Transcript

H. Lundbeck A/S

Transcript : Lundbeck Teleconference Q1 2015 :

Operator
Ladies and gentlemen. Welcome to the Lundbeck first quarter results 2015. Today I am pleased to present Håkan Björklund, CEO and chairman of the board. Anders Götzsche, EVP and CFO and Anders Gersel Pedersen, EVP, Research and Development. For the first time of this call, all participants will be in listen only mode and afterwards there will be a Question & Answer Session. Håkan Björklund, please begin.

Håkan Björklund
Today is a very happy day for us at Lundbeck because apart from announcing our first quarter result we have also announced that Kåre Schultz will join us as new CEO from 20 May. I believe that all of you know Kåre. He has been the COO of Novo Nordisk for a number of years. A very experienced and competent person. Has delivered impressive results through his career at Novo Nordisk, which has of course given him an excellent reputation. We are very happy to be able to attract a person of Kåre Schultz' calibre and capacity and both I and the rest of the management team I trust are pleased to look forward to working with Kåre and as I said he will join on 20 May already, i.e. two weeks from now.

So with that we will move into the quarterly results and I think it is fair to say that we have solid performance in the first quarter, of course significantly helped by FX primarily strong USD. I think we have executed on our strategic growth platforms. We have seen significant sales increases in our strategic core products, which we are very happy about. A couple of examples: Brintellix has done very well outside of the US markets where we have just made a significant number of launches. We are receiving a lot of positive feedback. Continued solid uptake of Abilify Maintena in both the US and in Europe. We launched Northera towards the end of last year. We have seen good uptake and especially Onfi has done very well on the US market. And the strong development that we have seen over the last years in Emerging Markets in Asia and in Latin American continues. We will also continue with our R&D investments. We have initiated a phase 3 study with Brintellix in Japan and we are also starting a study in Dravet syndrome in the United States with Onfi. For Brexpiprazole the regulatory process is continuing in the United States and we have a PDUFA date in July when we expect to hear more.

We are maintaining our 2015 financial guidance. We are of course, as we said, noticing a strong impact on the currencies, there is also a little bit of seasonality in the first quarter. If we look a little bit at the products and the regional diversification I have mentioned earlier that it is very important for us to diversify. We used to be a primarily European company but as you all know today we are much more of an international company with the rest of the world and the United States now making up more than 72 % of our sales. Similarly, we are moving away from being a 1 or a 2-3 products company towards a company with a better spread between our big products and we are very happy to see not that our big products are declining but that our new products are actually growing and as a consequence the top three products now only account for about 50 % of our total sales.

If we look at some of the strategic core products, let us start with Brintellix. As you can see there is a very dramatic increase in Brintellix sales compared to the last quarter or the first quarter last year. The ex-US sales represent approximately 20 % of the sales, doing very well. I will come back to that. And all in all a very positive reaction. If we look at what we have seen in some new markets starting with Canada, Brintellix or as it is called in Canada Trintellix has done very well. We have had very positive feedback both from physicians

and from patients. In reality you could say that international markets the uptake has been comparable with what have seen with previously launched anti-depressants. In Europe, sales are meeting expectations but it is very early days in Europe and we have not launched in the major markets yet so there are a lot of important things happening over the next few months. Similarly in Sweden, we have seen again positive reactions and what we are noticing all over is that when we are able to talk about commission that has a major impact and as you probably know we do not have that opportunity today in the United States. And that is of course the reason why we are seeing that Brintellix is a little bit inferior to historic launches but still superior to more recent introductions in the United States, but it will make a big difference for us if we have the opportunity to talk about commission. We are, however, in the United Stated seeing solid market share gains. We have also together with our partner Takeda started a DTC TV pilot programme in 12 US test geographies. And we expect to see some impact of that towards the end of the year.

