

16. februar 2015

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H. Lundbeck A/S

Transcript : Full Year 2014 Financial Results :

Håkan Björklund

Thank you very much and welcome everybody to this teleconference. I assume that you have all made yourself aware of our company disclaimer, I am not going to read it to you.

I think it is fair to say that we are pleased with the performance in 2014 which I believe has positioned us well for 2015 and of course beyond. What is key for us is the significant acceleration that we have seen of our core products, our new products. We have seen good development in Brintellix where we continuously take market share in the branded segment, we have done well with Abilify Maintena, both in Europe and in the United States. On top of that the QUALIFY study has shown the product to be superior compared to our key competitor. Selincro was a little bit tough in the beginning of the year but we saw a very positive uptake in France which is probably the key market for Selincro, we launched it in the fourth quarter and we are very pleased with the development but it is still early days for Selincro. Northera recently launched, Onfi doing incredibly well. While we are spending significant resources on launching our new products we are at the same time doing significant R&D investments, both in our existing products like Brintellix where we have spent a lot of resources on looking at cognitive dysfunction in depression and have seen some really exciting data, and I think that Anders Gersel will come back to that. We are also now looking at the potential use of Brintellix in ADHD. Brexpiprazole, we submitted our application to the FDA in the fall for two indications, for schizophrenia and MDD and we have a PDUFA date in July.

So even though we saw a decline, both in our top line and in our bottom line, we are still pleased with the performance in 2014. It is clearly in line with our expectations, and especially when it comes to core EBIT we are actually doing better than we had forecasted. 2015 will be a tough year, we have said that all through and it will probably be a tough year.

If you look at Lundbeck, I think the biggest achievement of the last couple of years is the change from a one-product company to a large extent dependent on Europe to a multi-product company with a healthier split of our sales between Europe and the rest of the world. We have seen a strong development in the US where we saw an increase in local currency with 43 %. That is very positive. So the US market will be very important for us going forward. As you know, the European market is more problematic these days, especially when it comes to pricing and reimbursement. Also the rest of the world, and especially emerging markets have done well, and among the emerging markets I would like to point to China which of course long term is a really, really important market for us. I am also very happy that we have a more balanced product portfolio than we used to have. That is also a good thing for the future.

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The year that we have ahead of us, 2015, will be an extremely exciting year. We expect to launch our new products in more than 50 countries, so 50 launches all in all throughout the world, and you can see on this slide here where we are launching the various products and it goes without saying that this will be both challenging and unfortunately also relatively expensive and that is why we have also guided 2015 to be a year where our core EBIT will be around zero. And I think it is very important that we do not refrain from doing the product investments that need to be done to secure the long-term future of this company.

Looking at Brintellix, we have seen that our share of the branded market is increasing month-by-month, week-by-week and I am very pleased with that, we are outperforming Viibryd and Fetzima and I think the key for us going forward is of course to be able to use the cognitive data in the various markets and we have a meeting with the FDA during the spring and hopefully that will make us closer to being able to use these very, very strong data.

0.05.03

Abilify Maintena is off to a good start, not only in Europe but also in the US, we are very happy with the performance, I mentioned the QUALIFY study that shows that we are superior to our competition, we have also recently had it approved in the US for acute schizophrenia, we are coming out with a dual-chamber syringe, we are looking at a different way of administering the drug in the Deltoid which we think especially in the US will be important. So Abilify Maintena is doing well and we are very excited about the product.

Selincro, I think I mentioned earlier that in the beginning of the year we were struggling a little bit, we always knew that the key market here would be France and we launched the product in the fourth quarter and as you can see from this slide we also saw a dramatic uptake in our sales of Selincro. The first half of 2015 will be key for Selincro, both in France, we need to see the positive development continue, but we also hope to see an equally positive development in Spain and some other key markets where we are launching the product. As you probably remember, this is primarily a European product, we will not launch Selincro in the US.

