

# FINAL TRANSCRIPT

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## **LUN.CO - Q2 2011 H Lundbeck A/S Earnings Conference Call**

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## CORPORATE PARTICIPANTS

**Ulf Wiinberg**

*H Lundbeck A/S - CEO*

**Anders Gersel Pedersen**

*H Lundbeck A/S - EVP, Drug Development*

**Anders Gotzsche**

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

## CONFERENCE CALL PARTICIPANTS

**Michael Novod**

*Nordea - Analyst*

**Tim Race**

*Deutsche Bank - Analyst*

**Peter Hugrefte**

*ABG - Analyst*

**Henrik Simonsen**

*SEB Enskilda - Analyst*

**Martin Parkhoi**

*Danske Bank - Analyst*

**Eleanor Fung**

*Goldman Sachs - Analyst*

**Carsten Madsen**

*Carnegie Bank - Analyst*

**Caroline Valdecabres**

*Societe Generale - Analyst*

## PRESENTATION

**Operator**

Thank you for standing by and welcome to the Q2 2011 financial results conference call. At this time all participants are in a listen-only mode. There will be a presentation followed by question-and-answer session (Operator Instructions).

I must advise you the conference is being recorded today, Wednesday, the 10th of August, 2011. And I would now like to handover to your speaker today, Mr. Ulf Wiinberg. Please go ahead, sir.

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**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Thank you. It's a great pleasure for me to welcome you to the Lundbeck second quarter investor conference call. Before we start the meeting let me just remind everyone about the forward-looking statement which is on slide number 2, and I assume you're all well aware of this. I promise not to read all of it. And with that let's move to slide 3.

Second quarter was a great quarter for -- operator, can we have slide 3. We have a technical issue, we're trying to move to slide 3.



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So we're very, very happy about the great quarter we have enjoyed. We see solid performance across geographies and pretty much across all the products. We have a 9% revenue growth for the quarter and we have good expense control and as a result we have an 18% EBIT growth. So from a financial point of view, a very positive quarter, and this now allows us to say that revenue and EBITDA is expected to be in the high end of the guidance range.

We have also announced that we will do a reduction of R&D staff in the US and in Denmark. This is unfortunate, it's not something we really want to do, but it's necessary. We are at a point in time when we have several product launches in several geographies around the world making necessary for us to increase our commercial investments.

And if we are going to deliver on our plans in view of health care reforms and generic exposures, we need to have tight cost control in R&D and all parts of the business. And as a result, we've decided it's necessary to take out roughly 150 positions. So we have announced this today and we will follow a consultation process with [work councils] and implement this over the next month.

In terms of new product opportunities, Lexapro is being launched here in Japan in August. It's a launch we're very, very excited about. This has been a top priority for Lundbeck over the last few years, and obviously a launch in August is way ahead of the original timeframes. And we're excited about the structures here and I -- so I will talk a little bit more about this.

We also have, although it's way too early to comment on Sycrest, the initial qualitative feedback is positive from our commercial organizations. It has been easy to make appointments with physicians and there seems to be a high degree of interest and our perception is also that the price negotiations are going well and we expect several launches to take place here in the fall in addition to Denmark and Germany where we have launched already.

Also from a pipeline point of view we're very pleased to see the great nalmefene data. This allows us to make a submission before year end for this exciting product. Then we have some setbacks. And of course in one way we have gotten so used to having great results. We had great results with clobazam. We had great results with Cipralex in Japanese patients. We have had great results with nalmefene. But now we've had a reminder of the riskiness of our business, so we had negative results with 24493 in Friedreich's ataxia. We continue not having solved some of the tox problems we have with 39959 and we have decided to take it out of our pipeline, and then we've had to terminate two phase I projects. So this all reminds us of the riskiness of pharmaceutical R&D and also in our field.

Next slide please. We are going into a very exciting phase here in 2011 and '12. And obviously we should see several additional launches of Sycrest in Southern Europe during the fall. We have the Lexapro launch in Japan which is taking place this month. We're preparing for the -- can you move to the next slide please, operator -- we have the Cephalon launch that's taking place first half of 2012 and we are building up to that. We have the clobazam regulatory approval process going on and we expect a launch in the first half of next year. And then obviously we hope to have submitted nalmefene filed by year end, enabling us to launch towards end of 2012. So a lot of key initiatives on many products around the world.

