that so far the year has been impacted by several one-off items, both from a positive and negative character, and more or less these negative and positive items has more or less washed each other out. So on the negative side we have the EU fine, the () impairment, and then the provisions of project 5th(?) and on the positive side you have the divestiture gain from the mature portfolio, and then the Otsuka payments for Abilify and Selincro. Net finances due to fluctuation in the intercompany; you should expect to have…that will be a little increased and you should expect between 100-150 million tax rate slightly above 40% for 2013 and that is due to that we cannot deduct the EU Fine.

That is concluding the financial presentation and then I will hand over to Ulf for the concluding remarks.

Ulf Wiinberg - Lundbeck

So again when you look at the main events in 2013, it's been critical with all positive product approvals. Maintena and Selincro, we had the presentation with Brintellix at the FDA. In San Francisco in May we presented 58054, and in Boston we have now started up the phase 3 programme for 58054 in Alzheimer's disease. We have the positive recommendations for Abilify Maintena in Europe and Brintellix in Europe, and the very important Brintellix approval in the US.

Before we start the Q&A, I want to say I'm very pleased for the year. We have to do a little shorter Q&A in order to catch flights to the US so we intend to finish the meeting at

2:45 and do this in 45 minutes instead of the hour. I apologise for that, but our investor relations are available after the call to provide additional insight.

We are now ready for questions operator.

Questions and Answers

Eleanor Fung – Goldman Sachs

Hi Eleanor Fung from Goldman Sachs. Two questions if I may on SG&A. Firstly I'm just curious, given that you're in the process of launching new products, it would suggest that your SG&A expense should be increasing sequentially quarter and quarter, yet if I look on an underlying basis, your costs between first quarter and Third Quarter this year in particular Third Quarter seems to be lower than first and second quarter despite flat headcount. Could you provide some colour on what is driving this lower base and how you're thinking about 2014? And then secondly, just on your EBIT guidance increase for 2013, just wondering if you could help us understand how much of the impact refer to SG&A spend that has been delayed to 2014, thank you.

Ulf Wiinberg

Just a general comment before Anders Götzsche comments, you know, we initiated the project REPRO which was a reflection of European operations which was finalised in the second quarter of this year, so we feel significant savings coming through fully second half of this year. Then the sales force expansions that we are doing in the US is hitting us in the fourth quarter. And then of course as final project REPRO, the European launch costs start from when we have real market access, so that's why the drivers look like they do. Anders, I don't know if you want to provide some more colour too.

Anders Götzsche

I think you should look at the SG&A levels year by year and not quarter by quarter because there will be swings due to marketing activities, promotional efforts, summer holiday, whatever, so there will be swings quarter by quarter. And the decline in SG&A, you should not expect that we'll then have additional costs in 2014, but you should not be…again, I want to emphasize that when I look into the EBIT guidance for 2014 I can see that consensus is beyond what we have guided, and I don't know if it's because people are too optimistic about SG&A but it is important to say three approvals in 2013; that will lead to launch costs an increase in SG&A, and therefore to have a consensus that is not within our range of EBIT I don't understand that, and that might be due to the fact the people are too positive on our costs. We have a tight cost control so we will take out costs wherever it's possible, but we will also launch to create growth because growth – we cannot save ourselves to success; the success depends on successful product launches and we'll do whatever it takes to create growth in the long-term.

And then you had a question about EBIT, what was that? It was what created the upgrade in EBIT. Two factors; tight cost control and less decline for Ebixa than we anticipated previously. We anticipated 30-40% declines and now we face 25-30%.

Eleanor Fung – Goldman Sachs

Thank you.

James Gordon – JP Morgan

Hello James Gordon from JP Morgan, thanks for taking my questions. I have two questions on Brintellix please. The first one is about the cognition data; so I know you recently got the positive CHMP verdict, but can you say does that include any cognition claim on the EU label? And in a similar vein in the US, are you still seeing a chance of getting cognition actually on the label eventually or is the best case on cognition for the US that you get it in a journal and that's how you'd market it cognition-side.