If we go to the US, our neurology products are up 44 % in the fourth quarter, so an incredibly strong performance on all our products, of Onfi, of Xenazine, Sabril and Northera was launched just before Christmas. We have seen a lot of interest from physicians and the feedback that we have from the patients so far is also very positive, but

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we should remember it is early days with Northera and I think we will know much more towards the summer. But all in all very, very strong neurology franchise in the US which is of course also the basis for us being able to launch our psychiatry products in the US market.

With that I am going to leave it to Anders Götzsche to go through the financials.

0.07.24

Anders Götzsche

Thank you, Håkan, and please turn to slide 10. As Håkan mentioned in his remarks, we only saw a modest decline in revenue for the full year and that is of course due to the uptake in the new products so we are actually very pleased with seeing this modest decline, also taking into account the loss of exclusivity for Cipralext in Europe and Canada. And as you can see, our new products portfolio is on track, we had total growth for the year of 44 % but we are actually also very pleased with the new products uptake in the quarter, which was higher, 54 %, and in general the fourth quarter was very good when we look into the new products. And then this was the first quarter where we had more than DKK 1 billion in sales in the US and of course we expect to see more sales in the US in 2015 and accelerate the growth quarter by quarter. So all in all, from a revenue point of view, we think it was a very satisfying progression in 2014 and there was basically no surprise in the quarter to earnings, we delivered on the full-year earnings and of course the quarter was impacted by the write-off of Desmoteplase and also the additional amortization related to Northera and Abilify Maintena which was also the cause of the increase in the cost line. R&D declined to 16 % of the revenue in the quarter and that is only due to quarterly fluctuations. And as you can see, then of course, as we have also guided previously, the SG&A margin is increasing and also increased in the quarter due to the increased launch activity, especially in the US but also now in international markets with Brintellix and Abilify Maintena in Europe. Cash flow, we actually achieved a better cash position, net cash position of DKK 300 million was higher than we have guided during the year so that was very encouraging and we had an operating cash flow of around DKK 500 million for the quarter.

0.09.45

Please turn to slide 11. And here you can see that 2015 will be an investment year and the outlook we have provided today is in line with the soft guidance we gave in November and this is based on the fact that we expect to launch Brintellix in the US and the PDUFA date is in July and here we will get the answer back from the FDA about the potential launch of Brepiprazole in the US. And then we have also of course included the cost for launching

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in more than 50 countries in 2015 in multiple geographies and that is of course increasing both the sales and the promotion costs and that is also the reason that you should expect that for 2015 that, our SG&A margin will go beyond 50 % and you should also expect that our R&D ratio will be around 20 % due to the investment in a new product portfolio and also the support for the already launched products in the market. You should expect a tax around zero for 2015 and financially you should expect a net loss around DKK 150-200 million. So all in all we think it has been an excellent 2014, we have concluded we have met our financial guidance and then we definitely hope that from a financial perspective 2015 will be a trough year and that we can regain growth momentum in 2016 but what is really important is of course the focus on the new products uptake. And with that I will hand over to Anders Gersel Pedersen who will walk us through the R&D pipeline.

0.11.47

Anders Gersel Pedersen

Thank you, Anders. And on slide number 12 I will first draw your attention to some of the key achievements in the already launched or late-stage pipeline products in the sense that for 2014 we both had some very strong data coming out on the cognitive capabilities in terms of improving cognitive functioning with Brintellix in depressed patients and we also initiated a proof-of-concept study addressing cognition and ADHD. For Abilify Maintena we had some very strong data on quality of life in a head-to-head study comparing Abilify Maintena to Invega Sustenna and finally we also got approval of acute schizophrenia indication in the US. For Brexpiprazole we had a robust set of studies in both schizophrenia and depression leading towards together with Otsuka to decide on filing already mid 2014 and the process with the FDA is on-going. What I would like to draw your attention to on the right-hand side of the slide is that even if we have met these achievements, the basis of some of the very significant investments in R&D are linked to these products and other parts of the pipeline where you can see that we have a very large number of studies going on with large patient exposures actually already at this early stage in the quarter of 2015.

