THOMSON REUTERS STREETEVENTS

# EDITED TRANSCRIPT

# LUN.CO - FULL YEAR 2011 H LUNDBECK A/S EARNINGS CONFERENCE CALL

EVENT DATE/TIME: FEBRUARY 08, 2012 / 1:00PM GMT





THOMSON REUTERS

## CORPORATE PARTICIPANTS

**Ulf Wiinberg** *Lundbeck A/S - President & CEO*

**Anders Gersel Pedersen** *Lundbeck A/S - EVP, Drug Development*

**Anders Goetzsche** *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

## CONFERENCE CALL PARTICIPANTS

**Tim Race** *Deutsche Bank - Analyst*

**Michael Novod** *Nordea Markets - Analyst*

**Peter Welford** *Jefferies - Analyst*

**Frank Andersen** *Jyske Bank - Analyst*

**Brigitte de Lima** *BofA Merrill Lynch - Analyst*

**Peter Sehested** *Handelsbanken - Analyst*

**Martin Parkhoi** *Danske Bank - Analyst*

**Florent Cespedes** *Exane BNP Paribas - Analyst*

## PRESENTATION

**Operator**

Thank you for standing by and welcome to the FY 2011 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. (Operator Instructions).

I'd now like to hand the conference over to your speaker today Mr. Ulf Wiinberg, please go ahead.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

Thank you and welcome to the Lundbeck fourth quarter 2011 full year results conference call.

We have -- before I start, I just want to say that we have the Company disclaimer on slide 2, which you are all familiar with so I will not read it loud, and we will then go to slide number 3.

2011 has been a very successful year for Lundbeck, both from a financial point of view, from a strategic point of view and operational point of view.

We have seen nice growth in revenue and EBITDA with 8% and 5%, in a very challenging pharmaceutical market with generic competition and healthcare reforms. And we're pleased to say that we continue to take market share on our products in markets where we do not have generic competition.

We have also been able to do a lot to drive new business, to secure long-term growth. We have started launching Sycrest and I will say we are still in the middle of this launch.

We launched in Spain, Italy and Australia just before year end and we are looking forward to launching in France and Canada before the middle of this year.

We have launched Lexapro in Japan, and we've had a good beginning in this launch. We have re-launched Lexapro in China after restructuring the agreements we had with Xian Janssen and for the first time we think that Lexapro has a chance to become a significant product in China.

We have just launched Onfi, or Clobazam in the US and we have filed Treanda. So many new opportunities for us to secure long-term growth.

In addition we have made a very good, or we have made a very strong agreement with Otsuka which, should we be successful with both products, in the first round this deal has transformational potential for Lundbeck.

I'm also very, very pleased with the progress we're doing in research and development, and we can see that we have submitted the Selincro registration or nalmefene in Europe.

We continue to have good enrolment on the 21004 program, but I will say I'm also pleased to see that we finally are seeing improved patient enrolment on desmoteplase and we hope to see some results of this beginning of next year.

So all in all, 2011 has been a year where we delivered financially and a year where we strengthened our long-term growth prospects.

And I just want to give you the list on slide 4 of all the products that we see as launches coming soon.

So obviously Aripiprazole Depot has been filed in the US and is expected to be launched beginning of 2013 and in the US and filed in Europe beginning of '13, launched in '14.

We start the launches of Cephalon products; we focus on Treanda for Canada by end of this year.

We have completed the sales force expansion for Lexapro in China, as mentioned we have launched Lexapro in Japan, the launch is still very early days but we had a 2% share in November and obviously this is in line with our expectations.

We are just in the process of launching Onfi in the US and I can say that the product has been well received by payers from a reimbursement point of view.

Selincro we hope to have approval by year-end and of course ,as mentioned, we're in the process of launching Sycrest/Saphris.

So just to give you some more specifics on Onfi or Clobazam, the product has orphan drug status and has seven years' exclusivity.

It's priced at USD18 per day, it's approved for adjunctive treatment of seizures related to Lennox-Gastaut Syndrome and this is obviously one of the most severe forms of epilepsy and where there's a clear need for new treatment options.