If we turn to Abilify Maintena, our long-acting antipsychotic that has done extremely well both in the United States and in Europe and you can see the increase compared to last year. We have seen strong initial launches in a number of European countries and we have recently launched in some major markets like France, Spain and Australia. We are also developing Abilify Maintena both in terms of additional data, we have just published some data on acute use of Abilify Maintena and we have also recently had approved by the FDA a pre-filled syringe which we think will add to our competitiveness in the United States.

Selincro again if we compare to last year a very impressive sales curve. This is primarily driven by France where we have had a solid start and actually more than 40 % of the targeted GPs have started prescribing it. However, we have to say that there are other markets in Europe where we have seen a considerably slower uptake and where we are also having some issues with market access. In the UK, although we have strong nice recommendation it is a very slow local implementation of that. In Spain where we recently launched we are now focusing on getting regional market access so it is a mixed picture with Selincro doing well in France – issues in some other markets.

A product line where there is not a mixed picture is our US neurology products which are actually up 65 % in US dollars compared to Q1 last year. And all our neurology products are doing very well Onfi being the star performer going with 130 %. Northera of course you cannot compare since we launched it towards the end of last year but doing also well and Sabril and Xenazile also very solid and strong growth. So all in all the development in the US has been very positive.

With that I will hand over to our CFO Anders Götzsche to walk you through some more details regarding the financials.

0.08.39.6
Anders Götzsche
Thank you very much Håkan. And as you can see from the very new line we are pretty much at the same level as last year and that is of course due to the fact that we have see declining mature products and that has been offset by basically two factors – a strong US dollar increase and then of course the new products. Core EBIT we are happy with a little more than DKK 200 million and of course, as you can see cost is impacted by the high increase in the number of launches so sNDA has increased dramatically compared to last year. There is some seasonality in our working capital and that is the reason for the negative impact on operating cash flow. By the end of the quarter we have a debt of DKK 3.3 billion and we have a cash position of DKK 3.2 billion and that cash position will, of course, during the year be used for investing in R&D and in the product launches. So 2015 will be a tough year from a cash position point of view.

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Please turn to slide 13. The financial guidance, I know that a lot of you will ask why are we not upgrading having a very solid performance in the first but we also need to say that we are 3 months into the year and there is a lot of moving parts. We need to have a good trend in our launch products and the uptake for the new products and we will also see continued decline for the mature products so for the time being we of course hope the dollar will stay at the high level but for the time being we stick to our guidance. I also know that one of the questions will be Brintellix. What are we according to expectations and I think it is very important to say what we also said when we announced the financial expectations in February that we will see very limited revenue from Europe during 2015 due to the fact that most of the major far countries – they will be decided upon in August-September. Market access, we will see Brazil, we will have some of the markets coming through in the spring and therefore what you should expect from Brintellix is material revenue from the US, you would see that we pick up in international markets due to the fact that we have launched in most Latin American countries, we have launched in Canada and South Africa. With that I should actually hand over to Anders Gersel Pedersen, but due to the fact that we have some technical problems and we don't know if that will go through – I will go through his slide and what I will just explain with his slide is that for Brintellix the SmPC (Summary of Product Characteristics) has been updated with some cognitive data during the spring. What we have also done is that we initiated the phase 3 study in Japan, you know we had a fail study in Japan, our partner had and now they are conducting a new round of 1 new phase 3 study. Otsuka has initiated Selincro in Japan and then there has been published data around Brexpiprazole. We have an extensive launch programme ongoing to support both the existing products in the market and also our pipeline that will hit the ground or the markets later – beyond 2015. With that I will hand back to Håkan for the concluding words.

12.40.5
Håkan Björklund

Thank you very much, Anders. Turn to the last slide page 15. We have seen significant sales acceleration of our strategic core products. We are very happy about that. What we are spending a lot of resources on, as Anders indicated, is of course additional launches of our new products in a number of countries so this is a very, very busy year for Lundbeck and as a consequence of our new products gaining ground we are seeing that diversification is continuing. We would like to turn over to Q&A right now but I have to admit that I am a little bit uncertain how we do this technically, but if you hold on we will a solution, I hope.

