

H.Lundbeck
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Wed, 07th November 2012
13:00 Hrs UK time
Chaired by Ulf Winberg

Ulf Winberg

Thank you all for calling in to the third quarter results 2012. Let me just go to slide two and I will not read the company disclaimer for you, you have seen it many times. So let me move to slide three please.

We have now finalised the second full quarter following the expiry of the Lexapro exclusivity in the US and I will say that we are very pleased with how our new product portfolio is developing and how renewing the company and how that is coming through post Lexapro. And considering the very tough market conditions in Europe I am quite pleased with our third quarter where we had a 2% revenue growth excluding Lexapro in the US. I also believe the EBIT of 661 million is acceptable especially when you consider the substantial investment we are making both in R&D and in new product launches. So we are on track for delivering on the guidance for the year and I will also say when it comes to new product launches this is the first quarter when we are presenting detailed sales figures for all our three new launches. \

We are very pleased with both Onfi and Lexapro in Japan while we continue to work on the rollout of Sycrest, which probably has been tougher than originally anticipated both with respect to uptake but also timing or pricing. We now maintain our original expectations of this as a product that should sell for more than a billion Danish krone. I will admit that there are times when I have thought it would be a significantly bigger product, but we are back to the original expectations. We have also launched Treanda in Canada and although it is very fresh the feedback is very positive on this launch.

When it comes to the development portfolio I am very pleased with the progress that we are making. We have filed Vortioxetine in the US, Europe and Canada and we will be filing in Japan second half next year. Our partner, Otsuka, has resubmitted Abilify [Maintainer] in the US and obviously with an expected six months approval time we should be launching this towards the end of Q1 beginning of Q2. We will also file this product in Europe towards the end of this year hoping for an approval end of '13. Before year end we also expect feedback on Selincro from the European authorities. So as you can see when you look at both the financial performance, the performance of the new product and the progress of our late stage portfolio we are going through very exciting times.

Can I go to slide four please? So we are now towards the end of '12. I think the year has been quite unbelievable. Looking back a few years, I mean who would have thought that we would deliver over two million in EBIT and have this level of investment both in R&D and in launching new products. So clearly we have made a lot of progress and so many

things have been happening and continues to happen for us and although market conditions are tough, things are—most of the things are going our way I would say.

We are for the first time going through a period where we are doing multiple product launches. Remember we used to launch a new product every three or every four years and right now we have simultaneously many new launches going on and it is nice to see therefore that product launches like Onfi and Treanda are doing really well. Obviously we should also start seeing the—get the Abilify Maintainer approval which allows us to launch into psychiatry in the US beginning of next year, to be followed by Vortioxetine and then we also hope for positive feedback on Selincro here at the end of this year.

Now, all of you should now—by now see that both Vortioxetine and Selincro will be significant products in their own right. Vortioxetine, with its unique mode of action, strong efficacy and very good safety profile can help many patients not treated very well today. And with Selincro we have a completely new concept, the reduction concept in treatment of high risk consumers and people who need to cut down to avoid serious medical issues. More articles will be published during '13 to give you more granularity but you should already now be able to see the key features of these two important drugs.

Next slide please. Lundbeck has substantial unrealised potential outside Europe. We now have more than 40% revenue outside of Europe and we continue to see very strong growth and we expect the US to be a key driver and Canada to be a key driver and obviously all the things we are doing in Asia, both in Japan with Lexapro, in China with Ebixa and Lexapro and also with Azilect which we are starting to launch out in Asia now. So we expect this positive development outside Europe to continue. Next slide.

And of course we are also very pleased with the new product development. We have both Onfi and Lexapro in Japan are already generating more than 100 million Danish krone in 2012 and we should hope to see some good numbers for Treanda already in Q4. So right now 17% of Lundbeck's revenue comes from new products compared to 8% a year ago. So I am optimistic that we will reach and exceed our target of 50% in 2015.