Only 10% of cases experience full seizure remission with current therapies, and obviously the more seizures you have, the more risk you have for cognitive impairment and refractory epilepsy and so the sense is that Onfi can make a difference in reducing the number of seizures significantly in these patients and there are roughly some 20,000 to 75,000 patients around the world.

I just want to give more granularity to Sycrest/Saphris too, and the price that we have secured is more than EUR3 in the markets where we have prices this far. And in general we view this positively because it means that the payers and the countries recognize the value of the product and are willing to give it a pretty good price. And in that sense we also say that the initial reception has been quite encouraging, we have had good feedback from the medical community, but of course it is very early days.

The big markets will be Canada, France, Italy, Spain and Australia, and of those, Australia, Italy and Spain have just launched and we're waiting for France and Canada.

So with that I want to hand over to our Head of Research and Development, Anders Gersel Pedersen.

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

Thank you Ulf. On this slide there is an overview of our late stage pipeline which, as you can see, is quite extensive and also gives us lots of activities in the coming years. I will, on this slide, just speak a bit to the Desmoteplase where we will have -- we have managed to get some increase in enrolment in the program so we are on track for the timelines that we had published earlier with this program.

The -- on the next slide I shall get into more details with some of the other products. First and foremost on starting here in the upcoming quarter will start to see some results from the Phase II proof of concept study with AE58054 in adjunctive therapy in dementia.

We will get the headline results of the remaining Phase III studies in 21004 and we will, based on that, expect to be filing in the United States and in Europe in the second half of this year.

We will also potentially have the approval for Aripiprazole and Treanda in the US and Canada respectively. We expect to get feedback from CHMP later on this year. And then, as we move into 2013, have headline results from Desmoteplase and from the I.V. carbamazepine studies that are still ongoing.

And finally also, have a submission on the Aripiprazole in Europe. So as you can see from this a very extensive program going over the next 18 months.

If we look at the, specifically the psychiatry disorder franchise that we now have following the initial initiation of the collaboration with Otsuka, you can basically see we cover a number potential indications within the area of mood disorders, anxiety, other developmental disorders and psychiatric psychotic disorders, which basically puts us in a unique position within the pharmaceutical industry of having a portfolio that addresses a very broad range of different indications in the psychiatric field. And we believe that is a strategic strength for us in the years to come.

If we move to next slide on 21004, as we have communicated earlier the profile of this antidepressant molecule is unique in the sense that you, because of the composition of multimodal activity, you get strong antidepressant activity despite a very low occupancy on some of the classical receptors and therefore distinguishes it from some of the known products on the market today.

We have seen and disclosed results on some of the early studies and have effectiveness from 5mg and we are still awaiting results of the higher dose levels, notably all from the US. But we will, with the program as it is complete, have those ranges from -- all the way from 5mg to 20mg that have been extensively explored. We'll have more than 5,000 patients and importantly we have a very clean side-effect and safety profile on this molecule as we speak. We expect to be filing it, as mentioned before, in the second half of 2012.

The Otsuka collaboration has brought us into an additional strong position. We will have a depot of Aripiprazole and the OPC has recorded compound which is a unique compound in its composition of receptors. And then we have the third leg of the collaboration is a collaboration on the earlier stage pipeline coming from Lundbeck.

So we, between the two companies, combine our intellectual and financial efforts to drive new medicines into this area. And the first one to potentially get approved is the depot in the US already sometime this year.

We will then, obviously you have to wait and see what the outcomes are of the ongoing studies, Phase III studies on OPC targeting the US filing first and foremost. We will, in order for us to file in Europe, also need to do some longer-term studies which we haven't initiated yet.

If we move to Selincro nalmefene we have submitted our registration file in Europe. This is the first molecule of medicine that will allow physicians to have a discussion with their patients on ways in which they can help them reduce excessive alcohol consumption without requiring that they go for abstinence up front. This is, we believe, a very important way of changing the paradigm of helping patients in this condition and we have, in the studies, seen more than 50% reduction in alcohol consumption; and patients taking nalmefene. And we have seen this effect sustained for more than 12 months.

So we believe very good data, and we will get the feedback from regulatory authorities also this year. We can say that those people in the scientific community we have discussed this with, are very enthusiastic about this approach.

