

Lundbeck – Full Year 2019 Results – broadcast held on 6 February 2020

Operator

Hello and welcome to the H. Lundbeck Full Year 2019 Results call. For the first part of this, all participants will be in a listen-only mode and afterwards there will be a question and answer session and today I am pleased to present Deborah Dunsire, President and CEO, Anders Götzsche, Executive Vice President and CFO, and Johan Luthman, Executive Vice President of Research & Development, so please begin.

Deborah Dunsire

Thank you very much, operator, and thank you all for your interest in Lundbeck. Welcome to the Lundbeck teleconference covering our Financial Report for 2019. I am joined as you heard by Anders Götzsche, our CFO, Johan Luthman, our head of R&D, Jacob Tolstrup, head of Commercial Operations and Peter Anastasiou, head of North America.

On slide 2, you can see the company's disclaimer which I know you have read many times before so I am not reading it out, I am sure you are glad to hear. Let us go directly to slide 3.

During 2019, Lundbeck has made significant progress against our Expand and Invest to Grow strategy. Our strategic brands continued to show remarkably strong growth in both volume and value across all regions. As you know, we made 2 important acquisitions which significantly supplement our pipeline and expand the range of brain diseases we address. We have also made important progress in our internal pipeline finishing the year with 14 clinical projects of which half were not initiated just a year ago. Our financial position is sound notwithstanding the significant investments that we made through the year. This gives us some headroom to make continued progress on Expand and Invest to Grow in future years.

With that please turn to slide 4. Anders Götzsche will elaborate in detail on the solid financial performance later in this call. I will just start by summing up the numbers. The expected loss of exclusivity on Onfi, previously our largest product, could not be fully offset even with the 28% growth in our strategic brands. Overall, revenue thus declined by about 6% but that was a slightly lower dip than in our original expectations provided a year ago. More interesting to me is the growth both in revenue and core EBIT realised in the 4th quarter of the year as the impact of Onfi wanes and that clearly illustrates that the next growth phase in Lundbeck's history is ahead. The core EBIT margin is largely unchanged despite our large investments in the commercial infrastructure.

Next slide please. Our four strategic brands generated substantial growth, up 28% in aggregate, adding DKK 2.1 billion in sales compared to 2018. These growth products constitute more than half of Lundbeck's sales. Each of the brands has achieved double-digit growth and are growing in all regions. The continued growth in these strategic brands is a testament to the value these products provide as well as the excellence in execution by our commercial organisation around the world.

Next slide please. 2019 has indeed been a year where the mature US neurology products and especially Onfi impacted the financial performance. If one excludes Onfi, Sabril and Xenazine, revenue in the US would be up 18%. With this transition behind us, Lundbeck is ready to enter the next phase of growth driven by the momentum on the strategic brands including the new arrival epti or eptinezumab.

Please turn to the next slide. As you know, the PDUFA action date on epti is set for 21 February and we have not experienced any major surprises so far in the dialogue with the Agency. Lundbeck Seattle Bio Pharmaceuticals is now an integral part of the global Lundbeck organisation. Our sales organisation to launch epti is also in place and importantly we started the Treat and Prevent study called RELIEF in order to characterise the early onset profile of this product still further. The regulatory submission process in

Canada has taken place and the file is now in validation at the authorities. Full publication of the PROMISE 1 and 2 trials are expected in the coming months.

Next slide please. As we consider our pipeline, we now have the potential for multiple launches in the next 5 years. Of course, as usual, earlier programmes carry a higher risk of attrition but this slide does give a perspective on how we are rebuilding the pipeline and Johan is going to talk further about that in a minute.

Next slide please. Lundbeck's sustainability activities aim to contribute to solving societal challenges wherever we can. We also act decisively to mitigate risks or potential adverse impacts related to our business activities across the value chain. We remain committed to the UN Global Compact principles and contribute to addressing 6 of the sustainable development goals. The table provides an overview of our ambitions, initiatives and targets. More detailed information about our sustainability policies, efforts and results is available on our corporate website.