0.13.26

If we go to the next slide, the reason behind us moving into ADHD with Brintellix is basically driven by our pharmacological understanding of Brintellix' impact on cognitive functioning and the fact that we in pre-clinical experimental situations can see that there is some effect, both on the executive functioning and also leading through that to some of the improvement expected in ADHD patients. We will know more about that when the study is completed mid 2016 and then potentially be able to branch into both childhood and adult ADHD indications moving forward.

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If we go to the next slide, you will see that just reiterating the filing of Brexpiprazole NDA which is driven by the unique profile of this molecule in terms of a mixed serotonin/dopamine activate modulator which is a design molecule and the design molecule in terms of where we expect effect and importantly diminished side effect from the pharmacologic study is exactly what we have found in the clinical studies that have been presented at various conferences so far. We do see significant impact on core symptoms, both of depression and schizophrenia, while preserving a good side effect profile as planned from the design of the molecule and that leads to a product that has a more predictable profile when its physician is having to decide on changing or adding on therapy to a patient without knowing to what extent will that individual be impaired by some of the side effects that we know all the other molecules have. So this is a good effect size with a good predictable tolerability and safety profile. And with that I will hand over to Håkan for a summary.

0.15.24

Håkan Björklund

Thank you very much, Anders, and that will be a very short summary before we go over to Q&A. As I think you have understood and heard, what is very important for us is our new core products and we have seen significant positive development in 2014. We are confident that that will continue in 2015 and as I mentioned earlier, we expect to do around 50 launches this year of various products in various countries, so an extremely busy year for Lundbeck. This of course means that our diversification will continue and I mean then diversification both in terms of products going from being a more or less one-product company to a multi-product company but also a geographical diversification where Europe used to be the great majority of our sales, it will relatively be smaller, the United States will be bigger and you heard from Anders Götzsche that we had more than DKK 1 billion in turnover in the US in the fourth quarter and we are very, very pleased with the development in the US and of course if you are in the CNS field, the US is the key market. Having said that, the emerging markets are also very important, we see an increased interest in our products also in emerging markets and again china of course long-term is absolutely key. So all in all we are confident that we are on the track to deliver sustainable long-term growth but we also realize that 2015 is challenging, is important and will very likely be our trough year. So with that we will open for Q&A's.

0.17.12

Operator

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Thank you. Ladies and gentlemen, if you have a question for the speakers, please press 0 and then 1 on your telephone keypad. I remind you, you have to press 0 and then 1. Our first question is coming from Mr. Peter Welford from Jefferies, please go ahead sir.

0.17.26

Q: Peter Welford, Jefferies

Hi, thanks for taking my questions, I have got a couple. Firstly, I guess just in terms of foreign exchange and impact on 2015, obviously positive tail wind you are going to have for the sales line but I wondered just with regard to costs if you could give us some sort of visibility on the currency breakdown but I guess put another way is the US a profitable region for you? Secondly, on Brintellix, curious as to your comment DKK 840 million in market sales in the US in 2014. Is that a run rate or is that the actual in-market sales number we should be using and if so I wonder if you could just rationalize the revenues that you are booking in the US? And then finally just on the new antipsychotic, 35700 I think it is, I wonder if you can give us any information on the mechanism of action or thinking behind that? Thank you.

0.18.26

A: Anders Götzsche

I can start. Effects. You know, in 2014 we were negatively impacted revenue-wise with around 2 percentage points and we will probably regain some of that in 2015 and that will be the impact. From an EBIT point of view we have had limited impact in 2014 and will also have limited impact in 2015. And yes, we are profitable in the US and we also expect to be profitable in 2015. And Brintellix, the split in the US is that we, from a revenue point of view, have a shared split with Takeda and we, ballpark figure, we book one third of the sale and Takeda books to thirds of the sale. And then you mentioned a gross figure and then you have to of course deduct gross-to-net discounts and also the royalties. So you can follow the, and it is the run rate you have seen in 2014? No, definitely not, we expect Brintellix to grow also in 2015 so we are not aiming for a run rate as we have seen in 2014. So what will be important for the US market is of course to see some of the additional marketing activities on-going in 2015 having an effect and that we see more prescriptions in the GP area that we get this kind of spill-over effect from the psychiatry field. That will be the important thing to watch for in the US in 2015. Did you have more questions, Peter?

