H. Lundbeck A/S

Moderator: Ulf Wiinberg
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11:15 a.m. ET

Operator: Thank you for standing by and welcome to the H. Lundbeck A/S Full Year 2013 Financial Results conference call.

At this time, all participants are in a listen-only mode. There will be a presentation followed by a question-and-answer session, at which time, if you wish to ask a question, you will need to press star-1 on your telephone.

I must advise you that this conference is being recorded today on Wednesday the 6th of February 2014. I would now like to hand the conference over to your speaker today, CEO, Ulf Wiinberg. Please go ahead.

Ulf Wiinberg: Thank you, operator. Welcome to the Lundbeck fiscal year 2013 teleconference. I’m joined by our CFO, Anders Gotzsche and our head of R&D, Anders Gersel Pedersen.

On page 2, we have the company disclaimer which you are all aware of so I will not read that.

So 2013 has been a very, very successful year for Lundbeck. I can remember in late 2012 when we revised the guidance down for the year, we could see a challenging 2013 ahead of us. And now, with the year behind us, I can say that it was a really great year in every sense. We’ve delivered financially, we delivered operationally and we have also had an unbelievable year in R&D.

There are many things to be proud though in the year but I want to particularly emphasize that we have a very good growth in the U.S., plus 22 percent, and
we were 8 percent up in then international markets, with China leading the way, plus 30 percent. So we can now see that we are realizing our global footprint the way we have envisioned the previous years.

Net product delivered, we were up 45 percent and that gives us confidence in the launches that we are executing on now.

We have five approvals, three in Europe and two in the U.S., very, very good performance. We saw a strong performance in Europe although Ebixa (hasn’t start) where we have exclusivity we continue to take share. Also, after we had finalized our very successful restructuring of the European operations, and as a result, we have seen improved profitability in Europe.

You know that we have used the various efficiency measures as a way to create headroom for investment in expansion and investment in R&D with (its decision now first). We did RECO and last summer, we announced Fit-for-the-Future. I’m pleased to say that this project is going ahead as planned or maybe is a little bit ahead of expectations which is very good enabling us to continue to invest.

In 2013, we upgraded our performance three times and then we delivered on the guidance. And I also think that we have a very strong EBITDA in spite of the foreign exchange adversity that we experienced. So all in all, the way we came through ‘13, and we’re sending out ourselves up for long-term growth.

I know that many of you are very interested in Brintellix, so Brintellix was launched in the U.S. and we have the sales meeting where the Lundbeck sales force and the Takeda sales force started to promote the product in the U.S. market two weeks ago.

I had a chance to be at the meeting and I met our sales force that we hired. It is fascinating for me to see that we have recruited 200 people. The profile is that they are on average with 10-year experience, all have CNS experience, coming from leading companies like Astra, Lilly, Forest, Pfizer, and all wanting to join Lundbeck because of our focus on CNS.
And these 200 were selected out of 6,000 applicants. So having been in the industry all my life, it’s a pleasure to see a sales force that’s ready to move immediately at the time of launch.

Now, you know that we have said that we want to benchmark against Viibryd and the performance there at the first six months. It’s not so much about the financial result or the product performance. It’s more a metric for us to see whether our organization can benchmark with one of the strongest organizations in the field, Forest.

So hence, we have picked this benchmark, and if we do that well, I am optimistic that with the differentiated label we have, Brintellix will perform much better over time as patients get treated and physicians get experienced from the drug.

You should also know that we have approval in Europe. And as we are experiencing with Selincro, you should not expect significant sales in Europe the first year. We have the effective healthcare rationing going on in Europe with the various market access issues that you face on old products means that 2014 is a year for market access and then we hope to see sales coming through in ‘15.

We are also hoping to get approvals at the end of ‘14, enabling us to launch in ‘15 in Canada, Mexico, Brazil, and we already have approval in Australia, and it could well be that we see a faster uptake in all those markets than we do in Europe.

We will also get the important CONNECT study results coming up by the middle of the year and Anders Gersel will comment on the importance of Brintellix in commissions.

So all in all, we have done everything to prepare for the launch with our partners Takeda. We feel that all the actions that were necessary to do ahead of launch has been done and been well done. We don’t expect major market access issues in the U.S. and we are optimistic about this launch for the year in the U.S.
So with that, next slide please, so where do we stand? As a result of all the things we have done in the last few years in building a global multi-product company, we can now see some very significant growth opportunities in years to come with these six drugs that we have here, drugs that can make a big difference for patients and can help create the new Lundbeck.

And obviously, the patient promise of them are that Abilify Maintena is better tolerated which will enable you to use depot drugs earlier in treatment which is a tremendous advantage since every time you have breakthrough disease not only it’s expensive but is a bad prognostic factor for the patient. So Abilify Maintena we think will expand the markets and we are optimistic that this will do well.

Selincro is the first type of drug that reduces drinking and alcohol. We are going to -- as we have communicated many times before, we’re going through the access process in Europe. We -- clearly in ‘14, we need to get access in the major markets and then we need to train the physicians in how to utilize this new product. But the critical success factor is to get access in the big markets in 2014.

I have just talked about Brintellix. I think Brintellix has for Lundbeck a sales potential of 5 to 10 billion. And I think where we stand now, we stand perhaps stronger than we first communicated these numbers.

We have achieved the differentiated label in the U.S. and we have a differentiated label in Europe. And since this is a market where you have a lot of patients not successfully treated, there is really a need for a new drug that does different things.

And with the unique mode of action, the efficacy we have and the very clean side effect profile, I’m very optimistic for Brintellix.

We’ll then move into Brexpiprazole, Brex is obviously a better product and from a toleration -- tolerance point of view than Abilify. We all know the tremendous success Abilify has experienced in the market and obviously, we believe that Brex can be an improvement of Abilify and be a big commercial success to.
Desmoteplase, we will get phase three data here in the spring. This is a market with tremendous unmet needs, very difficult markets, there is no real good treatment today. We hope that desmo can come true. Obviously, it’s a risky program but if it comes through successfully, we will make a huge difference for patients and for Lundbeck.