Next slide please. Lundbeck's continued efforts to reduce CO2 emissions and energy consumption have been recognised as world-leading by the independent interest group, the Carbon Disclosure Project or CDP for short. This group sets and monitors progress against the global standard for actions against climate change. Lundbeck is included in the CDP's new 2019 Climate A-list, the highest possible rating awarded to only the top 2% of the more than 8,400 companies worldwide surveyed by the CDP. The A-listing is recognition of Lundbeck's many different efforts to reduce its impact on the climate by reducing CO2 emissions and energy consumption. Since 2006, Lundbeck has reduced its CO2 emissions by 68% with 32,000 tons and its energy consumption by 35% or more than 51,000 MWh. The energy savings would power more than 11,000 households for a year. In addition to our own direct initiatives, Lundbeck seeks to participate in partnerships to further reduce climate impact across the value chain. For example, we joined the global movement, the business ambition for 1.5°C and we also participate in the Danish government's Climate Panel for Life Science and Biotech. Taking action to reduce climate change is a shared responsibility and here in Lundbeck we are dedicated to do our part.

Next slide please. To summarise before I turn the presentation over to Johan Luthman, firstly we expect continued growth for our strategic brands and the portfolio will now be fortified with epti pending approval later this month. Additionally, we have a very stable cash generating business which continues to provide financial flexibility to drive our business for both near and long-term growth. We have the optionality from our expanding pipeline with novel and exciting science which can create additional growth opportunities in the future and I will now hand over to Johan to provide an update on the R&D pipeline

0.08.52

Johan Luthman

Thank you, Deborah. Please turn to slide 12. When I joined Lundbeck a year ago, one of my key priorities was to refine and expand the pipeline. While I would always like to see more projects in the R&D portfolio, in particular in the mid-stage development part, I still think we have achieved a lot. Projects have come in from the two acquisitions we made in 2019. We have also managed to move internal projects forward and added 3 projects from our own labs into Phase I. Finally, we continue our work to get the full value from our brands through potential new indications, both by running pivotal programmes but also by getting additional data on our products. We have also stopped the variety of products which we did not believe were strong enough to continue.

Next slide please. Here we have listed some of the late development projects we have initiated during 2019. As in previous quarters, I have elaborated on the projects around Brexpiprazole. These programmes are progressing as planned and we expect to see a lot of data during 2021 from these. We also continue to

gather more data on Vortioxetine and initiated the RECONNECT study to further investigate adult patients with depression co-existing with general anxiety disorder. Finally, we have started the RELIEF study on epti in November last year.

Next slide please. The RELIEF study is conducted in order to characterise the profile of epti in more detail. To underscore its very fast onset of action. The study will enrol 450 individuals with migraine who are eligible for preventive medication. The primary endpoint is to evaluate the effect of epti compared to placebo with respect to time to headache pain freedom and time to absence of most bothersome symptoms during intercurrent migraine. Included in our secondary endpoints are patients achieving freedom from pain and absence of most bothersome symptoms both measured 2 hours after start of treatment. We expect to finalise this study before the end of the year and share the data at the relevant conference. I will now hand over the microphone to Anders Götzsche to expand on the corporate financial picture.

0.11.20

Anders Götzsche

Thank you very much Johan. Please turn to slide 15. Revenue declined 6% reaching DKK 17 billion. This is driven by the loss of exclusivity for Onfi and Sabril, which is partly mitigated by the strong growth from all four strategic products. Please also note that the effects from hedging has moved from a gain of DKK 242 million in 2018 to a loss of DKK 322 million in 2019. Cost of sales declined 2% to DKK 3.4 billion for the year. Our gross margin thereby reached 80%. This is fully in line with our expectations. We maintain good control of our operational costs. The SG&A costs only increased 6% which is mainly linked to FX investments in China and Japan as well as other growth initiatives and operational costs related to our two acquisitions. The SG&A ratio was 37.6% compared to 33.3% the year before. The increase in ratio is a consequence of the decline in revenue compared to last year. R&D costs decreased by 5% to DKK 3.1 billion representing 18.3% of revenue which also is in line with guidance. Considering the sales performance I believe we have managed our costs effectively. Thus reported EBIT reached DKK 3.6 billion. We see this as a very solid result. The effective tax rate for 2019 amounts to 23.4% compared with the 27% last year. The significant decrease is primarily due to tax benefits realised in Q4 relating to the Alder integration activities. Earnings per share reached DKK 13.42 per share.