Next slide. I just want to illustrate one country for you that we normally don't talk so much about, and that's Canada. Canada is experiencing very significant growth rates, and we believe that Canada soon will surpass DKK1 billion in revenue. It's already now the second largest Cipralex market. They have growth of 25% despite having generics on Ebixa. And obviously next year we should be launching Saphris and Cephalon in Canada. So very, very exciting developments in Canada.

Next slide. Operator, we're two slides behind, but I'm now on Lexapro approved in Japan. So just to remind everyone that this is a very significant market opportunity. Mochida has developed the product and has proven that Lexapro is effective in Japanese patients. We've had approval and we've had a price of JPY212 per tablet. And Mochida and Mitsubishi Tanabe will launch this product here in August. And as part of the regulatory process, Mochida has advised authorities that peak sales could be JPY33.8 billion. And obviously there should be some -- could be some variance to that number, both positively and potentially also negatively. So we're very excited about what's going on in Japan and we look forward to seeing the evolution over the next 12, 18 months.



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So with that let me handover to Anders Gersel Pedersen.

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

Thank you. Could I have the next slide, slide number 7? The slide mainly illustrates the current pipeline with the projects that have been taken out and with the -- from phase II, III and onwards, indicating that we have a strong phase III portfolio at this moment and clobazam in the filing process. Since last time we had taken out the Lexapro Japan file because it's completed now, so there is only one product in the filing process at this moment.

Could I have slide number 8, operator? Could you move the slide to number 8? It's two slides ahead of where we are right now. It's slide on 21004, vortioxetine, data presented at the APA in the spring. We have at that meeting presented three -- four phase III studies of which two European studies were there. The one study that we have on the slide here is a relapse prevention study which basically indicates the strong impact of 21004 in preventing patients from having recurrences in their depressions after an initial stabilization on 12 weeks of treatment with active drug. And it's indicative of the strength of the molecule.

Also there are data at the bottom of the slide showing the very benign safety profile in terms of adverse events on 21004. We have concluded the enrollment of the last of the pivotal studies that Lundbeck conducts during this month here also, so we are expecting things to move well on track for the filing in 2012.

I would like to move on to slide number 9 on nalmefene. We have in the past quarter had the last set of data on nalmefene which are strong and clearly supporting the filing process which we have formally initiated now with the European agency in terms of signaling timing of filing and having (inaudible) appointed by the European community. We expect to file by the end of the year. The concept is novel concept.

We have discussed that with regulators and with various authorities who accept and understand the concept in terms of being a valuable contribution to helping individuals with an excessive alcohol consumption and also in the fact that reducing alcohol consumption from a very high level to a lower level is of medical benefit and is part of a reduction in risk to these individuals of delivering -- of developing health care issues later on in life.

The data also clearly support the as-needed-treatment concept which is novel and basically allows the individual to be in control of their own scenario in terms of taking the medication when they feel there are need and not having to be on continued medication because they have an alcohol control issue. So basically we are very confident in moving forward with the filing within the European community on nalmefene.

And with that I will handover to Anders Gotsche on the next set of slides on the financial figures.

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

Thank you. Next slide. Thank you, Anders.

We are very pleased with the overall revenue growth in the second quarter, and we are happy being able to maintain the solid momentum from the previous quarter. And if you -- even if you exclude Lexapro we see revenue growth of close to 8% and we think that is pretty solid. And compared to the same quarter last year we saw a reported growth of 9% and 13% in constant exchange rate.

For the second quarter itself the growth for our key products, have been very satisfactory, and we are happy with the increasing market shares in most markets. It is in -- it is pretty important to also stress that Ciprallex in constant exchange rate showed a 6% increase which is driven by significant growth in several markets both in Europe and international markets. And this very



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nice growth is offsetting some of the negative growth we have in Spain, Portugal and Finland where we see health care reforms or generic competition.

When we look into 2011 as a whole, Cipralex will of course be charged due to health care reforms and generics. But a positive upside will be the upcoming launch of Lexapro in Japan where we start to recognize revenue in the second half of 2011. You should also be aware of that in third quarter this year we expect to receive a milestone from Mochida and that will be -- sorry, be put under the revenue line other revenue.

Ebixa also continues a very strong growth momentum, and this is actually one of the strongest quarters in Ebixa's history, it's 19% in constant exchange rate of growth. And we expect that this growth will continue for the rest of the year and we also expect double-digit growth for the full year. And it is driven both by volume and market shares increases.