And with that I will hand over to Anders Goetzsche, who will speak about our achievements in 2011.

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

Thank you Anders. We're now on the slide with strong performance in 2011.

We're very pleased with the overall revenue growth in 2011, and also with the final quarter of the year. We have been able to maintain the solid momentum from the previous quarters, even excluding Lexapro we have seen a revenue growth of 8% in the quarter. And also compared to last year, we saw a growth of 8%, both in local currencies and in nominal value.

In the fourth quarter we also saw a growth for our key products that has been satisfactory; also taking into account the generic pressure on Cipralex; and we are happy with the increasing [margins in most markets].

Cipralex showed a modest decline of 2% in constant exchange rates in the quarter, and that was driven by solid underlying growth in most markets in Europe, and especially international market, which was compensating for the considerable decline in Spain.

We also saw, in Q3 and Q4, that Germany was declining, following generic competition and healthcare reforms. It is also very important to note that in Germany, in December, the fixed pricing group was lifted by a court order with immediate effect.

So Cipralex is back in the market in Germany, with reimbursement; of course it's too early to make any estimates of the impact, but of course we hope to see a positive impact in 2012.

The decision by the court can be appealed, but so far we see a good uptake in Germany.

Europe continues to be impacted positively by increased market share in many of our markets. When we look into 2012, of course the growth for Cipralex will be a challenge, due to healthcare reforms and generics; but a positive driver will, of course, be the launch of Lexapro in Japan, where we now have 2% in the market share.

Ebixa is actually also continuing the good momentum from previous quarters, and we showed a growth of 14% compared to 11% last year; and that was driven both by volume and increasing market share. And we actually expect, in the coming year, to see a modest growth in Ebixa.

Xenazine and Sabril also showed a nice growth, and we are really pleased with the momentums; and we can see that there is a favorable demand, and also the compliance rate is very good for these two products.

Of course I'm aware that you are all very interested in the progress of Sycrest, but as Ulf alluded to, it is very early days; but what is important is that we will, during the next half year, be watching the launches, especially in Canada, and Spain, and Italy.

Please flip to the next slide. As I said before, we are excited by the revenue growth of 8%, and actually getting above the DKK16 billion, which is the first time in Lundbeck's history. And we are also pleased with the 5% growth in EBITDA, actually hitting our expectations for the year.

Of course, EBIT is hit by the write-off of the DKK350 million we did in Q3 for the restructuring in our research facilities in the US; and then we have taken into the P&L, additional Otsuka-related costs based on the newly-signed agreement.

We feel that these numbers demonstrate tight cost control, and also demonstrate a very positive momentum in the business. And we feel that the cost increase is under control; we know that the increase is due to these pre-launch activities that has been planned, and hopefully will create growth in the long run.

For 2012, you should expect that the SG&A percentage will increase by approximately 3 percentage points to 4 percentage points compared to '11; and that is due to, of course, the declining revenue base, but also ongoing launch costs for Sycrest, Onfi, pre-launch cost for Selincro, as well as for (inaudible) depot.

From an R&D cost perspective, you should expect a level of approximately 20% or so in 2012.

Please flip to the next slide. As you can see from this slide we have been able, again, to show a very strong cash contribution, in spite of investing in these product launches; and we also saw a positive cash flow in the fourth quarter.

Even following the Otsuka deal, we ended the year with a cash position of DKK3.9 billion, and a net cash position of DKK2 billion.

Please turn to the next slide. The financial guidance for the year; we are now finally in 2012; a year we have, from a strategic point of view, been addressing for the past several years. And therefore I am very pleased to announce our guidance for 2012, because it is exceeding the floor guidance that we laid out in November 2010; and also taking into account our considerable investment in both new product and development pipelines.

And it is important to say that we will invest approximately DKK500 million more in the launch activities, pre-launch and launch activities, compared to 2011.

We will have an all-time high investment in R&D, and we will invest approximately 20%, from a P&L perspective; and then on top of that we will have approximately DKK1 billion investment, which will be capitalized due to the Otsuka deal, on our balance sheet.

And we feel that we are in a really good shape to continue the diversification of the business, but at the same time have a tight cost control. And that will be a focus area, also, in the year to come.