The other question on Brintellix; consensus expectations for the initial pace for the launch. Consensus has DKK570 million (Danish Krone) for next year and next year most of the sales are going to be in the US because EU will take time to get reimbursements sorted out and I think you're only going to consolidate 35% of the US sales, so that seems to imply that you're going to do US sales with about US$250m in market next year, so just does that seem achievable.

And also just a final one to squeeze in, you mentioned what SG&A would look like but what about R&D for the full year; is R&D going to be about flat or could it even be up slightly for the full year?

Anders Gersel Pedersen

Starting with your question on Brintellix labelling, first and foremost we have not applied for cognition data in the label. I think that's very important and I think I've stated that earlier on, and that's simply because there are the requirement that we need to work with agencies on to fulfil before that is a possibility. In itself, having it as a claim as such on the label is not a necessity in itself; it's a desirable thing, but not a necessity. I think the important first step is to have good data that supports that what we believe about the product is something we can show in patients. The next stage is then to see how will authorities allow us to use that data and that will depend on policies in the various policies in the various countries including the US.

For the European scenario we have not a language within the label itself around cognition, but the cognition data that we have submitted are part of the European assessment report that's going to become publicly available in conjunction with approval of the product. We will obviously as we see data maturing and you will have access also to see the data on the first of these studies in conjunction with AC&P and the next study in the midst to the second half of next year, we will know where we stand in terms of discussions with the agencies of changing the label situation or even discussing that with them.

You had a second question that was about the R&D spend.

Anders Götzsche

You should expect it to be around 20% of revenue for the next couple of years. We will be very busy with a lot of studies, a lot of say three pipeline early phase studies, so usually expected to be around 20%. And then you had a question around guidance for Brintellix

first year in the US. We are not giving any value guidance and I think we will at our investor day go more into detail of what is actually the blended mix of price, volume, how do we see the uptake, and therefore we will give more details on how do we see the market, how do we see the pay structures, so we will try to give a more transparent and clear picture of how we as Lundbeck see first year traction for Brintellix.

Thank you and can I just ask one quick follow up on R&D, what about R&D for 2013; is only 20% of sales realistic for year 13 or could it be slightly more?

That is realistic.

The 20% is realistic.

Yes.

Thank you.

Frank Anderson - USCO

Hi it's Frank from USCO I have two questions, my first question is regarding Ebixa;, could you elaborate on how you see the drivers of the generic erosion - you clearly expected a stronger generic erosion in the first part of the year, and now it seems to ease up a little bit. Could you also shed some light to whether that will apply for other products that what we have seen the trends on Ebixa, and my second question is to Anders if he could just reiterate how he sees SG&A for the full year 2014 as percentage of revenue; I didn't get that, thank you.

Anders Götzsche

I just want to say on the generic erosion on Ebixa. We will not read into this situation that we will have less generics in '14. We think it's a tiny issue in '13 but we expect full generics in '14. You should not read into the generic erosion rate here that we will have less generic erosion on Cipralex. We will have full generic competition on Cipralex next year, so do not chance your assumptions on that. I will hand over to Anders for the SG&A question.

Anders Gersel Pedersen

The SG&A for 2013 I gave the guidance with 40% of revenue, excluding one-off and around 45% including one-off for 2013, and you should expect 2014 also to be an investment year. We haven't given any specific guidance for the percentage for 2014 and we will come more to detail when we give the guidance in February 2014.

Okay thank you.

Tim Race – Deutsche Bank

Hi there it's Tim Race here from Deutsche Bank. First of all, just congratulations on the approval of Brintellix, glad it's worked out and as you say, hard work starts here I suppose in launching it. Now on the line of Brintellix, just first your friends at Takeda

recently openly discussed how excited they are to have Brintellix on board. They also mentioned that this week you were going to finalise sales force plans. Could you just help me understand how the split is actually finally going to be, and the market responsibilities, how many reps you've decided on and really what Lundbeck does, what Takeda does, and just how we should think of this as an individual cost; is it a straight calculation of say $200,000 per fully loaded rep x200 or how should we think about that?