Please turn to slide 16. The execution on the new strategy including the acquisition of Abide and Alder impacted non-core items in 2019. There is however no difference in core and non-core revenue. All integration and acquisition costs have been recognised in Other operating items net and amount to DKK 514 million. These costs have been excluded from the core numbers. Therefore, our core EBIT margin has mainly been impacted by our investments in the commercial infrastructure across the globe.

For the fourth quarter, the margin is almost unchanged compared to the same period last year. Core EPS in the fourth quarter is positively impacted by the lower tax.

Next slide, please. Revenue from Brintellix/Trintellix reached DKK 2.8 billion in 2019, growth of 30%. In the US, Trintellix continues to increase its market share. We have seen continued strong growth driven by an increase in new patients as well as improved persistence on therapy. Demand has risen 23% during 2019. Rexulti is still mainly a US franchise. In Europe the product has been launched in Denmark, the Netherlands, Norway and Switzerland. Additionally it is launched in Australia, Chile, Mexico and Saudi Arabia and more countries will launch in the coming year. Rexulti achieved more than DKK 2.2 billion in sales in 2019, which represents impressive growth of 32%. The demand growth has risen a healthy 24% in 2019, impressive in its 5th year on the market. Abilify was launched in 2013 and grew by 23% to close to DKK 2 billion. In many markets, Abilify Maintena is now the second most prescribed long-acting injectable treatment for patients with schizophrenia. Northera grew 29% finishing the year above DKK 2.3 billion. We do continue to expect

good volume and value growth for this product in 2020 as well. We expect the strategic brands to continue the double-digit growth in 2020.

Next slide please. In the North American region we are very pleased with the continued strong growth of our strategic brands which now constitute more 70% of the regional revenue. Actually, if one takes out Onfi from the equation, then growth is 13% for the year. North America constitutes 56% of our revenue. International markets increased 11% reaching DKK 3.9 billion or 23% of our revenue. This region is still in the early part of the roll-out of our strategic brands which show growth of 32%. We expect to see significant long-term growth for these products in the region. The largest markets among our international markets are Brazil, China, Japan and South Korea. These constitute more than 50% of regional sales. Japan is an investment area for Lundbeck as we have just launched Trintellix there together with Takeda and it is very early days but so far the product performs in line with expectations.

Europe is delivering solid growth with revenue increasing 9% to DKK 3.2 billion. The main driver is volume growth though we have benefited slightly from quarterly swings in the fourth quarter. The European region is important as part of our overall performance and is driven by our strategic brands which grew 29% and now constitute more than 50% of sales in the region.

Next slide please. We expect continued growth from our strategic brands. Abilify Maintena, Brintellix/Trintellix, Northera and Rexulti and soon also epti which will now more than offset the impact from the continued generic erosion on our mature portfolio. I think it is also important to point out that following the corona virus outbreak, Lundbeck sees increased uncertainty on product distribution and sales in China for 2020. China is our second largest market and the potential impact is difficult to quantify at this point in time. This is the background for having a wider guidance range than normal in our guidance for revenue and EBIT.

We therefore expect growth in revenue of 2-6% to a revenue range of DKK 17.4-18 billion. We will continue to be disciplined in our spending in 2020 but as previously communicated. We will make considerable investments in the long-term development activities related to epti which will impact our 2020 EBIT.

Core EBIT is expected to reach a range of DKK 3.5-4 billion, which is a margin of at least 19%. Reported EBIT is expected to reach between DKK 2.2 and 2.7 billion for 2020.

For the financial items, you should expect a net expense of DKK 200-250 million depending on currency developments. The reported tax will be impacted by the Alder transaction and will probably be in a range of 22-24% this year and going forward. The cash tax will be 5-10 percentage points lower the next five years and thereafter as it looks now, it will go up as amortisation on epti is not tax deductible.

Next slide please. Lundbeck continues to generate a solid cash flow although the level being impacted by the major investments we are planning for the year and this has the highest priority. We will also prioritise reducing the level of debt in order to continue to have financial flexibility. Lastly, we plan to live up to our dividend policy by proposing to pay out DKK 816 million in dividend for the year, which is a pay-out of 31%.

We expect the net debt position by the end of the year to be in the range of DKK 6-6.5 billion. With that I will now hand back to – hand over to Deborah for the concluding remarks.