So just to give you some headlines on the new products; Xenazine is performing very well, the positive trend continues and we are slightly increasing our expectation for this product to beat 1.5 billion Danish krone. It is also very early to say where we are heading with Onfi but needless to say we are very pleased with 174 million after only nine months. Sycrest and Saphris has been launched in 20 countries, the revenue is just exceeding 75 million krone, which is less than I had hoped for. At the same time we have done good launches in Spain, Italy and Australia. We have important launches coming up in Brazil, Canada and we are also waiting for [price] in France and the feedback from the physicians on the product has been pretty positive too. So this is still very much work in progress.

Slide eight please. We have also seen a good performance for Lexapro in Japan and the latest share is 6.1%. And I know that our partners Mochida and Mitsubishi Tanabe are excited about the opportunity and are continuing to invest heavily behind the launch. Just to remind all of you that we reported sales for Lexapro for Lundbeck basically as a royalty income, so it is very important for us.

I would now like to hand over to our Head of Research and Development,

Anders Gersel Pedersen

Good morning. The pipeline as you will see on slide nine has a weight of phase III and registration programmes ongoing and also the Alzheimer's disease product, AE58054, which we are currently working on, hopefully moving into phase III in the short future. The Selincro which I will not discuss further here basically is in the final phases of review and we expect this plan to have a decision on the CHMP by the end of this year.

If we go to slide number ten, you will see here that the progress that we have made for the quarter on Vortioxetine, which is very significant, I am pleased that we have been able to file virtually simultaneously in the US, Europe and Canada, fairly shortly after we got the last set of data. We have a very extensive file with more than 7,000 patients for safety in the file. We have established efficacy at dosages from five to 20mg. It also includes, which is important for particularly Europe, but potentially elsewhere a positive relapse prevention programme. We have a study in the elderly which is positive.

And notably we have, with the symptomatology that we have seen and potential effects as you can see obviously a good effect on the mood, good neutral effects on sexual dysfunction, strong data in the elderly on the cognitive profile and also clear data on soft scales on reduced anxiety and good insomnia profile. This is all clinical translations of the receptor profiles that we have described earlier as part of the multimodal profile of Vortioxetine. So at least with the data that we have as part of the trials and some of them will be presented, the ones on a later date, so dosages—a high dosage will be presented at APA in May 2013.

If we go to the next slide the Abilify Maintainer which is the injection of Abilify and we have filed that as you all know with the FDA and resubmitted it in September, expecting to have a PDUFA date end of February for the FDA. Also the MAA in Europe is on track for a submission by the end of this year. And we have a study initiated in acute schizophrenia and bipolar disorder as we speak. So basically we have an extensive effort going on, both in terms of regulatory activities, but also in clinical trials both with these products and the phase III studies, programmes that I alluded to before.

And with that I will hand over to Anders Götzsche.

Anders Götzsche

Thank you very much, Anders. And we are now at page 12 and as you can see the headline is actually what is really important for the quarter is that new products doubled for the quarter. And as you are all aware of we had laid out a strategy and what was important to increase product diversification but also geographical footprint and the finances are demonstrating that we are doing that. And of course you can see that Lexapro is declining. I have been asked isn't it going faster? It is fully according to the expectations that we have laid out in the market. We have said 500 to 700 million and we will hit mid of that range, but you should not expect any significant sales from Lexapro in the US going forward. That is history.

And then revenue from Lexapro excluding—or revenue excluding Lexapro is up with 2% and of course the European environment is tough but you can also see that the decline in Europe is actually less this quarter and that is of course due to that we are regaining

momentum in Germany and from next quarter we have also—we will have seen the full effect of the generics in Spain. For a picture, we have seen the first generics in Europe and that is in Germany. That is the only country. We have not seen any impact so far and how fast the generisation in Europe will take or start we cannot speculate so far. You should also be aware of that we have a growth of 9% for Azilect but you should still expect Azilect to have a low single digit growth for the full year. We have seen some seasonality and you should not expect that to continue. We still know that the underlying growth is double digit if you take in account that we gave back Germany to Teva by the beginning of this year.