Xenazine and Sabril, we are very happy that the good growth we have seen in previous quarters are continuing and we can also see that Sabril seems really to have [gotten] traction which we obviously are very -- are quite pleased with. And for both of these products we expect continued solid growth going forward, also considering the likelihood of additional pressure on federal health care spending in the US.

Azilect continues to perform nicely in countries like Germany and UK, but, of course, this product is obviously also impacted negatively by health care reforms in some European markets. And as Ulf alluded to, it's far too early to comment on Sycrest, but we are looking very much forward to the upcoming launches in some of the additional territories we have the rights for.

Please look to the next slide. A 9% reported revenue growth has been converted into 18% EBIT growth, corresponding to a EBIT of approximately DKK1.1 billion, and that's a growth in net profit of 21%. And even if you adjust for the positive impact of the divestment of Seal Sands, we are extremely pleased with the performance for the quarter.

And we can see from the figures but also internally that our recent year's cost containment programs are still carrying effect and we will continue as we have also announced in this release to be sure that we optimize our cost base going forward.

The only -- if you look in the -- when you look at the cost lines you can see that compared to last year we have some increases, and then you can ask if that -- they're talking about controlled cost, but the only reason for increasing cost, that is cost for Sycrest and increased sales of in-licensed products, so that's the only reason for increasing cost, everything else is actually flat or declining.

Going forward, you should expect COGS percentage approximately at the same level as in 2010. We still expect that the SG&A percentage will increase with approximately 1 percentage point compared to 2010 due to the ongoing launch cost for Sycrest and pre-market or market access cost for Onfi and nalmefene. The R&D cost percent is expected to be at the same level as 2010, and it will be approximately 20% to 21%. And that is due to the additional write-downs which we have announced in this release. And we expect these write-offs to hit the R&D line.

Please flip to the next slide which is strong cash flow generation in Q2. And of course, due to the very strong quarter you can also see that we have a very solid cash flow. The net cash flow for the quarter is approximately DDK0.5 billion, and that is after having paid out a dividend of DDK706 million in the quarter to our shareholders. So by the end of the quarter we have a net cash position of DDK1.6 billion. And by the end of the year we expect to be, have a net or a cash position around DDK4.2 billion to DDK4.4 billion that will lead to a net cash position around DDK2.5 billion.

Please flip to the next slide. As you can see from the quarter, the business is going extremely well, and that has also been the reason for us as a Company to upgrade our guidance. And we are now expecting to be in the high end of the revenue range, and that also goes for the EBITDA where we also expect to be in the high end. And we keep our guidance on EBIT, and that is of course the reason for not upgrading that, is due to the fact that we expect write-offs in (inaudible) figures DKK300 million to DKK400 million.

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But what is really important for you as analysts and investors is that we are increasing also our cash generation due to the increase in EBITDA. What you also should expect is that the depreciation and amortization for this year will be around, including the write-offs, DDK1.2 billion to DDK1.3 billion. So, all in all, we think this is a strong quarter, and we are happy with the upgrade in our guidance.

And having said that, I would like to hand over to Ulf Wiinberg for the concluding remarks.

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**Ulf Wiinberg** - H Lundbeck A/S - CEO

Okay. So thank you, Anders. So, the key priorities for the fall of 2011 is obviously to prepare for all the new product launches. So we have the continued rollout of Sycrest both in Europe and in rest of the world. We have the approval and preparation for launch of the Cephalon product range in Canada and Latin America. We have the launch of Lexapro in Japan. We have a launch preparation for nalmefene and Onfi. And we have the expansion to drive revenue in China. So it's a very exciting time period for us as a Company to see what we can do on these various opportunities.

From a pipeline point of view, we have the clobazam approval which we expect by before year end. We have a continued execution of the 21004 phase III studies. And then we have the filing and initiation of regulatory approval for nalmefene. So very busy fall in order to setup the ride for the future.

And so with that please let me open up for Q&A.

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## QUESTIONS AND ANSWERS

**Operator**

Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. (Operator Instructions) Michael Novod from Nordea.

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**Michael Novod** - Nordea - Analyst

I have a couple of questions. One is could you try to comment a bit on the statement you've made on cost levels because there is no doubt you are going to ramp up force for the launch of 21004? So what should we expect into perhaps 2012? Will you see cost levels that are very much on par with 2011? Maybe you could just shed some light on that because you have already now indicated that the sales and marketing cost will be going up, it seems like that.