0.13.31.1
Operator

Ladies and gentlemen. If you have a question for the speakers, please press 01 on your telephone keypad. It is 01 to ask a question. The first question comes from Mr Michael Novod at Nordea Markets, please go ahead.

0.13.46.2
Michael Novod

Yes, hello it is Michael Novod from Nordea Markets in Copenhagen. Just two questions. First of all in regard to the process with cognition in the US could you elaborate a bit more on the exact timing that you expect? When do you expect the FDA to get back to you? And also, how then do you expect the label to be updated? Looking at the European we see that sales it is quite limited what is actually in the label with regard to positions/physicians ??. Maybe you can elaborate a bit on the US? And then secondly on the Brexpiprazole, when you see the launch of that when do you expect you need to start ramping up the sales force in the US and secondly on that compound how do you expect the traction of

prescriptions to run? Will it be very similar to Brintellix or do you expect a much more rapid launch of that somehow?

0.14.44.3
Håkan Björklund
Maybe I should take the first question and then if Anders Gersel could take the question regarding cognition in the United States. When it comes to Brexpiprazole in the United States as you know we are in the regulatory process in the United States. We have a PDUFA date in July for two indications schizophrenia and MDD. We are optimistic, but of course at the end of the day we have to wait and see what happens with the registration. When we know more about that then we have to make decisions about how we should market this and what it comes to – recruitments and so on, so it is too early to do this. We will have a dialogue with our partner during December. Anders, if you are on and are able to, could you handle the question regarding cognition in the US?

0.15.41.4
Anders Gersel
Yes, I hope you can hear me now. I am with respect to the labelling in the United States we have had ongoing discussions with the FDA on that and the process that we would have to go through is similar to what you do in Europe that you may have to submit an sNDA to get some label language addressing the findings that we have we have we expect Brintellix effects on the cognitive functions in the first patients. You should not expect that that will have any impact on labelling before a year from now because that is the time these processes take in the US. We are together with Takeda working on a final SNDA proposal that we will submit to the FDA and as soon as we have submitted and that has been accepted by the FDA we will obviously notify the market on that.

0.16.45.6
Michael Novod
Okay so this will be more – will it be more sort of a relaunch of the compound or how do you see that pan out in the US?

0.16.55.8
Anders Gersel
I think clearly what we can see from markets in which we can talk about the data that are already available on cognition with Brintellix we can see that that has an impact on physicians' understanding of the differentiated profile of Brintellix and it is clearly our expectations that if that becomes part of the labelling in the United States that will also have a positive impact on our differentiated products with respect to patients that have cognitive problems with their depression so we will expect that to have an impact on the sales process area

0.17.40.5
Michael Novod
Thank you.

0.17.43.1
Operator
We have a question from Mr Peter Welford at Jefferies, please go ahead.

0.17.45.6
Peter Welford
Oh hi, yes, thanks for taking my questions. I have got a couple. First just with regard to Brintellix in the US. I appreciate that to some extent you have indicated terms ?? but I

wondered if you could help us reconcile the disconnect between the script trends and obviously pricing and what we are seeing in terms of your reported royalties or what I have seen is happening within market sales, particularly during the first quarter and also can you give us any insight into your thoughts regarding pricing given the recent price hike? There was intervention in the US. And then secondly just on Brex, whether you can give us an update. Is the FDA still presumably not planning to host an Ad Com? Presumably there has not been any sort of update on that at all and do you have any sort of update at all on the progress with the European phase 3 trials, please, on Brexpiprazole? Thank you.

0.18.36.0
Håkan Björklund
We will have Anders Gersel answer the first question.

0.18.44.0
Anders Gersel
Could you please explain what you mean by the disconnect in the script and – because what is of course happening – there is a clear link between the script which is the demand and what you see in the revenue line and the royalties but what you will see over a period is of course there will be increase and decrease in inventories and also there might be some gross to net you know reductions that will move between the quarters but you should expect then in general that the continued gross is, of course, a reflection of the demand and then of course also the pricing which you ask for and we have taken a price increase in the beginning of April so that will not have any impact on of course the first quarter, and that was 10 % so I don't know if that answers your question around – or your questions around Brintellix?