And then again, Ulf said it, but I want to underpin it, 44% of growth in US excluding Lexapro. We are extremely pleased with that for the quarter. And also as you can see in the slide, a 64% increase for Xenaxine that is also a pretty okay result for the quarter. International business, it was actually flat for the quarter but the Canadian business is actually continuing to impress and increase 22% for the quarter, up to 265 million krone and also you can see internationally that Lexapro in Japan, we saw a revenue of 133 million krone for the first nine months and we expect that to continue during the remainder of the year.

What the international market has been facing is of course revenue in Turkey has been declining due to [heavily] price decreases and we also saw some generic impact in Brazil for Cipraleth in the [quarter]. I would say from a financial point of view that we all know is actually quite satisfied with the revenue progression for the quarter and also for the first nine months. Of course it is difficult business environment out there but I think that we, in the quarter, have shown that we can make—we can execute on the geographical expansion, that we can actually expand our product portfolio of new products.

Please flip to the next slide. We think that the P&L actually demonstrates that we are also in good cost control even though that we are investing heavily in the partnerships and in our research and development. So the cost is actually declining and of course you should also—you are aware that we last year made a restructuring and that is of course also one of the factors that impacts the decline. Cost of sales was up 10% compared to last year and that is of course due to the increasing share of revenue from in license products with royalties and then of course the decrease for Lexapro in the US. The quarter is fully aligned with our expectations and you should still expect that the cost percentage for the year will be around two percentage points higher than last year and around 22%.

The SG&A cost was down 2% but kept a relatively high level due to the launch activities, especially with Sycrest, Onfi and Treanda. And you should expect the SG&A margin for the full year to be around 42 to 43 percentage points. R&D costs excluding one offs for the quarter was flat and you should still expect the R&D ratio to be around 20% for the full year. And as a conclusion the EBIT landed at 661 million Danish krone and we are very pleased with that. Please turn to the next slide.

As you can see from the slide our cash flow generation continues to be satisfying, also taking account the decrease from Lexapro in the US and also the continued investment in product launches. For the quarter we had a positive operating cash flow of more than 500 million and a total change in cash, ballpark figures the same amount and we now have a cash position of 3.2 billion and a net cash position of 1.3 billion. You should, by the end of the year, expect that we will have a net cash position around two billion Danish.

Please flip to the next slide. Based on the quarter and with less than two months left of 2012 we are very confident in maintaining our financial guidance for the year and as we have said in connection with the first half year result, the guided [unclear] are excluding costs related to the restructuring of our European commercial operations. And revenue is still likely to be in the lower end of the range due to price pressure, especially in Europe.

You should also be aware that if we—the growth for the full year would have been seven to 9% higher if—points higher—if we hadn't seen healthcare reforms due to generics and price cuts. With these concluding remarks for the financial presentation, I will hand back to—hand over Ulf for main comments for the last page.

Ulf Winberg

Thank you, Anders. So the next thing here is the news flow for 2012 and '13 and already here in Q4 we expect feedback from CHMP on Selincro. We will submit the Marketing Authorisation for Abilify Once-Monthly in Europe. We expect to hear back from FDA with respect to acceptance of the NDA for Vortioxetine. There will be a presentation of Abilify Once-Monthly data on ACNP.

First half next year we should have or hope to have approval of Abilify Once-Monthly in the US. Approval of Selincro and presentation of Vortioxetine data at APA in San Francisco in 18 to 22 May.

Second half we have—hope to have approval of Vortioxetine in Europe and the US. We should see headline data on brexpiprazole phase III studies. We also hope to conclude the desmoteplase phase III study, DIAS 3. We hope to approval for Abilify Once-Monthly in Europe and there will also be a presentation of 58054, our exciting Alzheimer's drug at the AAIC 2013 in July in Boston.