And then, secondly, Ulf, you've been out saying that you have much higher ambitions and targets for Cipralext in Japan and 500 million in royalties. Takeda is -- sorry, Mochida is guiding for 2.3 billion in sales, meaning around 300 million in royalties to you. Is that the target you are looking at or are you even more bullish than that?

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**Ulf Wiinberg** - H Lundbeck A/S - CEO

First of all I'm more bullish and then I think I also expect that if the 2.3 billion has been right, I would expect to receive a larger piece of that than what you have in your model --

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**Michael Novod** - Nordea - Analyst

Okay, so you have a much high royalty than that?

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**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Yes, so -- but I'm also more bullish on the sales than what they have guided.

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

Okay.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Anders, you want to answer?

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

Thank you for the question, Michael. It's -- I think it's a little too early to make guidance for 2012 and onwards. What we have said is that we expect the SG&A margin to be between 37% and 40% in that period, but definitely it could be in the high end of that range. We announced the 37% to 40% when we made the floor guidance in November. So I think you should expect that it could be in the high end of that range.

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

Yes, especially in connection with launches like 21004.

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

But again, it's too early to say because it's a matter of all the time optimizing the efforts behind the launch of the products, but also balancing that we secure that, we have the right power to actually get the maximum value out of the products.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

And, of course, we have to be very disciplined in the rest of the business with expenses and keep good expense control in place.

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

Ulf, will you show us the exact royalty when you start to report on sales from CipraleX in Japan?

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

I will not do that, but -- yes, I will not, but we will try to see if we can be a little clearer on how we communicate, but I cannot give the exact royalty, so.

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

Okay, thank you.

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**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Next.

**Operator**

Tim Race, Deutsche Bank.

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

First question, in terms of the health care reform, could you just give us a bit more quantification in terms of the sales and EBIT impact we've seen in the first half of the year and how you expect that to change in the second half of the year?

Next question just on guidance. Just in your previous guidance, was the DKK95 million for the Seal Sands plant gain already included? And if my calculations are correct, underlying, if we're looking at EBIT guidance staying the same, are we talking effectively of a, depending on the Seal Sands, a 3% to 6% EBIT, hopefully, for the year in terms of the where the business has progressed so far?

And then just a fourth question, just, obviously, I understand that the German situation with CipraleX has been in your guidance, but perhaps if you could just talk about CipraleX in all the European major countries and what you expect for the next 2 to 3 years in terms of any changes there are upcoming headwinds that we might expect? Thank you.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Can I start with Germany and then Anders comes back on the other things? Let me just say that we -- when we gave guidance for the year we had a general plan allowing certain health care reforms to impact the business and still being able to deliver the plan. But when we gave that guidance we don't know exactly which one will happen and how they will impact us. We had hoped that CipraleX would continue to be reimbursed in Germany following what we thought was a positive dialogue with your health care authorities in Germany. And we were therefore a little surprised when the decision came through.

We were aware of the process, we were aware of the risk, but since there is evidence showing that CipraleX is a great product and also that it's probably a better product than Cipramil, we had hoped that that would come through in the reimbursement decision in Germany, and it did not. So clearly our business, we will lose significant sales in Germany. The -- what has happened in Germany and in some other countries we will be able to absorb and it will not impact us for the year. But it just illustrates some of the volatility around health care reforms around the world and the need for us to be prudent and have some margin and buffers to deal with these issues because we don't really know which ones will happen and when they will happen and to what extent they will impact us.

So with that let me hand over to Anders to talk more about guidance.

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

Okay. Thank you for the questions, Tim. When we made the guidance in February, we had not included the sale of Seal Sands, the gain on Seal Sands. So that's on top of our guidance. When we -- but, of course, you can isolate that as a one-off, but then in the business we -- you might during the year have some kind of one-offs where you do not report that which you just take into your ongoing business. So to isolate that and say then you need to upgrade your guidance, that's not the full picture.

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Then you asked about how does the guidance for EBIT look like. And we have said we will be in the high end for revenue and EBITDA, and then we expect depreciation and amortization. It's difficult to make a very precise amount but it could be between 1.15 to up to 1.3. And then you can -- then you find where the outcome for the range of the EBIT, and that the same goes for the net profit.

And it is extremely important also to stress that the change in tax rate, that is reporting tax rate, it's not the cash tax rate. So it will not change the structure of tax rate going forwards, but will continue to be in the range of 26 percentage points to 28 percentage points.