0.19.56

Deborah Dunsire

Thanks, Anders. Please turn to slide 21. 2019 was a busy and exciting year. I am sure that 2020 will be just as exciting with the launch of epti in the US. We will also see data from the phase II programmes, at least

two of them, although these are relatively small studies which might limit how much we can conclude from these trials. We will continue driving our current business forward as we execute on our Expand and Invest to Grow strategy.

Next slide please. To summarise, we will continue to leverage our deep neuroscience expertise to restore brain health and that is our path to grow Lundbeck and create value for patients, for our society, for our employees and for all our stakeholders. Through this, Lundbeck will continue to be a robust and sustainable company in the years and decades ahead.

The outstanding operating results over the past years give us the strong financial foundation to go forward and achieve these goals. With that I would like to thank you all for your interest and open the Q&A session.

0.21.11

Operator

Thank you. So ladies and gentlemen, if you wish to ask a question and you haven't already, could you please press 0 and then 1 on your phone keypad now in order to enter the queue and then after I announce you just ask that question. And if you find that question has been answered before it is your turn to speak, just press 0 and then 2 to cancel it and there will be a brief pause while the questions are being registered.

Okay, in that case our first question is from the line of Wimal Kapadia at Bernstein. Please go ahead, sir. Your line is open.

0.21.50

Wimal Kapadia

Great. Thank you very much for taking my questions. Wimal Kapadia from Bernstein. So first, could we just get a better understanding of the impact of China on your guidance? So you previously gave ranges of DKK 400 million for revenues and EBIT but you have now given a range of DKK 600 million for revenues and DKK 500 million for EBIT so does that suggest a DKK 200 million impact on revenues and DKK 100 million on EBIT or is that the wrong way to think about it? And then tied to this, what is the adjustment assumed in terms of resolution of problems, i.e. does it assume business as usual starting in Q2 or Q3? My second question is on Rexulti and Alzheimer's agitation so maybe I am over-reading the language but you previously suggested headline data in early 2021. Looking at the current presentation, you say the study will finalise in H1 2021 so is this a delay or should we continue to expect data in early 2021? And then tied to this, I am curious to ask if this launch will require a significant increase of OPEX if you are successful or is the existing infrastructure sufficient? Thank you very much.

0.22.54

Deborah Dunsire

Okay, lots of questions there, Wimal. Anders will start on the guidance and Jacob will follow up on the return to normalisation in China.

0.23.03

Anders Götzsche

I think you take it too far if you assume DKK 200 million but we have not, as you know we have around DKK 1 billion in revenue in China so it is a bit less than DKK 100 million a month and I just want to be razor clear on that. We have seen no impact so far but it is also fair to say that you know our employees - we take their safety first and therefore they are working from home like many other companies also have their employees working from home and therefore there might be an impact or there will be an impact and that

is what we are signalling with a bit broader range but to take it to DKK 200 million then you are taking it too far and then Jacob can comment more on this.

0.23.52

Jacob Tolstrup

Yeah, a little bit on the operational side of it so true, employees are working from home these days like many other companies and are scheduled to resume work you can say outside of home on 17 February but I think right now I think your guess is probably as good as ours in terms of what will really happen on 17 February but that is the current plan where schools will re-open and then there will probably be some time before things are back at full swing for everybody in China so I'll just reiterate what Anders said: We have not seen an impact at this point in time but we are just taking precautions and expecting that there may well be an impact going forward.

0.24.34

Anders Götzsche

Maybe you could also tell about the expansion of the script period?

0.24.37

Jacob Tolstrup

Yes so what we also see is that the Chinese authorities take measures that are needed to help patients get through this period of time and that means for chronic diseases they are expanding the prescription period from normal 2 weeks and all the way up to 3 months so that means that patients can still continue their treatment while being unable to go to a doctor and eventually a pharmacy.

Deborah Dunsire

I think just summarising we believe that these brands are promotionally sensitive and when our sales force is not in the field, we believe that it will have some impact so we cannot quantify it and an abundance of caution widens the guidance range. Peter, would you like to..

Peter Anastasiou

Maybe

Deborah Dunsire

Johan, are you going to comment on the Rexulti?

Peter Anastasiou

I can comment on the commercial infrastructure question at the end.