0.19.49.5
Peter Welford
Yes, I guess in the first quarter were there any sort of significant destocking or changes in rebates at all that will be impacted on an ongoing basis?

0.20.00.8
Anders Gersel
No

0.20.07.1
Håkan Björklund
Okay, then I can try to answer the question around Brexpiprazole. There is nothing that indicates that there will be an Ad Com in the United States. In Europe, the ongoing clinical trials are on track so there is nothing new to report in the EU.

0.20.24.8
Peter Welford
Thank you very much.

0.20.28.5
Operator
As a reminder, it is 01 if you have a question. 01. We have a question from Mr. Terence McManus at Credit Suisse, please go ahead.

0.20.36.7
Terence McManus

Transcript

Hi, thank you for taking my questions. It was a bit of a strong quarter for Xenazine and I was wondering what your current thoughts were in terms of a potential generic entry and whether the sales in Xenazine throughout the year is cause of the push and pull you see within the 2015 guidance. And then just going back to Brintellix, I know you talked about cognition and submitting an sDNA to the FDA. Is there any time line on that? Forgive me, I may not have heard it. The line is quite weak.

0.21.14.2
This is Anders Götzsche. I can start with the Xenazine. We are not willing to speculate in any generics for Xenazine but what we can say is that there will be between the quarters you will see stock build up and also for some quarter it will decline but what is important is that we have said that we expect to see growth in Xenazine for this year so that is the guidance we have given and with respect to the time line for Brintellix I would assume that that question can be handed over to Anders Gersel Pedersen.
0.21.54.3
Anders Gersel Pedersen
Yes, we are working on a filing process together with Takeda and as I mentioned we would not expect to be able to have an approval on a label adjustment before – that could not have an impact earlier than a year from now so that is roughly the time line and normally what we do is we notify you when we have an acceptance and a reply from the FDA and that is also what we will do in this case here.

0.22.23.1
Terence Mc Manus
Thank you.

0.22.26.1
Operator
We have a question from Mr. Carsten Lønborg Madsen from Carnegie. Please go ahead.

0.22.31
Thank you very much. This is Carsten from Carnegie. When it comes to milestone payments to partners for the remaining part of this year Anders do you mind highlighting what we should put into our cash flow statement here? And closely related to that of course you had the net debt of 86 million for Q1. What is the outlook for the full year? Thanks

0.23.00.7
Anders Götzsche
Thanks for the question, Carsten. What you should expect is that as we have guided in previous years that cash flow from operations we expect around 1 billion then the regular investments in running the facilities and other stuff which is between DKK 400 and 500 million in Capex and then we have the known milestones to Otsuka which is 200 million dollars in R&D milestones and which we will pay during the year and then there are these two milestones of each 100 million dollars which are dependent on regulatory approval in the US, so in total 400 million dollars. If you say that we have a positive outcome for both indications then we will have by the end of the year a net debt of around 2 billion. That is our expected figures based on the guidance we have now.

0.24.05.9
Carsten Lønborg Madsen
Yes, but very clear, thanks.

0.24.10.4
Operator
We have a question from Mr. Peter Hugreffe, SEB, just go ahead

0.24.12.4
Peter Hugreffe
Yeah, hi, Peter Hugreffe. Thank you very much for taking my questions. Håkan, I was wondering whether you could give us some thoughts in terms of your new CEO in terms of grace period and the potential new strategy. How long should we wait for him now that you can become a chairman two weeks from now? Secondly in terms of just the housekeeping, in terms of the tax rate, could you just give us some insight into that – I don't know, it seems relatively difficult for you to estimate so any kind of thoughts on that – that will be appreciated. And then finally, just in terms of Brexpiprazole and then this is to Anders – what do you see the chances are for only getting one of the indications through – I know that at least if you look to the posters on the depression side then at least one of your studies has sailed on the primary analysis so I am just trying to understand what are the risks that you will not get both indications through? Thank you.