0.20.26

Q: Peter Welford

No, that makes sense, so I guess the answer on the 840 is the 840 million in 2014 is a gross sales number.

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0.20.37

A: Anders Gersel Pedersen

And then you had a question about 35700. It is a molecule that has a D2/D3 balanced effect which is important in the sense it has some different targets than we have been accustomed to in most of the antipsychotics. It has, from a principle perspective we know that the balanced effect that we have seen earlier on with Zicronapine is one that we can see in this set of molecules here and that is also why we, from a pre-clinical perspective and phase 1-perspective, have been very determined in terms of exactly how we are going to use it, we know that it has a very long half life, better than the other one, and we also know that the dose level that we need to be at, where that is pretty sharply. And therefore we can move fairly quickly into potential phase 3-studies with this molecule very quickly with a product that has a unique receptor binding profile on the dopaminergic system and also be possible to administer orally on a weekly basis.

0.21.52

Q: Peter Welford

So this would be an oral once weekly?

A: Anders Gersel Pedersen

Yes.

Q: Peter Welford

Thank you.

0.22.03

Operator

Our next question is coming from Mr. Michael Novod from Nordea. Please go ahead, sir.

0.22.07

Q: Michael Novod, Nordea

Yeah hello it is Michael Novod from Nordea in Copenhagen. Just three questions. Maybe you could give us a bit of flavour to the say renewals in terms of Selincro. I know it is early

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days in France but do we actually see patients coming back, how much do you see in terms of rate of renewals would be interesting especially regarding this product. Secondly, maybe you could speak about potential competition, how you see the market for long-acting antipsychotics, we know that Alchemist is likely going to launch a look-alike to Abilify Maintena. Is that incorporated into your guidance for 2015? And then lastly, just a housekeeping question. You say on page 9 that you had DKK 42 million in sales of Northera in the first quarter, that would be Q4 you say DKK 10 million in the release. What is the right number? I don't know, maybe I am not looking in the right places but I just had a question to that.

0.23.10

A: Håkan Björklund

Okay, maybe I can start with the first two questions. When it comes to Selincro in France, it is very early days so I mean the return of patients, yes we have seen it, but it is of course limited just due to the fact that most people have not had the product for a very long time so I think it is too early to say how that has worked out but so far we have seen a lot of positive responses and there are a lot of doctors that have been prescribing the product. Your second question regarding potential new competitors to Abilify Maintena, we are of course very much aware of the Alchemist product and we have baked that into our expectations. However, I think it is very important to remember that this is not a pure generic, it is not that it can be substituted in the pharmacies so Alchemist needs to go out and create their own prescriptions for this product so you should by no means compare it to when we get generic competition for instance for Lexapro when there is an immediate impact, in this case it is going to be very different and one should not actually exclude that it might be good to have more people out there talking about the benefit of using the product long-term.

0.24.37

A: Anders Götzsche

With Northera the sales in Q4 was DKK 10 million and the sales in Q3 was DKK 14 or 15 million, I don't have that here, so I believe it is a typing error, I will check up on that and then revert to you, Michael.

0.24.56

Q: Michael Novod

Okay, so it is not 42 million in the fourth quarter?

A: No, definitely not.

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Q: Okay, thank you.

0.25.05

Operator

Our next question is coming from Mr. Terrance from Credit Suisse, please go ahead, sir.

