

# FINAL TRANSCRIPT

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**LUN.CO - Q3 2011 H Lundbeck A/S Earnings Conference Call**

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**Richard Parkes**

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**Martin Parkhoi**

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## PRESENTATION

**Operator**

Ladies and gentlemen, thank you for standing by, and welcome to the Q3 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, November 9, 2011. And I would now like to hand over to your speaker today, Mr. Ulf Wiinberg. Please go ahead, sir.

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

Thank you, operator. Good afternoon and welcome to the Lundbeck third-quarter conference call.

First, let me thank you for your flexibility. This is not going to be the permanent new time, but we just needed to start an hour earlier. And obviously I am most grateful to our friends in the US, who are on the call at 7am.

I will not read the Company disclaimer, because you are all well aware of that. And I will go to slide three.

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So let me just start saying we have had a great quarter. I think we are performing on all products and in all geographies. Overall, we have a 9% revenue growth over last year. We have 12% EBITDA, which is offset by extraordinary write-offs in R&D, resulting in a negative EBIT of minus 22%. It's very important for me to emphasize that we have very strong continued solid cash flow.

Third quarter also marked the beginning of a new era for Lundbeck, in the sense that we are now starting the phase with the many new product launches. So we launched Lexapro in Japan in August, and initial sales are okay but it's mostly stock-ins. So it's too early to say, but we remain very upbeat and confident that this will be a successful launch.

We have -- we are in the launch process of Sycrest. We started launching in the spring. And here in third quarter we have had two very important price approvals in Spain and Italy, where we have managed to achieve our targeted prices. We also had Onfi approved in the US, enabling us to launch Onfi in the beginning of next year. And the label on Onfi was in line with what we had hoped it to be, so we have high expectations for Onfi in the US.

In addition, we have submitted Treanda. You may remember that we did a deal in the beginning of the year with Cephalon, where we secured rights to their products in Canada and Latin America. And one of the key products is Treanda, which we have now submitted. We have also started to build up our oncology organization in Canada, so that at the time of approval we will be fully competitive in the marketplace.

We have also done an equity investment in the British biotech company Proximagen. And this gives us first rights of refusal to some of their key early stage CNS assets. And it's a way for us to get access to potentially very, very interesting compounds, and also to manage with flexibility in view of the dynamics of products coming into Lundbeck's research and our aspiration of holding a relatively even high R&D spend.

Next slide, please. So, over the last few years we have worked with preparing ourselves for a life without Lexapro. We have done decisions now. We have done a number of deals and other things. And on this slide you can see the margin improvements that we have had if you excluded Lexapro already in 2008. Clearly, what we see now, the 11% we have after nine months, is obviously not something that we are satisfied with or target, but this is the journey we are on as we are preparing the Company to live without Lexapro.

Next slide, please. So we are now, as I mentioned, entering a new product launch era. And obviously our success in launching new products will determine our ability to secure strong long-term growth. On this slide we have listed the key initiatives right now.

So obviously Sycrest and Saphris launches are very, very important for us. We have launched in Denmark, Germany and Malaysia. I highlight the price approval in Italy and Spain, but we have also secured price in Australia and the UK and more countries. And we are also hoping to have full commercial launch in France and Canada during the next six months. So obviously launch preparation and price negotiations are going as planned, or maybe slightly better.

The Lexapro launch in Japan took place in August, and we are very excited about this project. And as soon as we have good in-market sales data and prescription trends, we will share them with you.

We have also reorganized our business in China and the relationship we have with Xian-Janssen. And the result of this is obviously a much stronger Lundbeck and a much more committed effort from Xian-Janssen in terms of helping to drive Lexapro towards market leadership. So currently we have about 200 reps detailing the products, and we are accounting for a third of that effort.

The Onfi launch will take place in January 2012. Treanda is expected to be launched by end of 2012. And obviously the other key Cephalon products have been filed in Latin America. Nalmefene filings are progressing according to plan, and we expect to file by year-end or before year-end, and we hope to have approval at the end of 2012.



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So, obviously a lot of very exciting new product efforts, and also efforts to drive business outside Europe in international markets and in the US.