And the last question, health care reforms, I think I said when -- when we made the guidance for the year that we expected to be impacted around 3% from generics and 3% to 5% from health care reforms. And that has also -- that is also the fact for 2011 and for the first half of the year. And then, definitely, Germany will have a greater impact for the latter part of 2011.

Does that answer your question?

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**Tim Race** - Deutsche Bank - Analyst

It does. 3% is that on to profits rather than sales?

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

Sales.

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**Tim Race** - Deutsche Bank - Analyst

Sales, okay. Thank you.

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**Ulf Wiinberg** - H Lundbeck A/S - CEO

Next question, please.

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**Operator**

Peter Hugreffe, ABG.

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**Peter Hugreffe** - ABG - Analyst

First of all, in terms of the R&D cuts you make today, you previously guided approximately 20% for '12 to '14. Today you've slashed 150 people and you have also slashed four projects. Is this still the 20% level going forward or -- and if that's the case what has changed then?

Secondly, on 21004, the data you announced on the APA had clearly had a much lower nausea rate. Now we are talking about you can low-teens, and in connection with the phase II trials we saw a 38% in the [10-week] study. Do you have a reason, any kind of explanation of this?

And then finally on Germany, one thing is of course the impact on Germany, but what impact should we expect outside Germany from this jumbo process? Thank you.

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**Ulf Wiinberg** - H Lundbeck A/S - CEO

Peter, thanks for your great questions. I think on R&D expense and long-term guidance we've said 20%, but we have said it will be very project-dependant. And we have expected greater variability there. So when we said 20% that could be 17% or it could be 23%. There is a wider margin to that number.

Then I think it's important to say that the four pipeline negative updates we had on cEPO and the other three products, they are not part of a portfolio decision. These are outcomes related decisions. cEPO failed in Friedreich's ataxia. Had it succeeded, we obviously would have continued to develop the product. And the 39959, I think it is a product that we have been extremely interested in both from a mode of action point of view and an efficacy point of view. But we have had a tox issue that we have worked on for a long period of time and we have not been able to resolve, and we have felt since we have been doing this for so long we should take it out of the pipeline.

And two other phase I is typical phase I issues where you find out things about the pharmacological profile and which would mean that they are not suitable to develop, so -- to be developed. So it's not part of a portfolio decision to have these terminations. And, obviously, we will work to find new projects both from internal research and development and from external partnerships to strengthen our pipeline.

I think the overall reduction in staff is a reflection on the need for us to be very disciplined on spend across all the businesses as we are going through the commercialization on the other projects. Anders, do you want to answer on 21004 and nausea?

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

Yes. It's quite correct as you observed that the level of nausea that was reported in the initial study was considerably higher than in this one -- in these ones, yes. We do not have a very good explanation as to why that is the case. We have in the studies that are both the -- all of these studies that have happened and also the ones that are ongoing, we are still seeing low levels of nausea. So we believe that the original observation was an aberration rather than the platform which is good news and which is also one of the reasons why we have without any hesitance gone to the high dose levels in the ongoing phase III program.

**Ulf Wiinberg** - H Lundbeck A/S - CEO

So, Peter, just coming back to your R&D question, I mean we will be below 20%, probably around 18% with where we are now. But as I said, it's highly project dependant. You were also asking if the German decision will impact other countries.

And traditional Germany hasn't been a reference country; (inaudible) has sometimes build over with their decisions in the UK, but we haven't seen the same from Germany. And clearly -- and you shouldn't be surprised for saying this, but we thought we were right in insisting on getting reimbursement, and although we lost the battle we still think we're right on the issue and on the science in that discussion. And that argument we will carry to other countries as well.

**Peter Hugrefte** - ABG - Analyst

So this is of course from a, you can say from a reference perspective, is there any risk in parallel trade and do you take any kind of corrective measures --?

**Ulf Wiinberg** - H Lundbeck A/S - CEO

Well, we are not lowering prices in Germany.



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**Peter Hugreffe** - ABG - Analyst

Okay.

**Ulf Wiinberg** - H Lundbeck A/S - CEO

So we will sell into the private market, but we will not agree to lower the price because we feel they -- they have made a poor decision.

**Peter Hugreffe** - ABG - Analyst

Understood. So you virtually just expect to lose the sales in the public part, so to speak?

**Ulf Wiinberg** - H Lundbeck A/S - CEO

In the public part, yes.