So, following also that we will see generic competition and healthcare reforms, we expect to have a revenue guidance of DKK14.5 billion to DKK15.2 billion, and an EBITDA of DKK3.0 billion to DKK3.5 billion. And as you know, our quarterly amortization is approximately DKK250 million, then on a yearly basis our EBIT will be reduced with DKK1 billion to DKK2.0 billion to DKK2.5 billion in 2012.

You should also -- in these figures we have included approximate impact of these generics and healthcare reforms, of approximately 5%. We saw an impact of approximately 6% in 2011, so we actually expect that at the same level.

This was the concluding remarks for the financial part, and now it is time for Q&A. So operator, if there's any questions we are ready to take them.

## QUESTIONS AND ANSWERS

**Operator**

(Operator instructions). Tim Race, Deutsche Bank.

**Tim Race** - *Deutsche Bank - Analyst*

Thanks for taking my question gents. First question is on just M&A policy and what you're going to do going forward. Following the Otsuka deal do we still have -- are you still looking out for more deals, going forward, and do you still have an active BD department, or should we expect this to be it for now?

Then just a question on Cipralex and Ebixa trajectory; you kind of answered my Cipralex question on the Germany side of things; but if we strip out Japan, should we expect Cipralex to actually be growing in 2012, with the positive news on Germany?

And just on Ebixa, could you remind me of the patent situation in key markets, and the type of growth to expect in Europe versus international markets particularly?

And then maybe just one last question for the other Anders. On Lu 21004, slide 10, you talk about a headline of unique pharmacological profile. Can you just remind me of exactly what benefits you're hoping to see in terms of speed of onset, side effects and efficacy, in terms of marketing messages that you'd be able to put forward, in what is likely to be very much a generic market? Thank you.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

So let me start, Tim, thanks for all your questions, they're very [extensive].

With respect to M&A, we still have a fair amount of money. We have very good business development processes. We have done several significant deals where other significant companies have selected us, based on our CNS experience, both in developing and commercializing drugs.

So, if we get more great opportunities, we will definitely go after them. But at the same time it's also important to recognize that three or four years ago, we didn't have anything, and we needed products desperately; and we were chasing everything very hard.

Now we are quite busy with what we have at hand. But, again, if we find good projects that can make a significant, positive difference for Lundbeck, we will go after them.

And I pass over to Anders Goetzshce, and then to Anders Gersel.

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

And the Cipralex, we still expect to see a slight decline on the top-line of Cipralex. But of course that is if you exclude Lexapro in Japan. And including Lexapro Japan, it will be flattish for the years to come.

And Ebixa, we expect to see growth in some markets for the coming years, but for competitive reasons we are not going to elaborate about our patent situation.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

And Anders, do you want to comment on --

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

Yes. 21004, the important part here is that we expect some of the outflow increased levels, particularly in the pre-frontal cortex of the noradrenaline and dopaminergic activities and (inaudible) inhibitors without having systemic effect of that, which means you can get some of the nice activities that will help patients beyond just the simple improvement on MADRS score without getting the systemic side effects that you would see if you give these drugs directly.

That's a key part that we would expect to get out of the results and we are working on trying to show that also in a clinical setting.

---

**Tim Race** - *Deutsche Bank - Analyst*

Can I just follow up on that? So, when we're talking about the pre-frontal cortex, are we talking about cognition here and those sort of effects and would you be able to actually get a label claim on those effects?

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

You will not be able to get a label claim in cognition and you will be able to demonstrate activities that may help the patients beyond just having improvements in their depressive symptoms, yes.

**Tim Race** - *Deutsche Bank - Analyst*

Okay, great. Thanks.

**Operator**

Michael Novod, Nordea.

**Michael Novod** - *Nordea Markets - Analyst*

Just a few questions. Could you try to give some flavor on the Lexapro dynamics going into March, because there's no doubt that the numbers have been surprising us? I guess, also revenues for 2012 or royalties will be somewhat higher. So, could you give some dynamics, but also perhaps tell us what you've put in, in terms of levels for Lexapro?

Then secondly, the reform impact you mentioned of around 5%, is that some kind of estimate of what you've spent, or is already including what you have seen perhaps in the latter part of 2011? I think there was a Turkish reform.