Lastly, 58 or 54, we have started the phase three program here and if we can execute them well and come through with positive results, it looks like Lundbeck will introduce the next significant new anti-Alzheimer’s drug ahead of the big pharma companies. So all in all, we think if we do this well, we have the ambition to double the business by 2020.

And with that, I like to invite Anders Gersel Pedersen to make more comments about progress in our late-stage pipeline.

Anders Gersel Pedersen: Thank you, Ulf. First and foremost, we are continuing to invest substantially in the pipeline also in 2014, a number of the large programs both in 58 or 54 and Brexpiprazole running during ‘14 and we have a lot of emphasis on the execution on these big programs.

We will get some readouts of data from Brexpiprazole and Brintellix during the 2014 and some of these will appear also at conferences during the year. We’ve already seen the first set of data on Brexpiprazole just coming out for the March conference in Europe.

The readouts, they will get also on additional studies in Brexpiprazole is in MDD and schizophrenia that will come later on -- in this first half of this year.

Two other important readouts for us will be this desmoteplase data in the DIAS-3 study which we -- will be the first results indicating to what extent we have met our primary endpoint in this big program.

And lastly the Brintellix CONNECT study which is the second study that we are running with a primary endpoint of cognition in depressed patients with Brintellix.
Next slide. Already at this stage, what we look at with Brintellix is that we have a good efficacious antidepressant with a strong label in terms of multi-model profile with efficacy both in adults and elderly patients and with a positive outcome in functioning and quality of life in the label.

We also have data in the European label and in publications showing the effect of Brintellix is patients who have not responded adequately to SSRIs and SNRIs and significant steroids to a head to head comparison.

And finally, we have the readout that we had (relayed) this year on the cognitive study showing cognitive effects as primary endpoint basically substantiating the findings that we had also in the elderly population but this time with as a primary endpoint in a study in adults.

On top of this which is important for depressed patients, the safety profile that we have and the tolerability profile we have with Brintellix and continues to look very competitive.

We look at the next slide, then Brexipiprazole, we have -- with the date we have so far both in terms of understanding the blinded safety profile but also the efficacy data that we have seen so far.

We have a good confirmation of the mechanisms that we believe are driving the differential profile of Brexipiprazole relative to other atypical antipsychotics.

We have data coming out in depression and schizophrenia as mentioned later on this first part of this year and then we are initiating programs in two new indications, agitation and post-traumatic stress disorder based on the preclinical profile that we see with this molecule.

And with these four potential indications coming out over the next three years, we basically see a strong molecule in the hands of Otsuka and Lundbeck.

Next slide is on desmoteplase basically just to highlight for you who have perhaps not followed this closely up until now. There is a potential breakthrough therapy in the sense that first and foremost it is looking at
patients in different way in terms of the particular group that has a (actual clotting) at the time of being looked at.

It does at the time point which is a window than has been proved for rt-PA. We have a low bleeding risk rate with the molecule and we also have no neurotoxicity as seen so far in the -- up until now concluded studies.

We will get the data, as mentioned, later on this first part of 2014 and we will based on that to be able to conclude as to what will be the regulatory path that we can follow forward.

With that, I will hand over to Anders Gotzsche to comment more on the 2013 results.

Anders Gotzsche: Thank you, Anders. Please turn to slide 10. Both Ulf’s and Anders’ overviews clearly demonstrate how Lundbeck from a regulatory and clinical development point of view had had yet another successful year.

And I can add to that it also from a financial perspective has been a very solid year, and also that fourth quarter ended up as we had expected.

First of all, the total revenue grew by 3 percent reported. And if you adjust for Lexapro and Ebixa the year-on-year gross was actually shows to 15 percent. And what’s really important is that the gross is broad based, it’s driven by several regions and several project -- or products which is fully aligned with our strategy of diversification.

As many other companies you are following, we are actually facing strong headwinds especially in Q4 from several currencies, the U.S. dollar, Canadian dollar, Japanese yen. And also the Latin American currencies have been declining.

In local currency, our revenue increased by 4 percent for the year and, of course, for 2014, we will continue to be under the influence of difficult business environment in some countries but our strategy around product diversification and geographical expansion is on track.
And you can also see from the result in 2013 that a grow in new products of 45 percent reported and 55 percent in the quarter. That will be actually fueled by having more new products next year or in 2014, Brintellix and Abilify Maintena will be launched in Europe.

And we have actually been very proud of our performance in the U.S. Xenazine, Sabril and Onfi is doing really well and Onfi having 156 percent in growth in the quarter is very satisfying. And then, of course, we look very much forward.

The two really important products to follow in 2014 is the uptake for Abilify Maintena in the U.S. and, of course, Brintellix. So we hope that will be part of in continuing the strong growth in the U.S.

If you look into Cipralex and the performance of Cipralex, it actually increased slightly. For the year, it was driven by Japan, China, also some European countries. And we’re actually pretty happy with the performance with Cipralex if you take into account that in some countries, we have (lost big) the facilities and also due to the currency impact. And it is important to highlight that we saw a growth in Japan in Danish krone of 5 percent. But if we see -- look into the local currency Japanese yen, we actually had a growth of 35 percent.

Our Ebixa sales turned out to be a decline of 25 percent fully in line with the expectation we set in Q3. And we also have to remember that we will see at least the same speed of erosion for Cipralex when we look into ‘14 and ‘15.

But overall, we are very satisfied with the revenue progression also in Q4 and that has also lead to that we are happy with the earnings for the year and, of course, for the quarter. As we said in Q3, Q4 would be an investment quarter and we have created the foundation for a strong growth for Abilify Maintena and the launch of Brintellix in 2014.