So conclusions on the quarter; we are very pleased that we are on track to deliver on guidance for the year. We are pleased for the progress of our strategic growth drivers, also with respect to the new product sales uptake, but also geographic expansion. You should expect that we will continue to have high investment levels in launch activities and also high investment levels in R&D. And obviously we have a lot of news over the next 12 to 15 months, which potentially can give a very exciting long term growth platform for Lundbeck.

So with that, we are ready for questions.

Questions and Answers

Tim Race – Deutsche Bank

Just a few questions please. First of all just on the guidance, you are very confident you say on the 2012 guidance, just given the investments that you are going to make since you originally gave the floor guidance up to 2014, how confident are you of being able to meet that sort of floor of EBIT out that far? Do you have good enough visibility? Are you going to stick to that floor at all costs? Obviously I mean I have been expecting you just

to be there or thereabouts on the guidance for a long time, but I just want to know what sort of visibility you have on that and is this a target that you will stick to at all costs despite sort of investment levels you may need to make ahead of product launches that could be quite sizeable? Then just a few simple questions just on the Abilify resubmission; it is considered a class two response. Given that it was only a third party water supplier that was a problem, is there anything else in the submission that means we should look at generally or is it just simply that third party water supply issue? And then maybe just a couple of more questions on the Selincro, is it going to be the November or December meeting for the CHMP and what would you expect to—or what would you say makes a good or bad label for Selincro from CHMP? And maybe I will just leave it there and get back in the queue for further questions.

Thank you, Tim. Now that we have the questions we know it is Tim Race and not Roce. So just on guidance, you know we gave the floor guidance in 2010 and we delivered '10, '11, '12 we are on track to deliver and we also believe we will deliver in '13, but at the same time you know our focus is long term growth and it is executing on the pipeline, so we will not sacrifice the long term growth to deliver on the floor guidance. That is important, but so far we are on track to deliver on it still, introduced in '10 and we hope to do so in '13 too. Anders, will you comment on Abilify and Selincro?

Yes. First and foremost the resubmission, the issue is purely on the water. It is a technical matter why it has been stipulated as it has for that review time and so the PDUFA date that we have received there is at that stage got to do with label language, not from an indication or safety or anything perspective. It is simple technical language around the water supply. So we don't necessarily think that they have to spend as much time on that but on the other hand legislation [audio] time that they are allowed to have to do this and it is also difficult for an FDA to make independent decisions on different timing, so what we plan on is that we will get on time.

With respect to Selincro, it is still on track for a feedback from the CHMP. We expect a formal opinion from the CHMP in December which is in line with our previous expectations on the process going forward with the CHMP taking the feedback and discussion processes into consideration that we know always are going on with the CHMP. So we don't expect to get an adopted opinion in this coming month—I am sorry this coming week, we expect an adopted opinion by the CHMP by December.

And I think we don't want to speculate on good or bad label as we are in the midst of that discussion externally. Other than that we are optimistic that we will get an approval that allows Selincro coming in as a new concept to make a difference to people who have unhealthy drinking levels.

Okay, thanks guys.

Peter Hugrefje Ankersen – ABG

A couple of questions as well; first of all if we start with the pipeline related, the status of the partnership decision on 58054, what is that? And maybe could you also elaborate in this context about a potential phase two study for [unclear], will you go directly into a phase III study or how do you see that? Then on the [brexipiprazole] I can see that you expect to announce phase III data in this context I have two questions. First of all I can

see that you lifted the number of patients in some of the studies is there any drama behind that and secondly will it be you can say conclusive and subsequently also a filing question or will it more just be the initial stages of the product? And then finally just in terms of the [Cephalon] products outside Canada what is the status of these products? Thank you.