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

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**Anders Gersel Pedersen** - *H Lundbeck A/S - EVP, R&D*

Hello, everybody. I'll just briefly comment on the mid- to late-stage pipeline that's in front of you. Obviously, as I will speak to on the next slide, it is a pleasure that a project has graduated from this with the approval of Onfi, and also with the launch of Lexapro in Japan.

We have nice progress on the other products in Phase III, both with respect to 21004 in terms of enrolment of patients and finalization of studies according to the plan. We also have finalized the writing part of our Nalmefene dossier in technical format, so that we can be on track for the filing with -- in the EU later this year. Also, studies related to Zicronapine are progressing as planned. And both IV Carbamazepine and Desmoteplase are also on track for that.

We will have results on the Lu AE58054 for Alzheimer's disease some time next year, in the first half. And we will look forward to reporting to you on that.

If you turn to the next slide, seven, basically we had approval of Onfi by the FDA at the PDUFA date, which was a great pleasure for us to receive the approval immediately with the label according to our hopes. This is a drug that clearly meets the needs of some very sick children with Lennox-Gastaut, a fairly uncommon epilepsy form, which have dramatic drop seizures as part of their clinical picture, which leads to a lot of damages for these children, both socially but also mentally. And to have a drug available that can prevent these seizures is obviously a great pleasure for us. And the results and getting the approval on a single pivotal study with very significant effect sizes obviously is a great pleasure.

With that, we expect to launch the product in the beginning of next year, and are in the process of recruiting sales people into the organization. And we expect to have sales that will have the possibility of reaching around DKK1b.

As Ulf mentioned, on page eight, we also entered a research agreement in the earlier stage of the pipeline with Proximagen, where we got access to a set of products that we think are of interest for us if they meet certain milestones. We have made the entrance in the form of an equity investment in the company, and with a collaboration with them in terms of advancing their late research projects for further decision making on that.

With that, I will pass over to Anders Gotzsche, who will give you more details on our figures.

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**Anders Gotzsche** - *H Lundbeck A/S - CFO*

Thank you, Anders. And now we are at page nine, and overall we are very pleased with the revenue growth for the third quarter. We have been able to maintain the solid momentum from previous quarter. And if you exclude Lexapro, which soon will be the business going forward, we saw a growth of actually 14% for the quarter. So the reported growth was 10% and 8% in constant exchange rate, but it is important to emphasize that it was 14% without Lexapro.

And basically, when you see this slide, you can also see that we have had a satisfactory growth for actually all products and all -- in all markets. Cipralelex showed a growth of 2% in constant exchange rates, and that was driven by solid growth in several markets, both in Europe and international markets. Of course we have seen negative growth in countries like Spain, Portugal and of course the situation in Germany, where we see generic competition and have faced healthcare reforms in some of these countries impact negatively for Cipralelex.

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When looking at 2011 as a whole, we expect growth for Cipralex will be flat or low single digit, and that is of course due to the mentioned healthcare reforms and generics. A positive upside this year, and especially in the years going forward, will be the launch of Lexapro. However, it will only have marginal effect in 2011.

Please also bear in mind that in the third quarter we received the launch milestone from Mochida of around DKK200m, which is booked in the line item other revenue.

Please flip to the next slide, slide 10. And I think it's important also to say that we have actually been able to translate the sales growth into a nice development in our EBITDA, which is increasing with 12% to nearly DKK1.3b. And of course, if you looked -- or if you see the difference between the EBIT line and the EBITDA line, it's of course the ongoing amortization of the product rights for the US and then the write-off of -- which was linked to the R&D costs. So, this EBIT is for us fully expected and we are very pleased with the strong EBITDA and the cash contribution from that.

If you look into the cost development, we think that the quarter has been very satisfying also. And the fully controlled increase in SG&A cost and cost of sales are the result of the launch for -- of Sycrest and the increased sales of the in-license products.

For the full year, you should still expect that the SG&A percentage will increase with approximately 1 percentage point compared to 2010, and there's nothing new compared to what we have said in earlier quarters. The R&D percentage, you should still expect that to be approximately 20% to 21%. And that is of course due to the additional write-off which was carried out during the third quarter.

Please flip to the next slide, which is page 11. And as you can see in this slide, we have had a very strong cash contribution in spite of investment in product launches. So the third quarter we had a positive inflow of DKK1.3b and we ended the quarter with a net cash position of DKK2.8b, leaving on the balance sheet approximately DKK4.7b in cash.