From a cost perspective, the cost of sale is down 4 percent for the quarter and that is on par with same period last year.
R&D cost model is unchanged for the quarter as a percentage of revenue. And you should be aware and you know that it is typically a bit higher in Q4 and compared to the remaining quarters of the year. SG&A at a high level percent wise in the quarter but that is, of course, due to the launch activity.

The only part I need to make, net profit is that it is, of course, impacted by the E.U. fine and that this fine is not tax-deductible which is why -- is why the tax rate is so high compared to the previous years.

We are proposing to the AGMs to increase the dividend together with the board and that is due to the fact that we have generated a rather solid cash flow and we are confident in the future. And as I said earlier, we have a payout range of 25 percent to 35 percent indicating it would be 35 percent.

Calculating the dividend, we have excluded the E.U. fine and therefore the payout ratio, if -- 35 percent if exclude for that but in the reported figure it seems as we have paid out 64 percent.

Please turn to the next slide. This slide actually illustrates that our cash flow generation continues to be satisfying and especially taking into account the unexpected payment of the fine from the E.U. Commission in the third quarter of 700 million.

And in the fourth quarter, we also generated a strong operating cash flow and we ended the year with a cash position of 5.9 billion leading to a net position of 3.7 billion.

So all in all, a very strong cash contribution from the business but you should also expect in 2014 due to the high R&D commitments to Otsuka that our net cash position will decline with approximately DKK 1 billion in 2014.

Please turn to slide 12. Guidance 2000 -- sorry, I definitely hope that what I just explained, you accept that we have actually a good momentum in the company. And as we have said also previously, 2014 and 2015 will be a transition period.
And it is a period where we would invest in the new products and what we have said is that there will be a number of variables that can impact the guidance for 2014 and that is, of course, the launch uptake, it’s the generic erosion. We will give our best guidance on that but we -- it can be pretty difficult to predict, and then, of course, a continued investments in R&D and launch of products.

And it is important to say that the 13.5 billion in revenue for 2014, if you take in -- if you compare to when we made the guidance in December 2012, we have actually -- headwind in effect has actually impacted the revenue line with 1 billion. And that is the reason for us being actually happy with 13.5 billion for a revenue guidance for 2014.

EBIT is as previously guided, 0.5 billion to 1 billion and you should be aware of -- that as we will be hit by the generic entrance for Cipralex in the second half, most of the earnings will be recognized in the first half of 2014.

From a ratio point of view, you should expect that cost of sales will be around 29 percent of revenue in the next year and this is, of course, mainly caused by the decrease of Ebixa and Cipralex sales and increase of product sales with higher R&D costs.

And then, of course, also amortization will increase due to more amortization of Abilify Maintena in Europe in 2014.

SG&A-wise, you should expect a ratio of around 45 percent and the R&D, you should expect a ratio around 20 percent.

Net financials, you should expect a range of 100 million in expense and the tax rate due to revenue mix especially from the U.S., you should expect the tax rate to be around 30 percent. But you should be aware due to the lower profit then the volatility in the tax rate is much higher than you have seen in the past and therefore very small deviations in profit and a profit before tax will have an impact on our tax percentage.

I want to remind everyone that 2015 will be as tough or maybe even tougher than 2014. In ‘15, we will see the full effect of the generic -- of generics on
Cipralex in Canada and Europe. And also 2015 will be the last year with (Azilect) in Europe as the agreement will be changed to a royalty agreement by the end of 2015.

It is, however, also our firm belief that our most recent product introductions will carry importance and thereby replace the lost revenue.

With that, I conclude the financial presentation and now, I will hand over to Ulf for the final remarks.

Ulf Wiinberg: Thank you, Anders. So 2014 looks to be a very eventful year for us with many important events driving our opportunities for long-term goals.

Right now, we have launched Brintellix in the U.S. as we’ve talked about at this meeting. Next thing to happen is to work on market access for Brintellix in Europe and to launch Abilify Maintena in Europe.

I think there is a distinction with Maintena in the sense there is an existing depot budget. Maintena, we do not expect to have to go through the same HCS scrutiny as Brintellix and Selincro has to do.

Later on, we will see the data on the second quarter for desmoteplase that Anders talked about. There will be a presentation on the first MDD study with Brexpiprazole at the EPA in March. We will also get the CONNECT headline conclusions before summer and we also hope to get the additional Brexpiprazole studies by mid-June.

Second half, we hope to have clarity with market access for Selincro in the major European markets and hopefully we have positive data for Brexpiprazole enabling us to submit the file in the U.S. Europe, we will submit one year later because of the requirements for long-term data.

We also hope to start the phase one study on our Alzheimer’s fact sheet. We have many good things going for us and we look forward to executing in 2014 too.

Now, we are ready for questions. Thank you, all.
Operator: Thank you. As a reminder, if you wish to ask a question, please star-1 on your telephone and wait for your name to be announced. If you then would wish to cancel your request, please press the hash key. But it’s star-1 to ask a question.

You first question Peter Hugreffe from SEB. Please go ahead.

Peter Hugreffe: Yes, hi. Peter Hugreffe, SEB. Thank you very much for taking my questions.

Firstly on Brintellix, as I realized, you’re not going to comment until the launched. Then maybe some -- maybe you can help me with some maths. Firstly in terms of, if you look at consensus, then right now the number is 486 for the full year which implies an in-market sales in the U.S. of $300 million. Is that a number you are comfortable with? That’s number one.

And number two, if we look at the formulary access then currently you are around about 31 percent and we can see that (inaudible) at 80 percent. What is -- is that a realistic target of 80 percent or -- and how fast would you get that?

And then maybe also in terms of Brexpiprazole, maybe you could remind us of your filing plans, let’s say in the incidence that the MDD (inaudible) study is positive, but it’s slightly more buried with the schizophrenia trials. Thank you.