**Peter Hugreffe** - ABG - Analyst

Okay. Thank you. Thank you very much.

**Ulf Wiinberg** - H Lundbeck A/S - CEO

Next question, please.

**Operator**

Henrik Simonsen, SEB Enskilda.

**Henrik Simonsen** - SEB Enskilda - Analyst

The question was on these R&D [saving] cuts. What savings do you expect to achieve from the cut in staff?

And secondly, Ulf, I was wondering, have you come any closer to your marketing plans for nalmefene or are we still to await the actual labeling before you will decide on whether or not you need partners in certain markets.

And then thirdly, will these setbacks in phase I and phase II do you think that your early pipeline looks a bit slim. So will you be gearing up on external projects or will you do much to advance internal project? Is there any priority on that front?

**Ulf Wiinberg** - H Lundbeck A/S - CEO

To take your last question first, we will do what we can with both internal and external projects. We will look a little slim. I will also say I'm not so obsessed by quantification on having a set number of projects as part of a model, but I think we're a little slim.



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**Henrik Simonsen** - *SEB Enskilda - Analyst*

Yes, yes.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

And I will also say that if I can choose between having several products in registration phase and phase III and being slim in phase I and II, we're having lots of phase I and II but nothing in phase III and registration. I always pick phase III and registration.

**Henrik Simonsen** - *SEB Enskilda - Analyst*

I agree, agree.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

But that said, we will try to look, bring in project which we think are scientifically novel and able to make a difference for patients.

As regards the marketing plans for nalmefene you summarized very elegantly exactly where we are. The priority now is to get the file submitted and get concurrence on the labeling and then that will be part of shaping our commercial strategy and potential partnership decisions. We remain very enthusiastic about nalmefene.

And forgive me, you had a third question which I have forgotten or missed to take down.

**Henrik Simonsen** - *SEB Enskilda - Analyst*

Probably the question for Anders Gotzsche to talk about the savings coming from the cut in R&D staff?

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

We will not give you specific detail on that but other than to say that this was really necessary for us to ensure we have good cost control in transitioning from '11 into '12.

**Henrik Simonsen** - *SEB Enskilda - Analyst*

Okay, that was all from me. Thank you.

**Operator**

Thank you. MartinParkhoi, Danske Bank.

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

Also with a couple of questions. Firstly, with respect to again the inventory level of Lexapro, I guess that with the strong numbers we saw in the second quarter your inventory level has probably increased from 7 to (inaudible) inventory have increased from 7 to 8 months. Eight months, this is exactly what is left before patent expiry if we start from 1st of July, could you again guide a little bit of how we should expect this to pan out. Will Forest actually still have inventory when the product will go off patent?

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And then secondly, with respect to Ebixa development, of course a very, very strong development here in the second quarter, and as you said they all will -- also will continue for the remainder of the year. Could you tell a little bit about how you expect this product to develop in your transition 2012-2014 period?

And then again going back to the guidance, it seems like you feel quite comfortable going up to the high end of the EBITDA guidance, maybe even high if you look at how you are guiding on your EBIT but then why don't you narrow your range because as I see it now you have just the same range which means that you have of course you still, your maximum level is still the 4.6.

And then I think I have a question more. We have now seen Forest Labs launch a new antidepressant, Viibryd, and it seems like it has come off more or less in line with what we saw with the launch of [Prestig]. Could you talk a little about how do you think you position 21004 versus a product like that? Do you -- how do you expect an uptake of your product compared to an antidepressant like Viibryd? That was all.

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**Ulf Wiinberg** - H Lundbeck A/S - CEO

Martin, on 21004 we expect to have a much more comprehensive set of data on our products than what exists on Viibryd. The exact uptake and positioning is still dependent on the final outcome, but with what we know now we expect to have a more comprehensive set of data than they do have. And, obviously, we hope that that would help in the launch phase. I'll --

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

The inventory level -- this is Anders Gotzsche. The inventory level in the US, you are right, it has increased, and that is from our perspective it was unexpected but we still expect that we will have a very limited inventory when we go into 2012. And what is important to remember is that our financial risk is eliminated when the API has been transformed, formed into tablets. And we basically expect that by the end of the year all API will be transformed into tablets. So then we have no financial risk. But we still expect that by the end of the year it will be more or less 2 tons or something like that that would be inventory level that then corresponds to DKK100 million, DKK150 million.