Okay, Peter, thanks for your questions. With respect to 58054, as you know we have had strong interest from many external partners, potential partners to join up with us here. What we have decided is that we want to have guidance from the FDA first for what would be a good programme and that will obviously address many questions including the one that you raised before, which we don't think we need to do but we don't think we need to do those findings but this is something we want to discuss with them before we finalise our opinion. So right now the first priority is to meet with the FDA and then finalise our phase III programme so that we can start that as soon as possible. In parallel we will have partnership discussions as we have communicated before but we do not want the partnership discussions to slow down the development of 58054, so hence we want to be in control of the FDA process ourselves first. Structure the programme and then run the partner discussions in parallel.

Has the FDA meeting been arranged?

Yes. And it is soon. That is all I can say and no more. And then the other questions, I want to pass over to Anders Gersel.

It is correct that the clinical trials on brexpiprazole have been expanded in numbers. It is quite a while ago, I think it is actually more than six months ago that was done. And it is—the main driver of that has basically been to secure that there is, with the [variance] in some of these types of patients we have to remember this is a new indication type so there was some uncertainty as to what were the spread of information we would get from these so we have as security actually expanded the number of patients to make sure that we are not falling short of that given that it is a new indication area that we are working in. There is nothing in particular to it. In terms of your question as to whether it could be pivotal for a filing, then I would say that that would have to be some very convincing and robust outcomes of the studies if that was the case, but I wouldn't exclude it.

And just on the other [Cephalon] products, we expect most of them to happen during '13 and to be clear we do not have Treanda in Latin America and Treanda is obviously the single biggest opportunity in this portfolio. But the other products will be a nice addition to our CNS franchise, particularly in Latin America.

Great, thank you.

Peter Welford – Jefferies

A couple of questions left please; firstly just on your Xenaxine target of 1.5 billion Danish. Is that irrespective of whether or not you have generics in 2015 when the orphan drug exclusivity goes? Or can you just sort of outline your assumptions when you make that target regarding the orphan drug exclusivity in 2015? Secondly then I guess a bit of a technical one on the financial side. Just on the depreciation and amortisation, it went down quite a lot in the quarter. Is this the runway we should now be using for future quarters or could you give us some sort of insight as to why it sort of went down about 50

million in the third quarter? And then lastly on Abilify IM, could just outline exactly what we will be getting at the ACNP in December, which trials is it that you anticipate to present at that conference? Thank you.

So I start with the depreciation and amortisation. You should still expect around one billion in depreciation and amortisation for the full year and for Xenaxine we are not speculating in when possible generic influence will happen. So what we have said is that we expect Xenaxine to deliver more than 1.5 billion Danish in peak sales.

And then you had a third question, or has that been answered?

Then there was a question about the presentation at the ACNP, it is the data from the Aspire study from Europe that is going to be presented there. The one with the—both the active Abilify Maintainer and the active control non priority study.

Okay, sorry, just coming back to the depreciations, so it should—the fourth quarter is going to see a big uptick then in that number? That is—there is some [unclear] and the fourth quarter should bounce back up again?

Yes.

Okay. Thank you.

Jo Walton – Credit Suisse

I will follow on from Peter to start with, to ask if you can explain to us why the depreciation was so different in the third quarter and why it goes back. Is there something in prior quarters, it all seems to have been quite stable. A couple of product related questions please; with Ebixa what proportion of your sales are in Germany and Portugal where you are now potentially experiencing generic competition. And for Onfi you have given us your peak sales, given that this is for such a serious condition, should we assume that this ramps very quickly so that we get to your peak sales sooner than you would with a typical drug? Or will this still be quite a slow ramp? And then a broader question on your European sales; you made a comment that your overall sales would have been seven to nine percentage points higher if there hadn't been generics, healthcare reform and price cuts. Now I think we all knew what the generics were, the unknown element is the price pressure and austerity measures. Given that they have been going for a year or so, can you give us a sense of what the year on year pressure is going to be like next year? Do we assume that there is another you know headwind of five to 7% or do you think that you have seen most of that effect now and on a year on year comparison basis it should start to ease?