0.25.12

Q: Terrance, Credit Suisse

Hi, thank you for taking my questions. Just returning to the Brintellix difference between gross and net, for the full year by my calculations it seems to be around 30 %, I was just wondering if you could comment on how much of this is rebate and are rebates an issue in this sector or this class and has that changed over time? And then just going to Brexpiprazole data, the ACMP, I noted earlier you didn't mention the cardio-metabolic side-effect profile and I was just wondering if there was any support for differentiation on that from the ACMP study read-outs? Thank you.

0.25.56

A: Anders Götzsche

For Brintellix we are not willing to give any overview of the discounts but it is, you know we are on par with other products in this field compared to the discounts and it is of course a mix due to what areas you are selling the product in, if it is private or in the public sector. And in the past we had limited, when Cipralex. When Cipralex was at its highest, we had less than 10 % of the prescription in Medicare and Medicaid.

0.26.35

A: Anders Gersel Pedersen

And with respect to the cardiovascular profile of Brexpiprazole then it is quite competitive, yes, there is in terms of metabolic profile there is no indication of any metabolic syndrome as such at all in the parameters, so it is very competitive on that. In terms of weight gain as an isolated phenomenon there is a very slight weight gain on the compound but not to any significant magnitude, but in terms of its defined metabolic profile then there is nothing in it.

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Q: Thank you.

A: Anders Götzsche

And just to add to Michael Novod's question around Northera, it is a typing error, the accumulated sales for 2014 is DKK 24 million. Next question please.

0.27.24

Operator

The next question is coming from Mr. Peter Hugrefe from SEB, please go ahead sir.

0.27.29

Q: Peter Hugrefe, SEB

Yeah hello, thank you very much for taking my questions. First of all, just maybe you could give us status on the hiring of a new CEO. Secondly, in terms of the FDA meeting with Brintellix, is this just like a discussion of data and deciding on whether you have the right end points or is this more like a pre-finding meeting? And then finally, could you give us some kind of status on what you expect in terms of Xenazine and Sabril and generic competition in 2015 and 2016? Thank you.

0.28.06

A: Håkan Björklund

Okay well, maybe I should start with the CEO search. We initiated the CEO search basically the same day that my predecessor left Lundbeck but as you might understand, this is nothing you do overnight. We are doing a very thorough evaluation of a large number of candidates and we are doing this together with an external consultant, Egon Zehnder, it is progressing according to plan, I have seen a long list of names and we will start to interview people over the next couple of months. But I cannot give you any dates when I expect us to be able to announce when a new CEO will be appointed. It is of course important to have someone coming in as soon as possible but it is much more important to identify and hire the right person. This is someone who is going to be with Lundbeck for hopefully a very long time and if it takes a month or two longer, so be it. And then I think I will leave the next question to Anders Gersel.

0.29.05

A: Anders Gersel Pedersen

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The question about the meeting with the FDA. We have had discussions with the scientific community in which also the FDA has been present throughout the year. The meeting, if you look at where the FDA were on this question 18 months or two years ago, they were clearly not enthused with a thought of having cognition as a separate point of target for drug development. They are moving on that and we will have that meeting and discuss with them in terms of where we are with the data and the conclusions of that meeting I will not draw any pre-empt at this stage in any way.

0.29.55

A: Anders Götzsche

With regards to Sabril we expect an increase for Sabril in this year of 20-30 % and we expect for Xenazine to have sales of more than DKK 2 billion and of course there is lots of exclusivity for Xenazine this year but we still expect to grow the molecule in the US and the same goes for Sabril

0.30.17

Q: Peter Hugrefte, SEB

Okay. Could I just follow up to, Håkan, back in November you said that you expected a new CEO to be in place around summer this year, is this still the case?

0.30.27

A: Håkan Björklund

Well, you know, I don't think I said I expected the person not to be there before summer. Whether it will be June, July, August, September, October, I don't know. And as I said before I don't think it really matters as long as we find the right person. And in the meantime I will hang in there.

0.30.46

Q: Peter Hugrefte

Thank you very much.