Please turn to the next slide. As mentioned previously, we are pleased with our performance, and we therefore also feel very comfortable in delivering on our guidance for 2011. And again, we expect both revenue and EBITDA to be in the upper end of the guidance range, so it will be much closer to DKK15.8b and DKK4.6m than in the lower end.

And of course we will continue also during the coming quarter and in 2012 to maximize our business and secure to invest for long-term growth. So it will be very important and also take some resources to do that.

The revenue growth for 2011 is expected to be, as I said, in the high end and it will be more than 6%, and that is based on the current exchange rate situation. The growth for 2011 would have been approximately 5 percentage points higher if we had excluded the expected impact from healthcare reforms, the German situation and increased generic pressure in some markets and price cuts.

Please -- the EBITDA, sorry, EBITDA is expected to show a modest growth, and that is of course due to the -- as I mentioned before, we will be in the range between DKK3.3b to DKK3.6b, and that is of course due to the write-off.

And that ends the presentation of the financial part, and then we will go for the Q&A section. Operator, we are ready to take questions from the audience.

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## QUESTIONS AND ANSWERS

### Operator

Thank you. (Operator Instructions). Your first question today comes from the line of Michael Novod. Please ask your question.

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

Hello. It's Michael Novod from Nordea Markets. I have a few questions. First of all, there is no doubt that Canada and France are doing extremely well currently. How long do you foresee this to continue?

And also, in that respect, what kind of view do you have on healthcare reforms in Europe for the coming years, especially, for example, a reform most likely being announced in France over the coming days or weeks?

And then, secondly, leading to the 2012 numbers, how confident do you feel on your own, say, budgets compared to how consensus is placed right now? You have a flow guidance of DKK2b on EBIT; consensus is close to DKK3b. How do you feel about that?

And lastly, Ulf, you have been quoted in the Danish press for saying that you want to double US revenues. Is that from the current DKK3.5b on an annual basis, or how should we interpret that?

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

Michael, thanks for your questions. I think Canada and France, we have two very, very strong affiliates in both of those markets. And clearly we expect to continue to gain market shares in both Canada and France, and we expect that to continue through '12 and '13 as well.

With respect to healthcare reforms, we have lived with the uncertainties of healthcare reform since the financial crisis in 2008, and we have taken significant hits during that time period. And I don't foresee this to change. I expect it to continue in a similar way. So, consequently, when we build our plans for the year, then we have to set up contingencies for unknown healthcare reforms. And I expect us to continue to manage the business the same way in the years to come as we have done in the past few years.

With respect to specifics, what's going to happen in France, your guess is as good as mine. So I'll stay away from that.

Just on the US, I think my short-term objective is to double the Lundbeck affiliate business, but obviously to double including Lexapro would be a very long-term stretch goal. But I can dream about that. But my first priority is for doubling the existing affiliate business for now. But I'll take the challenge on the long term. Thanks.

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

And then, back to the consensus and the expectation for 2012, of course we will give some guidance when we're announcing the annual result in the beginning of February. But of course, when you make the math for 2012, it is important to realize that we are losing three quarters of Lexapro revenue next year. And I think it is maybe a little optimistic to expect that we'll deliver an EBIT next year that will be close to the level that we are delivering this year. I think taking DKK2b out of Lexapro next year, I think it's maybe a little optimistic.

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

Okay. Thank you for the clarification.

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

Next question, please.

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**Operator**

Thank you. Your next question comes from the line of Richard Parkes. Please ask your question.

**Richard Parkes** - *Deutsche Bank - Analyst*

Yes. I've got a few questions, actually. Firstly, on Sabril, it looks like quarterly sales have been effectively flat on a quarter-on-quarter basis this year, and you talk about the growth coming from dosing, etc. I'm just wondering when or if you might be able to see a return to patient growth, and what efforts you're making to make any changes there.

And then, secondly, on Onfi, in terms of your aspiration for DKK1b in peak sales, I'm just wondering what's factored into that in terms of on versus off label use.

And then, thirdly, on Treanda in Canada, I'm just wondering how big an opportunity you think that could be.