Jo, thanks for your questions. Can I start with the last one first and then I hand over to my colleagues. With respect to Europe, what we have seen since the financial crisis story in 2008, we have seen a variety of price reforms where for instance one of our strongest markets, Turkey, has been hit several times. We have seen several measures taken in a country like Spain during the time, so for us it would be...I am certainly not in a position to say that this is now over and we will have no further changes within this respect in Europe. The key think that we have continued with this year has obviously been the big surprise in France. On a positive note when you look between '12 and '13 it is obvious

that downward pressure on generic in Spain has sort of worked through in the system because that market has gone generic now. And when it comes to Germany the—as you know we got reimbursement back in Germany and already this quarter we are now back to growth in Germany, so that was [audio] downward pressures in the European business. So I think you know that is the—gives you a flavour of where we are with the European business.

With respect to Onfi, I mean we are nine months into the launch of Onfi and I cannot—we have a very strange sound on the background on the call here that is very distracting operator. I don't know if it is [audio]. Okay, I will go back and try to answer the question. Onfi, we are nine months into the launch and we are very pleased with the performance. It is way too early for us to say—to predict the pace of growth and what the actual peak is going to be for Onfi. So we are not in a position to give you that. And with respect to Ebixa and depreciations I will hand over to Anders Gersel to answer those questions.

If I remember the question right with Ebixa you should expect that [audio] the fact that Portugal and Germany for Ebixa is less than 10% of total revenue. And for depreciation it is the underlying level of depreciation and amortisation that you should expect going forward is around one billion. But this year—for this year, there are some fluctuations and it might be closer to 900 million for the full year, but you should in your models expect one billion going forward. Because most of it is [audio] amortisations and the recurring amortisations of our [CAPEX].

And then can I ask a final question then please? Just in terms of any—could you give us any sense of any infrastructure build that you think you might need given that you have so many launches going forwards? Broadly speaking the staff numbers that you have today, should we see that that would be roughly the same going forwards or do you think you will need to be a significantly bigger organisation?

Jo, what we have done is you know we have done project [Rico] in Europe which aims to create a more [audio] more flexible organisation in Europe and so in reality right now we are a significantly smaller company in Europe at the yearend than we were when the year started. What we are also seeing is that we have made some additions during the year in China. I don't expect that to add many more people there in '13 and the big addition in '13 is obviously psychiatry sales force to launch Abilify Maintainer at the beginning of the year and then at the end of the year we are going to add further psychiatry presence to also launch Vortioxetine.

Thank you.

Martin Parkhøi – Danske Bank

Also a couple of questions, first is an acceleration in operations where you saw some little bit headwind from sales in Brazil and also in Turkey, you said you were hurt by generics in Brazil, can you say a little bit how much that has been heard and what is actually the risk in this market if we see a complete washout? And then secondly when should we expect to see a stabilisation in Turkey? And then final questions a little bit aligned with a question just before with respect to addition of sales reps and stuff like that, I was a little bit more interesting in maybe at the US market and your partner Takeda, do you have any

information of how they expect and how many reps they will support the launch of Vortioxetine in the US and if they expect to expand the sales force during this year?

Thanks, Martin for your questions. We are in regular discussions with top management for Takeda on launch preparation for Vortioxetine. The reality is that like it is for us, this is also a major opportunity for them. We will not be communicating on their planned changes or what they are doing from an organisational point of view. The only thing I can say is that I am very pleased with their overall commitment and engagement to make this a successful product launch.

Brazil; Martin we have seen generics in Brazil for a period, but this is actually—it is this year we actually really see the effect, so it will continue. It is not a—if what you call a complete washout, but of course we will see a decline in Cipralex sales in the coming quarters also for Brazil and that might impact international growth.

With respect to Turkey, you know these are not Lundbeck specific events. These are general events hitting the overall pharmaceutical market place. So if you look at the decisions that they have made you would expect or certainly say that that is more than enough, but I am not the decision maker and I am not an advisor to the Turkish government, so we hope that—as I said we hope this is it, but we don't really know. We have a very strong company in Turkey and certainly as soon as the market conditions change again, I am convinced this will be a very attractive market again and we will be there to take advantage of it. But right now we have to sort of deal with the realities of the decisions they have made the last 18 months.