Ulf Wiinberg: Peter, this is Ulf. Brintellix, I mean we just stay away from commenting on consensus but I think I’m comfortable with the U.S. sales numbers. I don’t know where the difference is coming from between the U.S. numbers and current consensus since we expect Europe to be a market access year and not a material sales in Europe this year.

I think with respect to the market access situation, by yearend, we expect to have achieved parity with -- compared to both Pristiq and Viibryd in terms of market access which sort of gives you 80 percent,85 percent.
But one very important factor in the U.S. to understand is that even if you are not on formularies, it’s not like in Europe that the patient cannot get your drug. And we believe that the great majority of patients can still get our drug.

You know, if there has been a -- if they have failed on another treatment then the doctor and the patient agree that they should have this product, they will still get it in the U.S. in the majority of the cases.

So the dynamics or difference from Europe where unless you have a positive reimbursement, it is really very hard to get any sales in Europe.

I think with the question on Brexpiprazole, I’ll hand it over to Anders on the filing.

Anders Gersel Pedersen: I mean the filing on Brexpiprazole depends on the data that we are expecting to see read out here over the next couple of months. And with that, we expect to be able to file in the United States only sometime in the second half of 2014. For Europe, it will be later because we need additional data to be able to file in Europe.

Peter Hugreff: But the question was, Anders, more in terms of the incidence that the schizophrenia data are less conclusive than the MDD data. Will you then just carry on with the MDD and then wait for schizophrenia and how should we see those two going together so to speak?

Anders Gersel Pedersen: There are so many scenarios, I can’t speculate on that at this stage. We need to look at the data and see what comes out for people making the decisions on that. You have to remember that one of the things that we need to think about here is that the regulatory process for a product takes roughly one year and as that process is ongoing, you are blocking yourself from moving on that particular product. So we need to think carefully through how we manage that when we see the data, so I can’t speculate on that at this moment.

Peter Hugreff: Thank you.
Anders Gotzsche: And also -- and also important is (inaudible), we get the results of four studies, two in depression, two in schizophrenia when we -- when we planned the program upfront, we obviously planned additional studies bearing in mind the typical CNS failure rate that you see.

And consequently, there are more studies coming through in both depression and schizophrenia as well. So that has to be considered in these various scenarios.

Peter Hugreffe: Thank you very much.

Ulf Wiinberg: Next question, please.

Operator: Thank you. Your next question comes from Tim Race from Deutsche Bank. Please go ahead.

Tim Race: Hello, gentlemen. I have a few questions if I may. First of all, Brintellix, of course, when we’re going to be tracking the IMS data of this drug? Can you just help me understand how much this data is actually going to tell us and how much effective sampling you’re going to do and what that may do to actually what we see in the first sort of two months or three months of (trying to track the) drug and just what your expectations there? I’m assuming that you are going to sample very heavily to take price out of the equation until the patient responds.

Second, just on the Brintellix launch costs, can you just give me an idea of how much is the 4Q step-up in SG&A was due to Brintellix and how much of the step-up in 2014 will be due to Brintellix?

Third, just on desmoteplase, if I may, perhaps if this goes well, I don’t think many people are expecting it to do so, but if it goes well, are you going to launch this yourself or will you look for partners and what would the extra spend be to launch a drug like this?

And then lastly, just on guidance in terms of currency sensitivity, you talked about the currency sensitivity on the top-line and the impacts it had since you set that guidance. What is your sensitivity on the bottom line given that I’m
assuming a bulk of Lundbeck’s costs are primarily European based and you have revenues all over the world. Thank you.

Ulf Wiinberg: OK. Let me start. I think, you know, Brintellix is a good point. Sampling is the number one marketing tool that we have, and we will use that to get patients started and when they respond well, they’ll get through. So I think that’s very important and that will obviously impact the script count initially.

I think with respect to the -- let me also comment on desmo. I mean we -- for a year ago or two, we looked at the partnering scenario to share the risks, but the deals we could get there, we didn’t find very appealing so we’ve decided to develop it ourselves.

Should it be positive, I think we have planned to launch it ourselves. We feel that the standalone that we have done in Canada has worked as a good pilot model for us. We don’t think we need that many people and that big investment to carry out the successful launch with desmo.

I think on the general cost situation, if I understood you right, I mean we have done a lot to change the Lundbeck cost base over the last five years. I mean when I started we had 6,000 employees and we were pretty much a European company. Today we have almost 1,000 people in the U.S. We have expanded in Latin America, Canada and in Asia, and we have 5,800 people in total.

It’s not obvious that we have a lot of new opportunities to change our cost base but when we see opportunities, we go after them because we need to be really efficient if we’re going to create the necessary headroom to invest in the new opportunities we have.

I will ask Anders to comment on the launch costs and if I missed anything, come back to me.

Anders Gotzsche: We will not give any specific guidance to the different products but, of course, Q4 was impacted by hiring 200 reps, additional reps. It’s impacted by pre-launch costs at Brintellix but it’s, of course, also impacted by other additional promotional activities for Abilify Maintena, Selincro and so forth.
So all in all, the increase in cost is primarily related to promote -- additional promotional activities. And what is important from my point of view is if you look into the SG&A line, you can see that our distribution and promotion cost has actually declined compared to 2012 due to the Project RECO. So we have taken out approximately 600 million in cost and we have reinvested some of this money into promotion activities.

Tim Race: OK. And the sensitivity of EBIT guidance?

Anders Gotzsche: And the EBIT substitute is, of course, much less than on the revenue side. So -- but, of course, if you had asked me would I expect the headwind impacting 1 billion on revenue 13 months ago, no, definitely not.

So it really depends on what kind of impact, if it’s Japanese, if it’s royalty stream from Japan that is impacted, it could hurt or the U.S. franchise if that we see a strong decline in these currencies, it has a bigger impact than in some of the other countries.

Tim Race: So, in terms of -- yes.