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**Martin Parkhoi** - Danske Bank - Analyst

Okay.

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

But I've been -- I should also say that I've guided each quarter on this inventory level, and I have been surprised for the last two quarters. So this is basically my best guess based on the knowledge that I have from production planning.

And then you asked about the guidance, why did we not narrow in the interval. It is because there is a lot of swing factors also in the second half, health care reforms, materializing, the lack of reimbursement in Germany and we have a lot of initiatives going on. So thus we are confident that we would deliver in the high end but there are still some swing factors, and that's for not changing or narrowing the guidance.

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**Martin Parkhoi** - Danske Bank - Analyst

So the swing factors is then only on the negative side or else you would have upgraded, made a new range around the high end?



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

I didn't say that, but I understand your question, but that's -- no, the swing factors can be positive and they can be negative. And we also need (technical difficulty) we have write -- expected write-offs DKK300 million to DKK400 million. We need to finalize that with the auditors all that kind of stuff. We want to be sure that we also deliver on the guidance in the second half.

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

Okay.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

We have many moving parts, Martin. And maybe we are too conservative but so many products in launch phase and at the same time so many external factors that we have little control over so if we should make an error somewhere we should be on the conservative side.

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

Okay.

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

And then you had the question about Ebixa?

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

Yes, exactly.

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

And I would say that we think our sales and marketing organization has done a fantastic job in actually breaking the curve positively upwards with the increased growth rate in [Danish price] exchange rate, and we actually do not see any reason for not continuing a very good growth momentum also in 2012. But of course it can come down but it goes very well for the time being. And so we expect it to continue in 2012. What the exact growth will be, well, I cannot say now, but we expect it to be more or less also at the high level.

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

Okay, what is the -- which year do you expect to peak?

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

I -- from my perspective I would say it also depends on how -- there has been announced that there will come some health care reforms and how will that impact 2012, it's guessing because sometimes you also hear about health care reform, you see drafts of proposals for health care reforms but before they materialize and how does it materialize for your products. So it's difficult to say.

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**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Okay, thank you Martin.

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

Thank you very much.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Next question. Next question, please.

**Operator**

Thank you. Eleanor Fung, Goldman Sachs.

**Eleanor Fung** - *Goldman Sachs - Analyst*

Two questions please. And firstly on your R&D rationalization, could you help us understand how much of that R&D savings would be reinvested in the higher SG&A spend versus directly benefitting the bottom line?

And secondly, on Sabril, you mentioned significant sales growth due to increased compliance and dosing for existing patients. Could you give us a sense of how you are seeing penetration into new patients please? Thank you.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

I mean on Sabril penetration of new patients is a slow process and it's a conservative process. And this is something that we work on a lot. And I think both physicians who have to get used to the REMS process and patients who have to get used to the concept of REMS means that you have a slower penetration. At the same time there are several patients out there who are not well-treated today. And the reality is that the patients who start taking Sabril seems to be very happy with the medication and very committed to staying on it as evidenced by the compliance rate that we are seeing.

So if you ask us how is Sabril doing, I would say we have much better compliance than we had expected and we are little behind on new patients. And we're probably about on or close to being on the sales forecast that we have had. And as soon as anything changes we will communicate on it to the market.

And Anders, will you comment on ---

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

I think we cannot be more precise on the R&D ratios and the SG&A margin. It will be a balance between we have -- we will say that the R&D ratio will be a little lower. I indicated that the SG&A margin will be a little higher in the period and that -- that's how we see the picture in 2012 and 2013 for the time being.

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**Eleanor Fung** - *Goldman Sachs - Analyst*

Thank you.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

And next question, please.

**Operator**

Carsten Madsen, Carnegie Bank.

**Carsten Madsen** - *Carnegie Bank - Analyst*

Thank you very much for taking my questions, you have only got two left. First of all, in relation to the write-downs you will be making here in the second part of 2011, which product rights are being affected. Ulf, based on your comments about Sabril, could it be Sabril that you are taking a write-down on?

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

No, no, no --

**Carsten Madsen** - *Carnegie Bank - Analyst*

No, no.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Okay, come on, second question.

**Carsten Madsen** - *Carnegie Bank - Analyst*

Okay. And then on the COGS rate, I must say, could you try to break it down a little bit for us so that we maybe could understand little bit better what will happen when Lexapro royalties are being removed from your P&L here late 2012.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Yes, just on the write-downs, we are doing significant changes to our research infrastructure in the US. And as part of that we are reviewing the assets linked to research in the US. We are looking at buildings and we are looking at IP. And this is a discussion between our finance team and our external auditors, and it's estimated to be DKK300 million to DKK400 million.