Then just a question for Anders on the guidance I suppose you've beaten () throughout 201, you are already at the lower bound of the guidance for the EBIT at the nine month point;, how conservative are you being and generally what is your outlook on guidance do you want to () going forward, is guidance realistic? You point out the consensus is perhaps too bullish for 2014 but you could have pointed out at early 2013 and been wrong, so just your outlook on guidance.

Ulf Wiinberg

Thank you for your kind congratulations we're very excited about the Brintellix approval and the reason we have to have this meeting a little shorter is that we will have a talk-to-talk meeting with Takeda in Chicago tomorrow to finalise the commercial launch plans for final finalise, I should say. We will shed more light on the exact launch information around the investor conference that we have here in early December in Copenhagen. That said, what you were saying, 200x200 for now is certainly not a bad estimate. With respect to cognisance on guidance, I will just say before Anders gives his more specific answers, we know the costs we're have in commercial and the build-up we have in the US. We know the generic erosions but what we don't know is the magnitude of the new product sales updates and the speed of access and so on, and that's the kind of transition we will have in '14 and we will have in '15. Anders, I'll hand it over to you if you want to add more to it.

Anders Gersel Pedersen

Yes I just want to say Tim that to protect a generic erosion for mature products what we do when we give you guidances we try to use history and how we see the environment and that will be our best estimate, and we do that country by country before we give you any guidance. So we try to give a realistic guidance, and then we have been positively surprised with Ebixa but I have also said that you should expect a 30-40% decline in 2014 for Ebixa. But when we guide for 2014, I can be more wise around that; that could increase if we see a faster generic erosion in the beginning of 2014 or by the end. So it's very difficult to predict. So we try to be precise but of course with so many products in the launch space, it is not an exact science, so sometimes we give the best guidance we can and hopefully it is helpful, but not always as precise as we wish it to be.

Thank you.

Peter Hoeg (?)

Thank you for taking my question;, a couple of ones just to clarify. In terms of () you have previously guided that you will announce data or the headline conclusions in 2014. I can see from Otsuka's communications that they state in late 2013; which one is right and what should we expect in terms of data announcements?

Secondly Ulf you have previously said in terms of Selincro that by the end of the year you will decide whether it was a success or not. Did you mean 2013 or was it another year and maybe could you give us a status on what you feel in terms of trigger for a successful launch of Selincro? And then finally in terms of Lexapro in Japan; it seems like it's moving back and forth. Could you give us some dynamics and understanding to do a translation from the market shares into your reported revenues, thank you.

Peter let me start with Selincro. What I try to say but may not have been clear about is the first key performance indicator for us is to see if patients get the prescription of Selincro, if they come back for a second script. And whilst we don't have the full commercial launch because of market access, the first full launch in the Netherlands. What we have seen in these early launches where people go in and pay the full price and don't get reimbursed is that they also come back for a second script. And so with that then translate to the full population later on? I don't know, but in the event people would have come in and said they had one script and then they don't come back for a second. That to me would have been a strong early warning signal. That is not what we are seeing to date.

Then whilst we recognise market access takes time, I might have underestimated that from a communication point of view. So full launch doesn't really start until 12/15 months after by the middle of next year. I think it's not just () I think it's a European problem in general and hence we will probably really not know until the end of 2014. In that context the investment model we follow which we introduced with project RETRO is very important because then we found market access and then we have market access and price we start spending money on it. So that's the situation where we are at in our understanding.

Just to conclude, we could have been in a position to say it's not working maybe from second scripts by the end of this year. That is not what we are seeing but I think in order to say that it's working we've probably going to guess towards the end of '14 for that.