And then just lastly, the timing of the 21004, shall we still expect late April, early May?

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

Okay. Let me start on Lexapro. It has done better primarily as a result of pricing. I'm hesitant to give very detailed guidance on Lexapro for the year. Our patent goes in March, but somewhere DKK500 million to DKK700 million for the year, but it's a fluid situation. So we have to watch and see.

With respect to healthcare reforms, as you know, we have used a model where we map risks and quantify the risks and then we set up a central risk fund to deal with the risks, so that we are able to continue -- have continuous execution and continuous operations. We don't flip-flop the operating plans during the year.

And so far, that has been -- we have been pretty accurate in finding the right level and going into '12 we expect to see more of the same as we did in '11.

But I cannot comment on specifics. We know we have a price cut on Ebixa coming in France, but other than that, I don't want to be too specific on other things because it happens when it happens.

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

But I can add that, of course, all the known reforms that we know today, we have, of course, included that in our guidance. And when we look into that, we see it will have an effect of approximately 5%.

**Tim Race** - *Deutsche Bank - Analyst*

Okay.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

So same procedure as every year. And then on 21004, you should not expect to hear anything until end of second quarter. Could be earlier, but I -- you shouldn't expect anything earlier and then end of second quarter and, obviously, filing to plan, is somewhere around end of third quarter.

---

**Michael Novod** - *Nordea Markets - Analyst*

Okay. Thank you.

---

**Operator**

Peter Welford, Jefferies.

---

**Peter Welford** - *Jefferies - Analyst*

Couple of questions. Firstly, on 21004, I was wondering if you could give us some sort of description of -- obviously, the trials are ongoing and reading out constantly. Can you perhaps give us some sort of feeling as to what proportion of all those trials in the next program so far you have in-house to give us some sort of comfort in terms of -- I understand you're not going to give us a headline, but what sort of proportion of the trials are in-house so far?

And also, can I ask a related question to Anders, which is in the outlook, what sort of assumptions are you making regarding milestones from Takeda?

Are you assuming that 21004, like you have done with the spend, is included in full in the guidance, or is there some sort of risk adjustment for that, with regards to the milestone income?

And then could I ask with regards to zicronapine? Should we anticipate getting any data from the small Phase III that you've started with zicronapine or is this very much going to be a study for you that then will trigger larger studies and we shouldn't necessarily anticipate to see any public data or headlines from that until I guess a few years' time? Thank you.

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

First and foremost, in terms of the studies that we know, we are still not -- we still haven't got the data from the US part of the program which we're still awaiting. And as you know, that is important for our US filing, so that's the set of studies we are still not having data from. But the Lundbeck program, pivotal program has been completed.

If we look at the -- I'll take your last questions also on zicronapine and say we don't expect to disclose any figures from that. It's more for internal decision-making on this, in terms of how we're going to proceed exactly, to fine-tune the final program on that.

With respect to the milestones, I will hand that over to Anders Goetzsche.

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

Peter, we have included the milestones in the guidance and you know that it is -- we have said it's approximately DKK250 million. And we have made a broad guidance to actually be able to have a guidance that covers all circumstances; no milestones or including milestones.

---

**Peter Welford** - *Jefferies - Analyst*

Sorry, just to be clear, the DKK250 million, that is, if you like, 100%, that is best case, if you like, and then essentially, it can go down from there depending on obviously whether or not there's success or not?

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

Yes, it's binary, so you could say either you are successful or not.

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

Well actually, it's not binary, there is also a scenario where we, for some reason, are slightly delayed or decide to file a little bit later, which would push the payment into 2013 and that's a possibility as well.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

But that's the reason why we've given such a wide guidance and which is -- I mean DKK500 million on EBIT is much wider than what we normally give and it's all about this milestone, otherwise it would be tighter.

---

**Peter Welford** - *Jefferies - Analyst*

Thank you.

---

**Operator**

Frank Andersen, Jyske Bank.

---

**Frank Andersen** - *Jyske Bank - Analyst*

I have a couple of questions also. First of all, could you share with me your view on sales on Ebixa going after 2012? What are your expectations from there going forwards?