0.25.33

Johan Luthman

Yeah, so this is Johan. Just a quick comment on the Rexulti so this is a study that has some adaptive elements to it in terms of some precise assessment etc. so that is why you have a little bit of variance at how we report this and what you see here is more conservative estimates. That is where we will be with the conclusion of the study, with the full enrolment of the study.

0.26.01

Peter Anastasiou

And then on the commercial investments of course we will leverage the existing infrastructure as much as possible with the recognition though that if we do get this indication, there will be some additional customers we would need to approach. Nursing homes but also some gerontologists and some people that

are currently not on our call list that treat patients that have agitation with Alzheimer's so there would be some investments related to that but of course we would leverage as much as possible the existing structure.

0.26.32

Wimal Kapadia

Great. Thank you very much.

Operator

Next question is at the line of James Gordon at J.P. Morgan. Please go ahead.

0.26.41

James Gordon

Hello. Thanks for taking the questions. James Gordon from J.P. Morgan. Just a follow-up one on China. If I heard correctly you said the only impact so far has actually been on promotion as in the reps are grounded, but you have not seen any impact at all in terms of prescriptions resting or people's ability to cash prescriptions. Is that right up until the end of January that there has been no impact on those aspects? And on China any disruption in terms of actual distribution of the product? Could that be an issue? And the second question just beyond China. Are there flex points for the guidance this year? Is there pace in your trial starts or is it further business development or anything else that could be a swing factor beyond China that we should bear in mind when we work out where we think it is going to come out?

Deborah Dunsire

Okay. Thanks, James. Jacob is going to take that

0.27.21

Jacob Tolstrup

Yes so I can definitely begin answering that. I think the comment we made around we have not seen any impact is on our sales for January. So sales for January came in as expected when we started the year. So that is the comment that is made at that point and it is too early to say for February, but true, we do expect in the future some impact on sales potentially. On the logistics side, I know our distributors are working really hard to keep things and products available all across China. So far we have not seen or heard of anything that will give us cause that products are not available but that is another thing that we continuously look out for in the future to see if logistics are not up to normal levels.

0.28.15

Deborah Dunsire

Anders, would you like to comment on swings in the guidance?

0.28.18

Anders Götzsche

I think it is actually from that perspective, the guidance is a bit boring isn't it? Because there is not a lot of swing factors. We believe that strategic brands will grow double-digit in 2020 and you will see a continued erosion of Onfi, Sabril and Xenazine. We anticipate a 50% decline for Onfi which is the most important decline that we will see in our business. But you have also seen that the mature products are actually doing extremely well. We had an increase in Cipralext this year and we are actually basing the growth initiative that Jacob has initiated across international markets and Europe, we will continue to go after that. That is of course also the reason for the increase in FTEs but it has actually paved or we have benefited from that so you see an increase in Cipralext this year which I think is pretty amazing. So I think the swing factors are limited. Of course, we have taken into account that we will get some revenue from epti but we are also

cautious so we expect it will take time to get epti up and running so as you know from earlier years, we are cautious guys and therefore we have built in a decent uptake, but..

0.29.47

Deborah Dunsire

I think other factors to consider would be if there were additional Sabril tablets that entered the market. Any other unexpected price increases in some of the international markets or Europe but, you know, those are unforeseen. We have said that we would be – we would continue to look at the Expand and Invest to Grow strategy selectively for partnerships, our regional deals, other types of supplements to the pipeline but that would be opportunistic and we are certainly not targeting major acquisitions in this year. We really want to consolidate and deliver on the brands that we have got.

0.30.33

Anders Götzsche

And you should assume that we will use around 20 to 21% in R&D costs in 2020 so of course that is going up as well as the SG&A margin due to the launch activities.

James Gordon

Okay.

0.30.54

Operator

Okay we now go on to the line of Marc Goodman of Leerink Partners. Please go ahead, Marc, your line is now open.

0.31.00

Marc Goodman

Yes, hi. We have two important Phase II readouts coming very soon. I was wondering if you could just set the stage for them and what will be considered, you know, good data? What will be considered disappointing? Things that we should be looking at, you know, other endpoints besides just the normal primary endpoint for the Parkinson's and Tourette's products that are coming in and just secondly maybe Peter can just comment if there are any inventory builds. Sometimes we see that in the fourth quarter in the US in some of the key products. Thanks.