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

Okay, Richard. I think on Sabril, the question you are asking, we are asking our team in the US, and have been since the time of launch. And I don't think I'm in a position to say today that we have had a significant change in trend with respect to Sabril. This is -- so that's a slow process in that sense. And I will also say that the dose -- higher dosing and higher compliance as a growth driver of course is encouraging, but in one way limits the potential, so obviously new patients is the key growth driver. But I cannot report a trend change in (technical difficulty) today.

**Anders Gersel Pedersen** - *H Lundbeck A/S - EVP, R&D*

And it's also important to say that of course we have two segments with Sabril; we have IS and we have rCPS. And definitely, as we have said earlier, that our penetration curve in the IS segment is very good and we have gained the market share we expected, and it has been more difficult in rCPS. And as Ulf just alluded to, the compliance rate has been very high for Sabril, and that is also a signal that the product is working very well. But we have a lot of action to do to try to get more patients into the rCPS segment.

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

With respect to Onfi, we had very, very positive Phase III data that drove the fast on-time approval and also secured a positive label on the product. The DKK1b actually assumes that we will capture majority of the LGS patients. We do not do a forecast that includes off label sales, and we don't do marketing plans or any activities to create off label sales.

And sorry, you had a third question (multiple speakers).

**Richard Parkes** - *Deutsche Bank - Analyst*

It was Treanda in Canada. I'm just wondering what kind of opportunity that would be.

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

I'm not ready to guide on Treanda, but the old rule of thumb is that if you use the 10% forecast compared to the US you are not far off. But I am not in a position to give you a specific forecast for the opportunity (technical difficulty), other than that I want

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to say that for Canada this is a major, major opportunity, and obviously we are doing everything to ensure that we can get a timely approval and be ready to launch it in a proficient way immediately at the time of launch.

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**Richard Parkes** - *Deutsche Bank - Analyst*

Can I just ask one follow-up on 004? I'm just wondering when you'll make the decision on disclosing that data. Are you going to wait for all of the studies to be in-house before you make an announcement, or could we see something sooner?

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

We expect to have data on Q2 when we are in -- as soon as we are in a position to say whether we can file or whether we cannot file, we will communicate it to the market. But we will not communicate ahead of having sufficient data to make that judgment.

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**Richard Parkes** - *Deutsche Bank - Analyst*

Okay. Great. Thank you.

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

And you should expect to have it by Q2. Thanks, Richard.

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**Operator**

Your next question comes from the line of Martin Parkhoi. Please ask your question.

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

Yes. Martin Parkhoi from Danske Bank. A couple of questions. Firstly, with respect to your chart on the development in the EBIT margin without the income from Lexapro, now I think it's a little bit unfair comparison that you compare with the nine months of 2011, given that Q4 normally are quite a weak quarter and your guidance for the full year certainly also suggests that Q4 2011 would be a weak quarter. So what would you expect to be the margin for your non-Lexapro business for the full year of 2011, compared to the 11% for the first nine months?

And then secondly, with respect to Nalmefene, you have for a long time discussed that you maybe would have a partner on Nalmefene. Now we are getting closer and closer, and you expect a launch maybe in 12 months' time. When have you set a deadline for such a decision and what are you expecting right now? Will we have one partner or will we have local partners, as you to some extent have today also with some of your products?

And then, with the Azilect you have historically given some indications of peak sales for this product. Could you update us on this also without now Germany?

And I have a fourth and final question. If we look at -- you said there was some kind of stocking impact from Lexapro in Japan in Q3, which I guess are included in your international markets. How much is that?



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

Okay. Let me start with commenting on the partnership in Nalmefene. We have said all along that we intend to submit the file, engage in labeling discussions with the authorities. And when we have a feel for that, we will decide on the partner strategy and whether we bring in a Pan European partner, do local partners or no partners. So that's very much dependent on how the labeling discussion comes out. So based on that, I think we are continuing according with the plan with respect to that.

We have had and continue to have various partnership discussions with different companies. But we have also said to them that we will not conclude on anything until we know where we stand, or have a feel for where we stand with respect to labeling with the authorities.

With Azilect, we are holding on to DKK2b. And on Lexapro Japan, we are not in a position to say how much is pipeline filling, so that -- we cannot. So it will be a while before you know exactly what's going on in market.