0.30.55

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I remind you once again, if you have a question you have to press 0 and then 1 on your telephone keypad. Our next question is coming from Mr. Tim Race from Deutsche Bank. Please go ahead sir. Tim Race, you are live now, please go ahead.

0.31.10

Q: Tim Race, Deutsche Bank

Oh, hi, I thought you shut off me and I was pressing 0 1 as you were speaking. Uhm, yes it is Tim Race here from Deutsche. Just a question on the ADHD indication. Are you, who is funding this? Is this Lundbeck only or Takeda and is your partner going to be Takeda without indication or is the partner only Takeda for the depression? And then just another question on Brintellix perhaps, how do you think you can accelerate this going forward? Obviously cognition is one route but the bulk of prescriptions seems to be from the psychiatrists. 60 % also and it is not really filtering into the GP sphere. Have you identified the issues and how do you get Takeda or your partner to address this, what are your plans there? And perhaps just one last one on the CEO search, obviously you have had more time to think about it. What profile of person are you really looking for? Perhaps somebody that has worked in pharma, worked with the Japanese companies and knows a lot about Lundbeck would be useful perhaps. Håkan. Anyway, perhaps you could just tell us a little bit more.

0.32.14

A: Peter Gersel Pedersen

Thank you, Tim. The first question about Brintellix and the ADHD. We have a partnership with Takeda on the molecule as such so obviously we have discussed this programme, but it is a programme that it is Lundbeck who is running the programme physically if that is what your question is and we are partnering it with Takeda as part of our partnership. At this stage we need to get the first study through and approved and hopefully with some positive findings and then we need to get into the next sets of studies and whether we will run them at Lundbeck or they will run some and we will run some has not been decided yet but the funding of them is shared in a way that we normally do in our collaboration with them. So it is a shared funding between Takeda and Lundbeck.

0.33.15

A: Peter Götzsche

And then for the Brintellix acceleration I think it is important to reiterate that we still expect that the peak sale from Brintellix it will be approximately one third from the US, a little more than one third from international markets and then a little less than one third from Europe. And what you should expect for 2015 is hopefully a continuation of the US sales and also we have some marketing activities including the DTC campaign that will

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start in 2015 and then we are discussing, we hope to progress with the discussion around cognition as Anders alluded to. And then you need to also remember that we are now launching in very important markets in the very important countries in international markets, we are launching in Canada, we are launching in Mexico and we also have launched in South Africa. And it is still very early days but we have seen a positive uptake in these markets and then by the end of the year we will also hopefully get through in some of the larger European markets. So you should not in 2015 expect to see material sales in Europe but of course we hope that we can demonstrate that we are also continuing or we see a good uptake in international markets.

0.34.41

A: Håkan Björklund

So and then about the CEO search, who are we looking for? It is a very broad search. We are looking internationally, we are not excluding any nationality, we need someone who has significant international experience, regardless of whether it is a Dane or an American or a Greek, whatever it is it has to be someone who has worked internationally. We are of course primarily looking at people with a significant pharma background but I will not exclude someone with a med-tech or a diagnostic background either. It has to be a good leader, that is for sure, and of course it has to be someone who can fit into a Scandinavian environment and a Scandinavian culture but you do not need to be Scandinavian per se. I think that is basically describing what we are looking for.

0.35.35

Q: Tim Race

Okay, thank you. Can I just follow up with Anders on the Brintellix ADHD? Is this study enough for regulatory purposes or is this just basically a larger phase 2 study and you need to do extras for this?

0.35.47

A: Anders Gersel Pedersen

The study is significantly sized so that it can function as a pivotal study in itself but it will not as a stand-alone for filing be sufficient. We would need a replication of such a study and we will for sure also need to do studies in paediatrics so this will not be a sort of one study in new indication types scenario.

0.36.13

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Understood, thank you

Håkan Björklund

Are there any more questions?

Operator

We have no further questions at the moment, Sir.

Håkan Björklund

Okay. If there are no more questions, thank you very much for attending.