0.31.37

Deborah Dunsire

Just to set expectations first. The two readouts, one on Foliglurax, one on 06466 in Tourette's. The Phase IIa trials are very small and I just want to make sure that we reiterate that. I know we said that before so they could be indicative trials so I will hand over to Johan for further comments.

0.32.04

Johan Luth

Yeah, that is very much correct so those are early stage proof of concept activities both of them. In terms of the Tourette's study we have a rich opportunity there. This is one of many indications we are planning to explore for this molecule and they will be indicative of the pathway forward and that is basically how we view them right now.

0.32.26

Deborah Dunsire

I think a thing that we have pointed out in our release is that if there was a complete failure in Foliglurax that meant there was no future path forward for that asset, it could trigger € 100 million write-down.

Peter Anastasiou

Do you want me to answer the question about the ...

Deborah Dunsire

Yes, go ahead, Peter

0.32.47

Peter Anastasiou

Hi Marc. On the question about quarter-to-quarter fluctuations in inventory, of course that always is the case every quarter and we see that here as well but nothing in particular to highlight for you but we do expect like in every quarter that there is quarter-to-quarter movement.

0.33.18

Operator

Okay we now go to the line of Dominic Lunn at Credit Suisse. Please go ahead, your line is now open

0.33.25

Dominic Lunn

Hi, so thank you for the hedging guidance for 2020. If you have a look versus consensus your impact between DKK 200 and 250 million is significantly ahead of consensus. Could you just remind us about your hedging mechanics and could you potentially give us some guidance for 2021 so we are aligned there? And then secondly, following the GPA price cuts in China last year and the 4+7 expansion for this year, could you just give us an update on where you are with your China portfolio? Thank you very much.

Deborah Dunsire

So Anders..

Anders Götzsche

For the main currencies as you can see in the release, we have stated what is the currency levels that we have hedged at and in principle we hedge between 6 and 18 months, up to 18 months, but on average we hedge 12 months ahead and that means that that's mainly you know Chinese Renminbi, it is Canadian dollar, it is US dollar and we hedge on a rolling basis so we don't expect that we can beat the market. We are basically not speculating. We are just doing it to secure that we can make a financial guidance that we know how we can actually deliver on that so you would see that every month we are making new contracts so in principle it is more or less an average of the dollar exposure or the dollar appreciation so net in 2021 then you would also see the impact of how the dollar is of course behaving during 2020.

And on China

Deborah Dunsire

Jacob

0.35.01

Jacob Tolstrup

So Lexapro was part of the very first 4+7 pilot that later on got expanded nationwide in China and we have seen an impact on that, primarily in terms of volume so we have been negatively impacted on in-market sales for Lexapro in 2019 but as you also know, we have taken back the product from our partner and that

means we are recognising an increasing, bigger part of the revenue so also in 2020 we will expect to see growth for Lexapro in our financial revenue for Lexapro in China. For the other products, none of them have been included in the VPP ??? 0.35.42 announced so far and also the latest one that has yet to be kicked off, none of the other products are included in that.

0.35.56

Dominic Lunn

Great, thank you.

0.35.58

Operator

Okay we are now over to Michael Leuchten at UBS. Please go ahead. Your line is now open.

0.36.06

Michael Leuchten

Oh, thank you very much. Just one question for Anders. In terms of phasing of the incremental expenses coming for Alder, how do we think about that both in terms of the year progressing but also geographically, US versus ex-US? Thank you.

Anders Götzsche

I think, you should assume that the phasing of the earnings should be more or less even during the year so there will be swings up and down but you should not anticipate big movements between the quarters so we have the sales force in place for the launch in the US so the cost is actually getting recognised as we speak and then of course some of the promotional costs will go up and you will see the normal seasonality between some of the quarters as you have also seen in the business in the past. But it does not change a lot with epti compared to the other products. We see that there are some swings but when you plan it, you should more or less see an even split of the earnings during the year.

0.37.12

Deborah Dunsire

And then geographic...

Anders Götzsche

And geographically, of course, what you would see is that Europe is more or less running on the cost base in international markets they have now. Very strong growth and they will continue and then of course it is in the US we will see the cost build-up and then of course all the R&D costs will be headed out of the headquarters with the clinical trials that we are conducting and additional R&D activities.