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**Anders Gotzsche** - H Lundbeck A/S - CFO

But Martin, it is really immaterial, the Japanese revenue figure so far what has been included. Please remember that we launched August 22, so it's an immaterial figure that impact international markets.

And then, with respect to the margin going forward without Lexapro, I think the best year to actually look into is 2013, because that's the first year without any Lexapro sales in the US. And you could use the floor guidance as actually the benchmark for the margins, because we will deliver more than DKK2b, and we have said DKK14b in revenue. So the aim is of course to be at a level more than 15% in margin, going to -- if you try to project that for 2013.

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**Martin Parkhoi** - Danske Bank - Analyst

But that really didn't answer my question, because now you show a nice chart showing that your margin has increased substantially, with 4 percentage points from 2010 to 2011. But if I took the first nine months of 2010, I am almost sure that I would have a margin which was higher than the 7%. So I think that it's a little bit misleading to compare nine months with a full year, since you normally have a quite weak fourth quarter.

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

I don't -- we don't have that. We'll do that chart for you and provide it to you but --

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**Anders Gotzsche** - H Lundbeck A/S - CFO

But in some respects -- in some sense you are right, Martin, but it will -- you can take -- we have tried to illustrate what is the momentum in the business, and that we are going for having this 15% or more margin in 2013. And if you look for the full year this year, of course the margin will not be 11% without Lexapro in the US, because you can take the guide -- we have guided for EBIT range, and then you know that -- what the Lexapro revenue will be more or less, and then you can deduct that and then of course it will be a little less. Okay?

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**Martin Parkhoi** - Danske Bank - Analyst

Okay. Thank you.

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

Thank you. Next question, please.

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**Operator**

Your next question comes from the line of Henrik Simonsen. Please ask your question.

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**Henrik Simonsen** - SEB Enskilda - Analyst

Yes. Henrik Simonsen, SEB Enskilda. A couple of questions, housekeeping mostly. I wondered if you could disclose whether you are still selling bulk product to Forest, since you have about DKK520m in prepayments as of September 30. I'm just wondering how long you expect to be delivering bulk product to Forest, or should we basically assume that the prepayment goes through the P&L in fourth and first quarter?

Secondly, would you be willing to disclose your Sycrest sales?

And then, just lastly, what would you expect as the underlying tax rate, excluding this write-down for the year? And possibly would there be any significant changes to the tax rate going into 2012?

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

Henrik, this is Ulf. We are not in a position to disclose the Sycrest sales. It's small yet. We are still focusing on getting the prices in the big countries. And obviously, when we did the deal we said this will be a slow build, where the product will contribute materially and meaningfully for us in around maybe '14, '15 it will really contribute. But -- so right now we don't have -- we are not in a position to report. But obviously we are very excited about the upcoming product launches over the next six months, as we alluded to in the presentation.

And on the other two questions, I'll hand over to Anders Gotzsche.

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**Anders Gotzsche** - H Lundbeck A/S - CFO

And I can add with Sycrest we definitely hope that we can report some figures during 2012, because then we are successful with our launch.

And for the bulk -- in respect of the bulk, it delivers -- we have -- the bulk deliveries have stopped now. So there will be no more bulk deliveries for Forest. And of course we will by the end of the year have eliminated a substantial part of the prepayment, and then we will of course have some sale also next year, but (multiple speakers).

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**Henrik Simonsen** - SEB Enskilda - Analyst

But did you have deliveries in October? Can I just ask that?

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**Anders Gotzsche** - H Lundbeck A/S - CFO

The last delivery was a very, very small delivery that we shipped in the beginning of October.

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

Okay.

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

It was less than 1 tonne, so it's less.

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

Yes, okay.

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

Financial impact is less than DKK25m. I don't have the exact figure, but that's (multiple speakers).

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

No, no, that's fine. Yes.

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

And then the tax rate, the structured tax rate what you should also expect in the years to come is 26% to 28%.

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

But you would expect it to gradually increase, or is that just moving in that range up and down?

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

You should expect it to be pretty much at the same level during the period.

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

Okay. Great. Thanks a lot.

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

Next question, please.

**Operator**

Your next question comes from the line of Peter Hugrefte. Please ask your question.