And also, if you could put a little light onto your CapEx as a percentage of revenue. In the longer term, how much should we expect CapEx to account for?

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

If I start with the CapEx, you should expect that the ongoing investments we need to do to run the business is approximately DKK500 million.

And then, if you look to the investments level this year, we have had additional -- or in 2011, we have had milestone payments of $200 million and you should -- if everything is successful with Otsuka next year, you should expect a total investment level of DKK2 billion; DKK500 million in running CapEx and then DKK1.5 billion in milestone payments to -- [up to then].

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

And then with Ebixa, we continue to expect that volume will increase and, of course, we don't know fully how healthcare reforms, etc., will play out.

We know that, as Ulf also alluded to, that this French -- there's a potential French price cut and that will, of course -- France is the biggest country from an Ebixa point of view, so, of course, that will have an impact on the growth in 2012.

---

**Frank Andersen** - *Jyske Bank - Analyst*

Okay. Thank you.

---

**Operator**

Brigitte de Lima, BofA Merrill Lynch.

---

**Brigitte de Lima** - *BofA Merrill Lynch - Analyst*

I've got three questions, please. The first is on Sabril. There's been now three quarters of flat sales, and I was just wondering if you're still expecting the product to grow further, or have we now reached the peak sales potential.

The second is on Xenazine; just curious what caused the jump in Q4 and should we anticipate similar increases in [subsequent] quarters.

And then final question is on the Ovation products. You had previously guided to a decline of 10% to 20% per year, but in 2011 it looks like it was only 5%. So I was wondering if you think that we should be less aggressive in forecasting the decline there. Thank you.

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

If I start with Xenazine, we were very pleased with the development in Q4, and we think we had a very good start, and then it slowed down. And then all the actions we took to actually improve the business is really impacting now. And we think that we are really good on our way to reach the [purchase] level between $200 million to $250 million.

Sabril, you're right that now it has been flat, but we are -- as we did with Xenazine, we are working hard to take actions to get the growth quarter by quarter back. But of course, as you know with the REMS program, it is more challenging with Sabril.

So we still have an aim getting over DKK1 billion, but it is tough to -- it's easier to grow Xenazine now than Sabril, but we will work hard on that.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

That is it. We're still holding on to our ambition on Sabril.

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

And could you repeat? You had a third question.

---

**Brigitte de Lima** - *BofA Merrill Lynch - Analyst*

I had a question on the former Ovation products. I remember you guiding to a decline [P] of around 10% to 20%. But I think it was only 5% in 2011. So I was wondering if I should model a less aggressive decline going forward as well.

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

You should not.

---

**Brigitte de Lima** - *BofA Merrill Lynch - Analyst*

Okay, thank you.

---

**Operator**

Peter Sehested, Handelsbanken.

---

**Peter Sehested** - *Handelsbanken - Analyst*

Could you just -- I think it's mentioned around DKK500 million, but could you just mention the absolute changes that we should expect on the costs line, SG&A and R&D are potential, so cost of goods sold.

And secondly, on the Otsuka milestone, could you split that DKK100 billion or DKK1.5 billion up in timing and trigger events?

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

The Otsuka milestone is a combination of development milestone and approval milestone, and I'll not go into more detail with that.

And then the question around the ratios. You should expect that the COGS ratio will be approximately 2% higher next year in '12 due to a larger part -- we're losing Lexapro in the US which is a high margin product which is our own invention, and then we are shifting to a more [in-license] product which will increase royalties.

Our overall cost development is decreasing. The productivity in our products and facilities is actually declining with approximately 1 percentage point every year due to efficiencies. But then you should add some additional royalties.

So, the best guess now is approximately -- a slight increase of 2%. The R&D ratio will be a little less than this year, approximately 20%, but it will of course -- you know that there's a lot of swing factors in that. And then the SG&A margin will be the one that will be impacted most, and that is due to all the loans cost.

So approximately DKK500 million in additional loans cost that is 3% to 4% in additional percentage point, in additional SG&A margin. Does that answer your question?

---

**Peter Sehested** - *Handelsbanken - Analyst*

Yes. So just to confirm that SG&A costs will be roughly DKK500 million higher in 2012 compared to '11.