0.25.11.3
Håkan Björklund
Well, if I start then with the CEO, as you probably have seen, Kåre Schultz will join us full time already from 20 May so there is a very short period between now and then. I expect him to hit the ground running – he is a very experienced man. He is not known for beating around the bush so I think he will be an effective CEO basically from day one. Do you want to talk about the tax rate?

0.25.43.9
Anders Götzsche
The tax – the way – it is very difficult to predict and the reason for that is we have the US neurology portfolio is taxed in the US due to the fact that the acquisition we made from Ovation the products rights are linked to that and that is taxed with 38 % and due to the very strong performance in the US we have to pay tax in the US and then we have a lot in Denmark, as you might imagine, and that is with the tax rate of 24 % and then we have in the rest of the world we have an average tax rate of 30 % and that means that despite the fact that you have a profit before tax or a loss before tax then in the quarter we are paying 49 million and if it continues with a very good development in the US we will also by the end of the year be in a position where we pay tax totally but it will be heavily dependent on what kind of products are taken off and where is the tax base for these products. As you know, Brintellix is developing in Denmark and it is taxed in Denmark so if there is a good uptake then it will offset some of the losses we have there so it will be very dependent on what kind of product so that is the reason that we are not more precise in the guidance and that it is a little difficult to predict. With the risk....

0.27.16.2
Håkan Björklund
That is for you, Anders Gersel

0.27.20.7
Anders Gersel Pedersen
Yes, obviously we cannot regulate on the risk of the re ?? to file to the FDA and until one is at the end of the structure with the FDA you never know how things will go. We have a very strong argumentation for both the two indications that we have been forward with the FDA and have at this moments expectations that things will be going as we have hoped for but obviously you never know until you have the final discussions and feedback

from the FDA. We have experienced that before in our previous filings that things can change late in the process. I will not speculate on that.

0.28.06.6
Peter Hugreffe
Very clear. Thank you very much.

0.28.10.7
Operator
As a reminder it is 01 if you have a question. 01 on your telephone keypad. We have a question from Mr Carsten Lønborg Madsen at Carnegie. Please go ahead

0.28.26.1
Carsten Lønborg Madsen
Yes, thanks, Carsten again here. Just another one to your cost of goods sold to sales ratio which in the quarter is a mere 66 %. Your high product cost is of course also driven by amortisation of launched products but Anders could you try to break it down a little bit more and maybe also give a long-term view just sort of conceptually what is the cost ratio for Lundbeck longer term? It is quite an important thing to model longer term.

0.29.00
Anders Götzsche
Yes, what we also said in February is that what will hit the cost line is of course a change in product mix and then what you also see is both royalties and amortisation and due to the fact that we have launched Northera last year in the fall you will see that the amortisation of the acquisition of the product rights from Northera will hit full year in over four quarters instead of having one quarter last year. What you are also seeing is that some of the amortisation of the more mature neurology portfolio – it is booked in dollars so that will also increase due to the dollar increase so that is the reason and that was also why we have said that during this year you should expect that the cost will increase compared to last year with 2-3 percentage points and if the dollar actually stays at this level it might actually, due to the translation from dollars to Danish kroner it will increase more. Then when we come to 2020 and going forward then of course the product mix will be that we will get more profit from Brintellix, Abilify Maintena and as you know they will be as profitable as – because Brintellix is our own invention with low costs and Abilify Maintena is also a lower cost than you have for some of the other products. So you go through a period where you have higher costs due to royalties and amortisation and also the – and then it will start to decline again when you get to 2020.

0.30.45.5
Carsten Lønborg Madsen
All right. Thanks.

0.30.40.1
Operator
As a reminder it is 01 if you have a question. 01 on your telephone keypad. There are no questions at this time. Please go ahead speakers.

0.41.04.1

Okay, thank you very much for attending this conference call. Our next conference call will be in August and then I will not be present. There will be a new CEO entertaining you. Thank you.