Just to follow up on Brazil, but you didn't say in absolute numbers how much sales are still at risk in Brazil.

No. It's deliberate.

Carsten Lønborg Madsen – Carnegie

Just two questions; first of all the main topic of discussion here around Lundbeck right now seems to be Ebixa and what will happen next year with the generic competition. Could you somehow provide some sort of guidance and where should be? The numbers seems to be all over the place and if for example what will happen if I say two billion krone next year, would you feel that that was overly negative or how do you feel? And also as a follow up to that, I think maybe it will also be worthwhile if you provide us some sort of information on sort of the profitability on Ebixa, how much are you paying out to [Merz] etc.? Those are the two first questions. I just have one more question after that.

I would say that I think it is too early to speculate on generics for Ebixa. We have seen, as you are also aware, that very different rules country by country across Europe, so it is extremely difficult for us to give you any guidance. But of course you know we think that of course that we expect to see a decline next year definitely. So that is how we are seeing the picture going forward.

But if I say two billion, is that a number where you think now you are simply ridiculous, Carsten? Is that something you could actually [unclear]?

I think you are not ridiculous.

Okay. And when it comes to profitability of Ebixa what can you tell us here?

We are not giving profitability numbers, but of course we will keep the profitability and we have double digit royalty rates too and the royalty rate will continue also after the patent expires.

Okay and then, Ulf, you mentioned on Selincro that it now should be more or less obvious to everybody that this will be a significant product and I just had to double check consensus estimates because I don't think it is obvious. Nobody is really putting much in from Selincro and you just recently bought a bigger share of the potential pie from Biotie here, so could you tell us what we are missing?

Carsten, I don't know what you are missing, but I think you know what you see is that this is a very big societal issue all over Europe. It is at the awareness of payer levels and on policy makers that something needs to be done to address the significant healthcare costs associated with overconsumption of alcohol. It is also clear that this is the first concept that is really consumer friendly in the sense all the other things—all the other solutions are if you drink too much you have to stop drinking completely. And let me also say you know there are some people who have been drinking so much or drink so much that that is still going to be the only solution, but of course there are millions of people in Europe who potentially could benefit from Selincro and what we know is that when you come to payers in this market place, there is a lot of drugs that they don't want to buy, but there is a lot of interest for this one.

Why is the consensus numbers where they are? Or why is this still high risk and a question mark? First of all nobody has had a successful launch of an alcohol drug yet and secondly our ability to predict patient behaviours in this market place is poor because no one has set up a model for it before. We took another stake in Biotie because it allows us to not only develop the product in Europe but also on the assumption that we will get a good label in Europe and [audio] to develop it outside of Europe in a different way to bring it forward to market. So personally I have been more than 30 years in the pharmaceutical industry, I haven't had that many chances to be part of changing medicine with any of the drugs we have come with but this is a drug that if adopted will change medicine when it comes to alcohol treatment and that is what I am excited about.

Alright. Thank you very much.

Tim Race – Deutsche Bank

Just a follow up question. In terms of—this is 004. You have a cognition study and a sexual dysfunction study reporting in December and January respectively according to clinicaltrials.gov should we— I mean given that these are going to be pivotal sort of claims in differentiating the product, are we going to see headline releases on the outcomes of these studies sometime in the first quarter or do you have a plan of when you are going to present this data? Or are we just going to have to wait and see until approval what that data is?

This is Anders. I think, first and foremost, I think you are a little early in terms of when we will see the data. One thing is completing enrolment, another is to see the data, but the—in terms of reporting on them, we have not planned to pre release this data so you should not expect to see these results in the public domain prior to the approval.

Okay. Thanks.

Closing Comments

Thank you. I don't think there are any further questions so again thank you for calling in and thanks for the many very good questions. Good-bye.