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

More or less, yes.

---

**Peter Sehested** - *Handelsbanken - Analyst*

Okay, thanks.

---

**Operator**

Martin Parkhoi, Danske Bank.

---

**Martin Parkhoi** - *Danske Bank - Analyst*

I have only two questions. One is a bit of a clarification with respect to -- I think that it was Michael who asked it earlier, with respect to Lexapro in 2012.

I can understand that you are expecting something like DKK520 million to DKK700 million in [rises] right now. Is that what you have included, like you have included DKK500 million in the low part of guidance and then DKK700 million in the high part of guidance?

And then the same question was just to -- with respect to Ebixa. It was a little bit on -- lower than at least consensus than I expected in the fourth quarter. You mentioned Turkey, of course, the price cut, but has there also been some kind of hesitant buying patterns in France ahead of possible price cuts that you have been talking about?

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

In Ebixa, you are right that the reason -- the comments you gave is spot on, but the underlying volume growth is actually really good in most markets. Whenever you view the countries we have, both in international market and Europe, we actually see growth, double-digit growth in most markets.

So basically the growth is only 14% due to price cuts and impacts from healthcare reforms.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

And on Lexapro, Martin, we have many, many moving parts when we do our P&L, so we won't get any closer than the DKK500 million to DKK700 million on question. We appreciate the question but it won't be more granular than that.

---

**Martin Parkhoi** - *Danske Bank - Analyst*

Okay. Thank you.

---

**Operator**

Florent Cespedes, Exane BNP Paribas.

---

**Florent Cespedes** - *Exane BNP Paribas - Analyst*

A few quick ones. First on nalmefene, could we have some color on the discussions ongoing with the authorities, and could you tell us where you stand regarding a potential partnership?

Second question on the full-year guidance, 2012. The consensus already stands at the high end of the guidance and I'm just wondering if you could give us which are the mainstream factors on your 2012 guidance.

A quick one on OPC product from Otsuka on schizophrenia, could you tell us when we should see the first for Phase III results? Thank you.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

Let me start answering part of the nalmefene question, and then Anders Gersel will comment on the labeling, and obviously then Anders Goetzsche will talk about guidance.

So in general, with nalmefene, the feedback we have from payers and policymakers is that we acquired a high level of interest. Alcohol is increasing the view that the driver of healthcare costs in society and there is a recognition that the general practitioners are not involved today because they do not have any [product to use] with nalmefene. They have a reason to -- they have something to offer the patient, and hence they can have a reason to be involved.

But of course, what eventually -- one of the very, very critical things deciding on this, where it's going to go, is the final labeling and we don't have the comments back on that yet. So that will be very important for us.

I think with respect to partnership, we have gone from a journey where we were first doing this on our own, then we were looking for a European partner. We've explored that. And now as we are learning more of the market, we say that there are some countries that are very, very policy driven where you don't need a lot of sales reps, and then there are some countries, particularly in Southern Europe, where it's likely that you need a lot of sales reps.

And what we will do is probably to do partnerships in these specific countries where we need more reps. Pretty much along the lines of the Cipralex model that we have used historically.

And I'll hand over to Anders to give more clarity on nalmefene and OPC.

---

**Anders Gersel Pedersen** - *Lundbeck A/S - EVP, Drug Development*

Yes, I think first and foremost if your question is in terms of formal discussions around the -- with regulatory authorities on nalmefene. We have to admit the file and as part of that process we cannot have discussions as we speak. So right now we are in a period where we not have interactions with the regulatory authorities on that.

But we had previous to that had discussions with a number of countries presenting the thinking around the data and what analysis we were intending to show and have had a fair amount of recognition for the novelty of this and what it brings to a patient in this particular scenario. Both, because the studies include a large proportion of patients who have not previously been offered any treatment and have come forward because of this treatment opportunity. And also because of the nature of the, as needed use, which is very unique with this program.

With respect to the OPC, we will get more insight to the ongoing Phase III programs roughly within a year from now, but in terms of the timing of disclosure we have not agreed with Otsuka yet about when we will do that.