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**Peter Hugreffe** - ABG Sundal Collier - Analyst

Yes. Hi. It's Peter Hugreffe. Thank you very much for taking my questions. Firstly, just to understand in terms of your net cash position, now you are standing at DKK2.7b. What is the sustainable level? I can see now you've started buying bonds. What is your goal in terms of cash position going forward?

Secondly, could you just give us the indication what has the cost been in terms of these patent litigations you have incurred in Q3? And is this a one-off, or is this a level where you are going to continue?

And then finally, in terms of Cipralex, you've lost approximately 50% of the revenues in Spain and Germany. What is the pace for the continued loss in these areas going forward? Thank you.

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

Let me start with your question three. I think that in view of the economic situation in Europe, I expect the genericization trend to be faster than what we have seen in other comparable models when you look at it historically. Exactly how fast I cannot say, but I think there is a lot of efforts being done to ensure that generics are used faster and earlier than what we have seen historically and -- so we are expecting a faster erosion rate than what you would get if you go to IMS and ask for comparable molecules over the last two years.

The other two questions I'd like to hand over to Anders Gotzsche.

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**Anders Gotzsche** - H Lundbeck A/S - CFO

The cash position now is DKK4.7b, not the net cash but the cash position. And it will be a little less by the end of Q4, due to tax payments in Q4. So we still expect to have a cash position around DKK4.2b, DKK4.3b by the end of the year. We think it's good to have a very solid balance sheet, also going into 2012 and '13. As I have said before, if we go three years down the road and we then have accumulated a pile of cash, then of course we need to rethink if we should pay back some more dividend. But for the time being, we think it's good to have the opportunity for any strategic initiatives we might take in the future to have this cash.

And then the reason for mentioning the cost for the different court cases is just to know it has been a little more this quarter. We do not foresee that will have an increasing expense for different defense of our IP rights. It has been more -- it has been -- we have had more expenses than Q3, but don't expect it to increase going forward.

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**Peter Hugreffe** - ABG Sundal Collier - Analyst

Okay. Thank you.

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

Next question, please.

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**Operator**

Your next question comes from the line of Carsten Madsen. Please ask your question.



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

Thank you. Carsten from Carnegie here. Thank you for taking my questions. Just a couple of questions to Anders and Anders, I guess. On R&D costs next year, what should we expect here? Which type of trials will you actually be running? And you have out-licensed a lot of your work to [Quintaz]; what will this mean for your total cost next year?

And then, on Nalmefene, I am a little bit uncertain about whether you can make a claim that says that you have a statistical reduction in the number of heavy drinking days or not, and whether this is important or not. Could you please try to elaborate a little bit on this?

And finally, we have previously talked on these calls about Lexapro in Q4, and as you said that we should expect revenues to drop by DKK150m from Q3 to Q4. Is that still the case? Thanks.

**Anders Gersel Pedersen** - *H Lundbeck A/S - EVP, R&D*

This is Anders. First, in terms of your expectations or our expectation for the forward going expense in R&D, we plan that that will be lower for the next year than it is this year. We do have -- as you allude to, we do have quite a bit of contract work going on with outside vendors also, and Quintaz is one of them. We have had that for quite a while. We have a model on that.

We do have still significant payments to be made on the -- both the 21 program -- 21004 program. We have money to be paid on Desmoteplase. And we will also have costs associated with the Zicronapine and AE58054 studies that are still ongoing out there, just as we need to consider investments in studies on 24530, and then potential post-approval commitments and studies that could be linked to what we think is appropriate to do for Nalmefene in the 2012.

With respect to the effects that we see, we are very pleased with the effect sizes that we see on Nalmefene, both in terms of total alcohol consumption and reduction in heavy drinking days, and the shifts that we see on the drinking risk levels that we have gotten guidance from during the scientific advice discussions that we had with the European regulators some years ago. So, we are seeing effect sizes that we are happy with. We also have statistical differences that basically are driving our confidence in the filing that we are submitting.

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

But which statistical significant claim can you make here?

**Anders Gersel Pedersen** - *H Lundbeck A/S - EVP, R&D*

What do you mean by which claims?

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

Yes, what will be the main claim for Nalmefene? Will it be reduction in heavy drinking days, total drinking days, or what do you expect the profile to look like?