Ulf Wiinberg: So Tim, I mean we are trying to -- our ambition is to try to double the sales of Lundbeck by 2020. And as a result, you know, ‘14 and ‘15 are investment years.

Obviously, we could have run the business in a different way to deliver a higher profitability in ‘14 but we would then have compromised long-term growth and the new product opportunities that we have.

But having said that, you know, when we now guide 0.5 billion to 1 billion, I would be very -- it would be extremely awkward for us to miss that guidance. I’m not saying we can -- it can’t happen but for us, it’s very important to deliver on that in this context.

And so in terms of mindset, you know, it’s not like we say, “OK, we have an FX issue or we have some issue, OK, we’re going to miss guidance.” I mean we have worked hard to build credibility over time so for us, hitting these numbers are very important.
Tim Race: And I was actually just…

Anders Gotzsche: And revenue is the line that will be most impacted because we also, of course, have cost in different currencies so…

Tim Race: I was actually just going to follow up and say, so it’s an underlying in constant exchange rate, upgrade to your 2014 guidance?

Anders Gotzsche: I full agree.

Tim Race: Yes, OK.

Anders Gotzsche: OK, from a revenue point of view.

Tim Race: Thank you.

(CROSSTALK)

Ulf Wiinberg: Thank you, Tim. Next question please?

Operator: Thank you. Your next question comes from Eleanor Fung from Goldman Sachs. Please go ahead.

Eleanor Fung: Hi, Eleanor Fung from Goldman Sachs. Three questions please, if I may.

Firstly on Brintellix, just wondering if you could provide some color on how your initial market access discussions in Europe are going, in particular, what’s been the feedback and push-backs that you’ve had and when you think market access will be fully in place in Europe?

Secondly, on a broad sense, I was wondering, if you could provide some color on how you think about SG&A spend over the next few years, in particular, when do you think the launch cost will peak for the three newly launched products?

And finally, just given the strong cash buildup on your balance sheet, just curious on your thoughts on how you plan to use it, in particular, is there scope for potential bolt-on M&A deals? Thank you.
Ulf Wiinberg: Eleanor, thanks for the questions. I mean I’ll start at the end. You know, we - - we have been open to -- from an M&A point of view, we’re open to deals that generate positive sales. We are not very keen on doing additional late-stage development projects at this time because we are so long and we’re so heavily invested in late-stage programs.

So if we see something that we believe can create value for Lundbeck and that fits, we will go after it. But that said, you know, many of the assets you have seen lately, prices are pretty high, so it’s not a given but if we find something, I think we have room to do bolt-on acquisitions.

And I think with respect to market access in Europe, it’s way too early to say what -- how it’s going to come through. But I think, you know, if you look at the experience we’ve had with Selincro, I don’t think -- I think eventually when we talk to people everybody likes Selincro, everybody recognizes.

The problem of alcohol in societies, the reason it takes time is just the bureaucracy that it takes time and I cannot see it go faster for Brintellix -- I mean with Selincro. And that’s what prompts me to say that, you know, we’re not going to see -- I’d be surprised if we see material sales of Brintellix in Europe in ‘14.

Exactly when in ‘15 and where and so on, we need to engage in a dialog and start working on that here. And obviously, we think that Brintellix like Selincro is a unique drug that needs met unmet medical needs in the sense that you have a lot of dissatisfied people with depression are not treated successfully.

And here, you have a product with a unique mode of action and that is different that I think comes through and hopefully help some of the people who are not treated well with SSRIs today.

I think, you know, the general lower cost level is going to continue behind over the next few years but Anders, please put some more color on that.
Anders Gersel Pedersen: What is actually the 2015 could from a launch cost point of view be a higher investment year than 2014, but it really is dependent on how is the -- what is the result of the clinical trials with desmo and Brexpiprazole because if we are going to prepare the launch of these products, we will add more costs than you see today.

If we get market access for Brintellix and Abilify Maintena in Europe, it will be depending on how fast we can get that market access and how much power we will fuel the launches with.

So the only thing we know is that Abilify Maintena and the U.S. launch will continue -- or Brintellix launch in the U.S. will continue with the same phase in ‘14 and 15 but the uncertainty is, of course, how much effort we will put behind the launches of the new products that are going to be launched in Europe.

Operator: Thank you.

Ulf Wiinberg: Next question please?

Operator: Thank you. Your next question comes from Riccardo Lowi from Credit Suisse. Please go ahead.

Riccardo Lowi: Yes, hi, thanks for taking my question. Just a very quick one. Why you mentioned that Takeda will need to run further studies before filing Brintellix in Japan?

Anders Gersel Pedersen: This is Anders Gersel responding. That’s because you need to have two independent positive studies in the Japanese population, and we don’t have that at this stage. The last studies did not meet this primary endpoint and therefore, they have to do it on the study.

Riccardo Lowi: OK. Thank you very much. And just another very quick one, when you’re referring to 80 percent to 85 percent of formularies in the U.S., what tier is this about, tier two, three, a mix?

Ulf Wiinberg: Sorry, could you repeat the question again?
Riccardo Lowi: Yes, you mentioned that by the end of the year you would like to have like 80 percent to 85 percent formularies in the U.S. What tier does this percentage is referred to?

Ulf Wiinberg: End of this year. Oh, that varies but I think a lot of it is going to be tier three but we cannot…

Riccardo Lowi: OK.

Ulf Wiinberg: … anticipate right now. And we don’t think, if it is tier three, we think that patients who are depressed, especially if they have failed on drug before, if being it being tier three is not (inaudible).

Riccardo Lowi: OK.

Ulf Wiinberg: So it will be just like any other drug in the market.

Riccardo Lowi: All right. Thank you very much.

Ulf Wiinberg: Any other brand of drug in the market I should say.

Riccardo Lowi: Sure.

Ulf Wiinberg: OK, thank you, Riccardo. Next question please?

Operator: Thank you. Your next question comes from Michael Novod from Nordea. Please go ahead.