With respect to brexpiprazole data, we do not and I also do not believe, I know that Otsuka will not have the full picture of data until into 2014 because the data is not available, it's not completed yet. So I would be surprised if there would be any disclosure of the data before we have the full insight to that. With that caveat I would say that obviously we need to discuss with them, but it's ultimately their decision on how they want to manage this, I would be surprised if there would be a change in prior practise, if they would have any data being released this year.

Ulf Wiinberg

Peter, was there any other questions?.

Yes just the dynamics of the Japanese market in terms of Lexapro in Japan, just to understand what is the read-through from market share gains and then into reported earnings, because it seems that it fluctuates quite a lot.

It fluctuates a lot, but I cannot say we fully understand all these fluctuations. When we had the 10% market share in the beginning of the year with and that was too high. We didn't know exactly why it was 10%, but we felt that number was too high and we guided

the market to that effect. We think the 11% we're seeing now is the true figure and we think that's a good number in there. I also know that I recently met with our Japanese partners, Mochida and Mitsubishi Tanabe and they are continuously very, very excited and aspire to be No.1 in the market. Had you asked me at the time of launch if I would be happy with 11% share now, I would have said I would be delighted to have 11% share now in September this year. So far so good, still work in progress but we aspire to be No.1 in the not too distant future.

Next question please.

Kerry Holford – Credit Suisse

Some questions please on Brintellix and a quick one on Onfi. Given the lead time we have now between approval and launch in the US, I wonder if you can provide us with any insight into your formulary discussions and acceptance of this drug ahead of launch, before launching it next year, just the attitude of the players, the expected tiering on launch and whether you think your position may be the same or better than (). You talked also about the 200 new reps in the US. Can I just check whether a substantial proportion of those are already on board or are you still in the process of hiring? Interested in your comments also about not investing in Europe ahead of market access for Brintellix and Abilify Maintena there. I wonder what sort of expenses we should assume that you do make before launch and what may come after. And then lastly on Onfi again a strong quarter in Q3. Could you tell us how widely you think you penetrated this market and whether the performance represented real demand in the quarter or whether there was a big contribution from price? Many thanks.

Anders Gersel Pedersen

Can I start saying we just had the approval of Brintellix in the US and now we are in the plan for getting market access and having all the payer discussions, so we cannot give a lot more colour of that today. But for those of you who are interested, we will have an investor day in December here in Copenhagen and then we hope to give more colour at that point. The roughly 200 reps that we have talked about on board today in the US and you should assume that they are all here now. I think with the project RETRO the investment concept that we have for Europe that you're addressing is that we invest in KOL activities (), we invest investment market access like activities, but we do not have full GP sales forces on board until we have market access, and all of the spend associated with that. So that applies to Selincro, it applies to Brintellix, but not to Maintena where we already have a specialist sales force on board in Europe. We may be tinkering with the numbers there a little bit but overall you shouldn't put too much attention to this. And just on the guidance question, we will come out in the beginning of next year when we get guidance and give a range on the SG&A and you should expect it to continue to be high because we are very ambitious launch activities on multiple continents and on multiple products at a level that we have never done before.

Ulf Wiinberg - Lundbeck

And for Onfi, you know it's not price increases driving the growth of course we as for other products have price increases in the US for Onfi but it's a limited part of the growth because you're seeing; this is demand driven.

And have you penetrated a big chunk of that market or do you think it's…

I think it's our insight into that is very limited so what we see is that we are very happy with the response from the patient that this works as well as we saw on the clinical trials and we have been positively surprised by the revenue gross we have seen and we hope that will continue not as good as you have seen in third quarter but of course we hope to have also next year double digit growth.

Many thanks.

Closing Comments

Ulf Wiinberg - Lundbeck

With that, I apologise for finishing the conference early but investor relations will be available after this and we will be heading over to the US to continue work on preparing for the successful interaction of Brintellix.

Thank you again for calling.