**Anders Gersel Pedersen** - *H Lundbeck A/S - EVP, R&D*

We will not position the product at this stage, but we have -- the claims that we are able to make are clearly linked to both the reduction in heavy drinking days, total alcohol consumption on patients in the studies, yes.

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

Okay. And then on Lexapro in Q4?

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

Lexapro in Q4, I might have been a little conservative saying it will decline by DKK150m. I think it will be a little less. It will be a slight decline, maybe less than DKK100m in decline.

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

Okay, okay. Thank you.

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

Any other questions?

**Operator**

Your next question comes from the line of Frank Andersen. Please ask your question.

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

Yes. It's Frank from Jyske. I just have one question. You are stating that you are comfortable in delivering in your high end of your guidance for 2011. And even though you will keep your broad range on both revenue and EBIT, we have only like six or seven weeks left of the year. Why do you still have to keep the guidance with the broad interval? What do we have to fear?

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

Let me say yes, of course we would have preferred to upgrade at this call if we were in a position to do so, but we still have many moving parts in our P&L and therefore we are not in a position to upgrade today.

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

Okay. So -- but you cannot be specific on what kind of things do we have to fear, even that you have to -- you still have DKK5b in your revenue and only like six or seven weeks left.

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

But if you compare, Frank, if you compare to last year, we -- the Q4 is normally a weaker quarter. And we are also saying that this will be in the high end, as we also indicated at Q2. So, if you look into revenue and EBITDA, it will be in the high end. And then you have the additional write-offs, which actually leave the guidance for EBIT between DKK3.3b to DKK3.6b, because you will have amortization and depreciation of approximately DKK1.3b. So that is important to emphasize.

So we still have to deliver a good Q4 to get into the guidance level, so it's not that everything will fall apart. And then also we have that Lexapro will not be in the same level. The Lexapro revenue from US will be less than Q1 and Q2.

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

Okay. Thank you very much.

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

Next question, please.

**Operator**

Your next question comes from the line of Brigitte de Lima. Please ask your question.

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

Good afternoon. I'd like to ask a few questions, please. The first one is on Xenazine, similar to the discussion we had about Sabril. Have the sales already plateaued? I didn't really see much of an increase versus previous quarter. So was there an initial bonus of patients that is already in therapy, or should we look at the third quarter more as seasonality because it was a summer month, i.e. do you expect an uptick again in Q4?

And then the second question is on SG&A. Given where SG&A is going and all the launch costs that you are incurring, unless I assume that SG&A drops pretty dramatically in 2012, would it be fair to assume that the SG&A ratio as a percentage of sales is closer to the 40% for 2012, i.e. rather the high end of the range that you've been guiding to?

And then just briefly on Azilect, I was just curious what the rationale was behind renegotiating the deal with Teva. And should we expect any impact? That's all. Thank you.

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

Okay. This is Ulf. Just to comment on Xenazine, in this quarter we only have sales in the US. In the previous quarter, we had significant international sales as well that we had. So de facto what you are seeing is a pretty good increase in the US between Q3 and Q2. And perhaps Anders has the specifics on that and can come back to this.

I think your assumptions on the SG&A is correct.

And I think on Azilect, we have reached an agreement with Teva that it's better for let one company promote the product. The agreement is profit neutral for us. Obviously we are not giving up anything in doing this. And so you shouldn't assume any changes to -- of significance because Teva takes back the product in Germany.

**Anders Gotzsche** - *H Lundbeck A/S - CFO*

The only thing you need to realize is that next year of course the growth for Azilect will be a little less, not from an EBIT perspective but from a revenue perspective.

And then it is important also to say that the SG&A margin will compare to the floor guidance. We expect it for 2012 to be in the high end, so it will be closer to 40% than the 37%.

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And Xenazine, we expect also in Q4 to regain some of the momentum there, swings between the quarters. So it's not that we have given up from a growth perspective. And we think that Xenazine is dragging against the peak sales numbers that we indicated when we acquired the business. So we still believe between \$200m and \$300m is the right peak sales number.

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

Helpful. Thank you very much.

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

So thank you very much for calling in and for following us. And obviously I think we have individual meetings here coming up the next few days, so we look forward to meeting you then and obviously take your questions on the phone offline. Thank you again for calling in. Goodbye.

**Operator**

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

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