Michael Novod: Yes, hello it’s Michael Novod from Nordea in Copenhagen. Just going back to the guidance and you say that’s very important for you to maintain 500 million to 1 billion. Does that also mean that you’re actually modeling in your assumptions that the Cipralex (inaudible) will be launched immediately after? The compound pattern expires in Europe in mid-summer.

And then secondly, reading the EPAR on Brintellix, it mentions that it needs more data for example against to lock it in in order to support a claim for commission. Do you believe the CONNECT study will be enough, but do we need to do more than that?
And then maybe if Anders could just comment on the tax rate from 2014 to 2016, maybe you already said it but then I missed it, but ‘14, ‘15 and ‘16, what the expectations are?

Anders Gersel Pedersen: Michael, the -- we expect generics on Cipralex and the patent expires so that’s a given. I think, you know, Anders Gotzsche can give you the numbers, erosions that we haven’t commented on the tax rate and then you can comment on the CONNECT study, Anders.

Anders Gotzsche: And for Cipralex, we expect that if you look into the totality of the Cipralex franchise, if you compare Cipralex numbers for ‘13 with ‘14, we expect a total decline of 20 percent to 30 percent for Cipralex in ‘14.

For the tax rate, you should -- you should expect around 30 percent until ‘16. Of course, the structural tax rate will be going down to 20 -- in principle, it should be down to 22. The reason for having a higher tax rate in this period is that the I.P. rights for the U.S. products, for the new -- we acquired -- where Ovation is actually taxed in the U.S.

And then, of course, we will, going forward, have some non-deductible promotion expenses as other pharmaceutical companies so that structured exchange rate going forward will be in the range of 25 percent to 28 percent depending on the product mix in the period after ‘16.

And CONNECT, with respect to the CONNECT in terms of (costs) of claim in depression, basically, this could very well be enough. We don’t know that for sure. Obviously, that’s part of the discussion that one will have to engage with the regulators on.

I think it depends on not just an endpoint in itself but the consistency of data across the data, how convincing that will be. So it’s not one way we just say that if you either hit or miss then you are -- you know exactly what the outcome is going to be.

Because this is the first time somebody is pursuing this avenue with regulatory authorities. It will be an area for discussion with the regulatory authorities.
But for sure, if you have a very strong, very consistent CONNECT study, it will give you a very good negotiation platform.

Michael Novod: OK, thank you.

Ulf Wiinberg: The next question please?


Martin Parkhoi: Hello, Martin Parkhoi from Danske Bank. Actually also a bit on some of the numbers that Michael asked.

First the guidance. You gave a guidance range on EBIT but a rough estimate on sales. So I was trying to understand why you have a guidance range on EBIT. Does that include a risk of write-down in connection with field outcome of the desmoteplase study?

And then secondly, just also to be sure on the Cipralex numbers that Anders mentioned, 20 percent to 30 percent down and all of that will, of course, be in the second half. If I look into ‘15 as you see as maybe even more challenging year, should I then expect, you know, like a 50 percent decline in Cipralex from ‘14 to ‘15?

Ulf Wiinberg: Anders?

Anders Gotzsche: The first question, Martin, was?

Martin Parkhoi: The reason for -- the reason for guidance range on the EBIT and not on sales.

Anders Gotzsche: The reason for having around the 13.5 and a range for EBIT was that you should think about why did they have the range in -- for EBIT and why one figure for revenue. There is no good reason for that.

The reason is that we believe it will be around 13.5 and there will be bigger swings in revenue because it’s the off-take. It’s -- the erosion rate is the effect so there is a lot of factors impacting revenue where there’s less factors
impacting the EBIT. So have been more confident in making a range. The range for EBIT does not include a write-off of desmoteplase.

And for Cipralex -- for Cipralex, I think you should -- we know it will be faster than Ebixa. We have seen a decline this year of 25 percent. We expect the decline next year of 50 percent for Ebixa, so, of course, year two will be very fast or a speedy year from an erosion point of view for Cipralex. And that is -- it goes with our saying that it is, of course, only Europe and Canada.

Martin Parkhoi: OK. But if you -- if you -- OK, because if you look at them, I don’t -- I know that you are not obliged to comment on consensus forecast but I can see consensus forecast of a 15 -- of more than 3 billion on Cipralex excluding Japan. And that seems somewhat too high with the numbers that you mentioned right now.

Ulf Wiinberg: Martin, we are not guiding for 15 today. So -- but you could well be right in your -- in this. But we need to see what happens in ‘14 and…

Martin Parkhoi: OK.

Ulf Wiinberg: But the one thing we know is that we think we will have -- in Canada and in Europe, we will face more efficient generic market than we have ever done before. So not to -- and you should not model Cipralex after Ebixa because then you are too optimistic.

Martin Parkhoi: Thank you.

Ulf Wiinberg: Thank you. Next question please?


Ulf Wiinberg: Hi, Carsten. OK.

Carsten Madsen: Hey, I’m here now, sorry. Can you hear me?

Ulf Wiinberg: Yes.
Carsten Madsen: That’s good. Carsten Madsen, Carnegie. Just a couple of questions for Anders. Just looking at the impressive improvement you had in working capital in 2013, I think it’s primarily the other payables lines in your balance sheet that are improved by DKK 1-point-something billion. Is this a matter of timing or -- and something that will be reversed in ‘14 or what did actually happen here?

Anders Gotzsche: Working capital, it’s important to say that the very positive impact is, of course, certain factors, but we have made these arrangements with Selincro and 58054 where we get prepayments. And, of course, that impacts a lot and that is what is also recognized under the accruals. So as we use the money, we will, of course, have a declining accruals in -- for that.

And from an investment point of you, you should expect that -- I need to double-check -- the investments we have in general, the ongoing investment is around 400 million to 500 million in, you know, facilities, machinery, et cetera. And next year, we have this two -- this year, we have this $200 million payment to Otsuka for the calibration with the Brexpiprazole.