There are no write-downs or changes linked to the former Ovation acquisition. This is all about what's in the research. And it's not like it's linked to projects being successful or unsuccessful as reported.

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**Carsten Madsen** - *Carnegie Bank - Analyst*

Okay.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

It's just an evaluation of where do we stand with assets now when we're making a significant organizational change in the US.

And, Anders, you want to take the next?

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

And the COGS percentage, you should expect, compared to 2011, that over the -- in the period 2012 to 2014 that the COGS percentage will increase. It -- depending on the mix of product, it could increase up to 2% to 3%.

**Carsten Madsen** - *Carnegie Bank - Analyst*

So also from an absolute level, it could actually increase because you have the high royalty payments, so.

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

From a what, sorry?

**Carsten Madsen** - *Carnegie Bank - Analyst*

From an absolute level, not in terms of percentage of sales, but also in an absolute level compared to 2010 and 2011.

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

Of course, if you expect that the revenue is unchanged, then in absolute levels COGS will also increase.

**Carsten Madsen** - *Carnegie Bank - Analyst*

All right. And one more question to the other Anders here on nalmefene actually. When I looked at your press release you sent out about the latest set of data, phase III data, you wrote that all assessments were consistently in favor of nalmefene compared to placebo, though some were not statistically significant at every single time point. So what does this really mean?

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

It basically means exactly as is said that you have assessment over six month period and we have in every measure that we have been doing and there are a number of these, very large number of these. We are looking superior on all time in all of these measures. So we are not statistically significant in all of them --

**Carsten Madsen** - *Carnegie Bank - Analyst*

-- on heavy drinking days, are you statistically significant there?

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

Given the specifics in terms of the subset of individuals, I cannot give you that off hand, but we are -- on the endpoint that we had to meet from a regulatory perspective to have a consistent picture of what the drug does, yes, then we feel confident with that and we also give that having discussed that with some of the regulatory authorities that they think that the profile looks good.

**Carsten Madsen** - *Carnegie Bank - Analyst*

Okay. Thanks.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Thank you, Carsten. Next question, please.

**Operator**

Caroline Valdecabres, Societe Generale.

**Caroline Valdecabres** - *Societe Generale - Analyst*

I've just two questions. First one is regarding Azilect because if we look at the growth of Azilect, in fact it's less than we could expect, what are you thinking for the full year and for the next years, it will be low double-digit growth?

And regarding Sycrest, when do you expect it to disclose the sales? Thanks a lot.

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

Thank you for your question, Caroline. Azilect, we have a lot of activities to accelerate the growth in the second half. But you should expect it to be less than -- I think it will be less than 20% for the year. I think that's a fair assumption.

And Sycrest, we will give specific numbers for Sycrest when it's material for the Group. And, of course, we will every quarter try to give as much update as we can from the launch activities. But I think you should expect us to -- that you should see specific figures during 2012. I'm not promising you any quarter, but hopefully, we can give you some granularity in 2012. At least we'll update you on how the different launch is going.

**Ulf Wiinberg** - *H Lundbeck A/S - CEO*

Caroline, this is Ulf. I mean the next piece of information on Sycrest that we are likely to communicate is obviously the reimbursement prices that we hope to achieve in the countries where we're launching in the fall to confirm that we achieve the price levels.

And that's what I hope to communicate at the next quarterly release where we stand with pricing approvals in terms of absolute approvals and price levels. And then it will probably go into '12 before we have material sales worthwhile reporting on.



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**Caroline Valldecabres** - *Societe Generale* - Analyst

Okay. Thanks a lot.

**Ulf Wiinberg** - *H Lundbeck A/S* - CEO

So with that if there are no further questions ---

**Operator**

There are no further questions, sir. Thank you.

**Ulf Wiinberg** - *H Lundbeck A/S* - CEO

On behalf of Lundbeck, thanks everyone for calling in and for the level of interest. And we are ready to take individual calls and we will also meet many of you on the road show, both here in London and in Copenhagen. So, again, we look forward to continue to communicate with you. Thank you very much.

**Operator**

Thank you. That does conclude your conference for today. Thank you all for participating, and you may now disconnect.

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