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

And regarding the milestone payment, I think in most consensus estimate I would assume that the milestone is included with 100%. And that also leads to that you should expect that if we get the milestone then, of course, we will be in the higher end of the range, and if we don't get the milestone we will be in a low end.

---

**Florent Cespedes** - *Exane BNP Paribas - Analyst*

Okay, so if I understand correctly, it's definitely the milestone which is the mainstream factor on the 2012 full-year guidance?

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

No, that is the most easiest swing factor to understand but of course when you are launching products like Lexapro in Japan, launching Sycrest, you are launching Onfi in the US, you are continuing to develop Xenazine in the US and Sabril. Then you have a broad range of launch activities that is the main swing factors.

---

**Florent Cespedes** - *Exane BNP Paribas - Analyst*

Okay, thank you very much.

---

**Operator**

Tim Race, Deutsche Bank.

---

**Tim Race** - *Deutsche Bank - Analyst*

So, I have actually got three questions, two quick and one maybe longer. First on dividend policy, can you just remind me of what your dividend policy is as we head into 2012 and obviously what we might see with Lexapro?

Second, just can you fill in -- complete the circle in terms of what we should expect for tax rate and perhaps the direction of net financials next year or this year?

And actually then the third question is more nebulous in terms of, we're seeing a number of large cap pharmaceutical companies pull out of research into the brain in the recent last couple of months. What does that tell you in terms of your R&D direction, does it make you sit up and think or does it actually make you think that these opportunities in terms of products are also personnel that you may be able to capture. Any comments on that would be great?

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

Tim, let me start. We have a broad late stage pipeline within CNS, which I think many of them, had they had that, they would not have made the decisions they are making. Obviously for us it's very important, we have many pipeline events coming up, we have 21004 data here in Q2, we should get some desmoteplase inside beginning of next year, we have regulatory efforts with Selincro and Aripiprazole depot and we're going to see where we stand with OPC.

But I think many of them are -- had they been in our situation they would definitely not pull out and I feel for a mid-sized company, which we are, I feel we are very strongly positioned. I think we may have the most comprehensive pipeline in psychiatry of any company today and we also have other exciting products.

I think the fact that Merck, Cephalon and now latest Otsuka selected Lundbeck as preferred partners, obviously recognition that it's not all about who has the most money to put on the table when you do a deal. But also a realization that they want to do things together with someone whom they think is likely to be committed and able to execute, both from a development and commercial point of view.

And in that sense I hope that our overall competitiveness in the business development market will have improved with the announcements from Glaxo and Astra. So, clearly whilst we are very busy we will be executing on the pipeline and on the product launches we're doing, I also hope that when there are exciting products coming within the CNS space, that companies will look to us as a potential strong partner.

And Anders, will you take --

---

**Anders Goetzsche** - *Lundbeck A/S - EVP & CFO, Corporate Finance & IT*

The dividend policy, our aim for the year to come is a payout ratio of 35%. We have a policy of 25% to 35% and we have been at 30% in the previous years but we expect to pay out 35% to keep above the dividend yield at least at a decent level.

The net finances, this year unfortunately we are actually -- if you look into the financials, a large part of that is actually currency fluctuations form the intercompany account we have between the US, Denmark and the UK. We have tried to get rid of that because it is a little frustrating that they are -- that we have the swings we see. Only one-third of the financial is cash-related, the rest is actually transitional swings. And we expect that going forward that it will be in a range of DKK50 million to DKK100 million and that would be due to this currency fluctuation on the intercompany accounts.

The tax rate, it will be -- we expect the reporting tax rate to be 26% to 28% in the year to come but of course the cash tax rate will be much lower due to hopefully some of these milestones through Otsuka.

---

**Tim Race** - *Deutsche Bank - Analyst*

Perfect, thanks.

---

**Ulf Wiinberg** - *Lundbeck A/S - President & CEO*

So again thanks very much for calling in. And just to say something more obvious. If CNS remains one of the areas where there is -- if the cost is [cognitive diseases] to society and where there are significant opportunities to improve treatment with better drugs, both from an efficacy point of view and a side-effect point of view, we hope to be the Company that makes the biggest difference for patients and that's what we hope to execute on in 2012.

Thanks for calling in.

---