So it will be a pretty high investment level also in 2014, and that is the reason for me guiding that you should expect a decline in our net cash position around DKK 1 billion in 2014.

Carsten Madsen: All right. And then just to the other (inaudible) on the Brintellix and the CONNECT study, I think at the APA, we discussed whether you would actually announce the headline data when you have them or if you would save them to be presented at conferences. Was that understood correctly by me and have you made sort of a decision on whether you will send it to the markets when you have them?

Anders Gersel Pedersen: I don’t think we will send them to the market the minute we have them. We will probably send them to the market in conjunction with
conferences or if we realized through discussions with regulators that it will have impact on our fileability and...

Carsten Madsen: All right.

Anders Gersel Pedersen: I mean we need to get that verified. Otherwise, we think that it will be more misleading than leading to report particularly on them. We don’t even know exactly what is going to be the reception of these data by regulators then we think it will not be the right thing to do but we have not -- I mean it’s going to be difficult to say how convincing some of these data are either one way or the other in terms of what they’re going to lead to. I think there will be adjustment call there.

Carsten Madsen: So you can say very convincing data will be sent to the market?

Ulf Wiinberg: I think Carsten, this is Ulf, you know.

Carsten Madsen: It’s OK.

Ulf Wiinberg: You know, to discuss them with the regulators, nobody has ever got recognition claim before so obviously, we need to talk to the regulators about what their expectation and how they think around this.

And then it’s about the data and then the interpretation of this and whether you have to a second discussion with…

Anders Gersel Pedersen: We also had to be considerate of the viewpoint that an authority may have as to whether you buy disclosing data that they are not yet comfortable with or whatever they haven't seen, are you pre-launching things that are off-label or something like that and particularly sensitivities around that in the United States is something we need to take into consideration.

So I can't give you any more specifics on that. It’s not that I don’t want to but we need to be taking a lot of things, you know, into that equation before we (inaudible) what to do.

Carsten Madsen: That makes sense. OK, thank you.
Ulf Wiinberg: Thank you, guys. The next question please?

Operator: Thank you. Your next question comes from Peter Welford from Jefferies. Please go ahead.

Peter Welford: Hi, yes, a couple of questions left. Firstly, can I just ask you could you possibly give us some sort of outlook for 2014, the other revenues in terms of the R&D in completion and then the deferrals?

I appreciate that obviously we're not assuming any new milestones or anything but just give us an idea based on the sort of deferral or amortization of the upfront payments you've received so far and how we should look at that number?

Could I also ask then with regards to, if we look at the full year numbers, could we just check whether the numbers are correct in terms of the booking of Cipralex in the rest of world? The -- I think the 65 million for Lexapro in Japan isn't included in one of the numbers but is in the other in terms of the disclosure by region. Can we just understand that for what the rest of world Cipralex and the Lexapro Japan numbers are for the full year just so we have the right numbers there? Thank you.

Anders Gotzsche: OK, the last question, I need to double check before answering them. I don’t have the same just in front of me so I'll come back to you on that question.

Other revenues, you should expect due to the fact that the revenue -- other revenue line has been impacted by one-off this year. You should expect it should be approximately 1 billion less next year.

Peter Welford: That's great. OK.

Anders Gotzsche: At the second question, I will bilaterally come back to you on that because I need to double check before I give you an answer on that.

Peter Welford: That's great. Thank you.

Operator: Thank you.
Ulf Wiinberg: Next question?

Operator: Thank you. Your next question comes from Peter Sehested from Handelsbanken. Please go ahead.

Peter Sehested: Yes, hi. It's Peter from Handelsbanken with a couple of questions, actually three or four.

I came in a bit late but just want to have a more feeling on the gross margin or COGS that you have. I think you said that 29 percent are cost of sales. Could you just elaborate how you get to that figure, I mean because if you are confident in the U.S. numbers then I mean, I guess that this high gross margins with the falloff should come from Cipralex or what have you. But I mean just to sort of get me to narrow in on why it should be 29 percent and not something else?

And also I mean I'm looking at my model, I have DKK 13.5 billion in sales. I'm roughly 8.70 on the EBIT line. I mean if there is a swing on the COGS line, it should be OK, but I mean how do you get the DKK 13.5 billion is sales?

I mean, assuming Cipralex is down by 25 percent, looking at some of the other momentum in the pipeline, it's basically Onfi where we really see strong momentum. Are you suggesting that you are banking and also taking other revenues down to that 1.4 but around -- or 1.5, around DKK 500 million? I mean what kind of magic are you looking for on the revenue lines? So that's with the revenues and the gross margin.

And then just two additional questions on -- the first one, the cognition data. You've previously, for the FOCUS used this mediation, just to comment, so to show the cognition impact. Will that also be the method that you use in the CONNECT study? And do you know if this method has ever been sort of acknowledged by any regulatory authority to show any sort of effect?

And the second is just on the -- fourth, sorry, on the sampling strategy. What is a sampling strategy and how many patients do you target sampling and during which time period? Thank you.
Anders Gotzsche: If I start with the gross margin, I have given you -- the figures I’ve given 29 percent, 45 percent for SG&A and 20 percent for R&D. That is, of course -- what I meant is around -- because I can't say to you now what will be the exact revenue mix.

And the gross margin will be heavily depending on the revenue mix. So if it will be 28 percent or 30 percent, I can't -- not all give you any insight into that now. What I can say to you is that based on the expectations we have of the revenue today, we expect the gross margin to be around 29 percent.

How you -- Peter, how you have included the different revenue line in your model is very complicated for me to understand based in a teleconference. But, of course, we have guided around 13.5 and that is -- it is a bottom-up exercise based on revenue for the different product lines, Azilect, Ebixa, Cipralex and Treanda. So we have a lot of moving parts and that is how we come to the 13.5

Peter Sehested: Could you just explain -- I mean, just coming back to Martin's question about the range, what kind of range should we be thinking about on the top line?

Anders Gotzsche: Top-line -- we have said -- the guidance we have given and the -- that might not be very clever but we have said 13.5 billion -- at around 13.5 and you can have a lower end of that, you can have a higher end.

The reason for giving around 13.5 is that revenue will be very dependent on launch uptake for Brintellix in the U.S., Abilify Maintena, uptake of Selincro, are we getting market access in Europe for Selincro for some of major parts and will the things -- how would the generic erosion be for Ebixa this year.

We believe it will be -- in 2014, it will be around 50 percent. It could be 40 percent, it could be 60 percent. You know, I said 30 percent to 40 percent. Last year, it turned out to be 25 percent so I was not very good in protecting that.

Then we have the erosion for Cipralex. You know, it’s Europe and Canada. What we have said is we expect 20 percent to 30 percent but we might be
wrong again. And that is the reason for saying around 13.5 and then you have the FX which will hit mostly revenue but not so much EBIT and therefore there’s a bigger uncertainty.

Peter Sehested: OK.

Ulf Wiinberg: Peter, on sampling, you know, we give -- we give samples for seven days treatment, and we give them liberally based on what the doctor wants to have. And I don’t want to give much more to color on that for competitive reasons, but sampling is an important part of our strategy.

And Anders, CONNECT?

Anders Gersel Pedersen: Yes, the CONNECT study, the endpoints both on the FOCUS and the CONNECT studies are endpoints that are composed of well-recognized trigonometric scales, and we have not had any pushback from authorities as to the appropriateness of these scales in terms of endpoints for the studies.

Anders Gotzsche: We had a -- this is Anders Gotzsche. We had a question around if Japan -- if I understand the question around Japan and Cipralex, if you -- if the question is regarding the table in the Q4 release where we have revenue for international markets and where there is a line called Cipralex, I can confirm that Japan is included in that line.

If that was not the question, please feel free to -- after the teleconference, to give me a call or investor relations.

Ulf Wiinberg: OK, Peter, did we cover your questions?

Peter Sehested: Yes, it was just on the intermediation methods whether that is also applied in their CONNECT study, I mean that was -- basically that's a particular question on that one.

Anders Gersel Pedersen: Are you talking about, is the intermediation method? Are you talking about the…

Peter Sehested: Yes, exactly, the statistical analysis, yes.
Anders Gersel Pedersen: Well, the statistical analysis plan for the CONNECT study is one that is being pre-defined and pre-discussed with the -- both the European and the American authorities before we unblind the study.

And the primary endpoint of the study in the CONNECT study is DSST. So that is a single functional scale endpoint.

Does that answer your question?

Peter Sehested: Absolutely. Thank you.

Ulf Wiinberg: OK. And the next question please?

Operator: Thank you. Your next question comes from Tim Race from Deutsche Bank. Please go ahead.

Tim Race: Hi, again. So I've got a couple of follow-up questions. First of all, we haven't really discussed your U.S. products. I noticed Xenazine and Onfi were beating consensus expectations. I don't expect you to talk about consensus expectations, but just talk about the potential progress of Onfi, it keeps progressing very, very well, so just what you are seeing from here? Why is it doing sort of picking up share and who is it picking it up from?

Then the second question for Anders on the dividend increase. Obviously, you mentioned it shows confidence. I just wonder and if you have any pressure from your main shareholders to deliver a higher dividend. And also just your thoughts around acquisitions going forward given that you accumulate cash.

And then lastly on the Takeda sales force, you commented on your 200 reps that you've hired. Previously, you wouldn't fully confirm the numbers. Takeda has 1,800 primary care reps in the U.S., how are they being put to work? Are they all going on the product or it's the only sort of a third of those product reps going behind the product? It will be interesting to know just the process behind that and whether you've gotten dedicated reps or what your sort of second or third detail?
Ulf Wiinberg: Tim, I think, you know, on the Takeda sales force, you have to sort of ask them for their specifics on that rather than us answering how they do. But for what I can say is that we are very pleased with Takeda’s commitment and level of preparation ahead of launch. And obviously, now, we have done everything, now, we need to see the results, but overall, we're very pleased with that.

With respect to Onfi, to be honest, I’m not sure we know what’s going on, but I suspect that, you know, Lennox-Gastaut has been disease mostly identified with young people before and maybe there is a recognition that there are doubts with Lennox-Gastaut. I’m not sure we understand the dynamics behind that fully and so we are…

If you were surprised, we are surprised too on, say, we're very happy but we're surprised, but we need to sort understand the dynamics better there. But obviously, Onfi appears to be a very good drug and effective product appreciated by the prescribers. But I don’t have more color I could give you than that.

And Xenazine, I think continues to deliver well for us. You know, originally, we had sort of (inaudible) we expected to do about 250 million peak sales and we're ahead of that now.

So overall, you know, all the three products are doing OK or better than expected and we're very pleased with the progress of our neurology franchise.

With respect to acquisitions and so on, you know, it will be very opportunistically driven but clearly, we have both money and -- on our balance sheet, we can leverage it if the right opportunities present itself.

But it has to be something that creates value and -- so that’s sort of the guiding ideas that we have. And I’ll hand over to Anders Gotzsche for the other comment.

Anders Gotzsche: Yes, the reason for excluding the 700 million is that we think it’s a wrong decision and therefore we have -- the management and the board has agreed
that we want to exclude that when we calculated 35 percent in payout ratio.
So there’s no other argument to that.

And yes, I think that covers all.

Tim Race: Yes, that was. Thank you.

Ulf Wiinberg: OK, thank you all for calling in and following us. As (Anders) was saying, 2014 looks a very exciting and promising year to shape the new Lundbeck. We look forward to keeping you abreast of our progress during the years.
Thank you very much.

Operator: Thank you. That does conclude our conference for today. Thank you all for participating. You may disconnect.

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