0.37.42

Deborah Dunsire

Yeah so we don't see a big commercial build-up in 2020 for epti outside of the US.

Next question?

0.37.53

Operator

We now go to Michael Novod of Nordea Markets. Please go ahead, your line is now open.

Michael Novod

Yes thanks a lot. Just 2 short questions, 3 short questions. In terms of the net financials. DKK 3-4 million is that all interest payment or how much is interest payment of the financial items in that line as well? And

then just to get a feeling on the potential pay-back time in terms of the debt you have now taken on board and then lastly the DKK 2.2 billion at the low end of the reported EBIT guidance. Is it fair to assume that this is only in play if epti was not approved? Because otherwise it seems quite unrealistic. Thanks.

0.38.37

Deborah Dunsire

Anders, would you like to..

0.38.38

Anders Götzsche

I don't think you could phrase it that way because the way we guide is of course we have a list of risks that you can always face. You can have price decreases in the different countries whatever so you know it is a basket of different upsides and risks so you could say: Yeah, if epti is not approved but what does that mean, is it a delay of 2 months? Then you cannot say that then we will go in the lower end. It is, the lower end is if we are hit by some disruption in China and then of course, you know, there are swings when you have 12 months to deliver but so far we have had a good start in January so we are not overly concerned but of course we need some manoeuvre room so there is no specific risk that we attach more amounts to than other risks so – and the debt repayment, of course we anticipate to end the year next year with a net debt of DKK 66.5 billion and that is of course due to the fact that if we are successful with some of the clinical trials then we will have to pay some milestones both for the by-products but also for the Foliglurax and for epti there are some partners involved in that where we have to pay the money and then we are paying dividend of DKK 800 million and then we will also have some CAPEX investment and then the rest will be debt repayment and then in 2021 it will start fast with the repayment and then you should assume maybe 3 years from now we are debt free if we don't do any more deals.

0.40.27

Michael Novod

And the interest payment, is that the entire 3-400 million or how is it..

0.40.29

Anders Götzsche

It is mostly interest. And there will of course also be swings in the currency but we have not built that in. It is based, you know, there will be – it can go up and down based on how the dollar or the FX is developing and that can have an impact on the inter-company FX booking but that is non-realised so this is what you should expect from a realised perspective.

0.40.58

Michael Novod

Thanks a lot.

0.41.02

Operator

Our next question is over to the line of Emily Field at Barclays. Please go ahead Emily. Your line is now open.

0.41.11

Emily Field

Hi, yeah so I also have a couple of questions kind of building on a couple that have already been asked. Just specifically on the FX hedging policy, I just want to understand how the calculations are made. Is the hedging loss kind of what was your FX/effect ??? 0.41.25 based on your current hedges based on the

difference between that rate of 6-40 and spot or that current rates and the worst spot is ??? and was the 6-40 rate used to calculate the expected overall revenues or was spot rate used just for modelling purposes? And then secondary, I was also going to ask on sort of the phasing of core EBIT over the course of the year and I was a bit surprised by the answer that you expect kind of like an even cadence ??? because I was thinking that one would rationally expect a weaker first half given the planned resets that we saw impacting the business in the US in the first quarter specifically and then also, you know, the investment in the epti launch before seeing the benefit of any revenue so is there anything else that is going to be a balancing factor in that you are expecting a level cadence ????. Thank you.

0.42.24

Anders Götzsche

From a quarterly perspective, I have no more to say. You know, I will not go into more detail and there can be swings but you should not expect big swings between the quarters and we are not optimising the business quarter by quarter so the very hardcore guidance or hard guidance you can see is what we provide for the full year and there might be swings but what I said before an even split is.. it could be the way it paves out.

And the, what was it? The hedging we book of course during the year and the way we have accounted for it is of course we look into what is the spot rate and we use that for revenue and then we look at what is kind of the – you know in all the quarterly releases we have a separate line so we book of course revenue at the spot rate and then you see what is the impact from a hedging perspective. That is how we do it.

0.43.25

Emily Field

Okay so the current revenue projections for all the products are based more on spot?

Anders Götzsche

Yes

Emily Field

Okay, that is very helpful, thank you.

Operator

Okay the final question in today's queue comes from the line of Peter Welford at Jefferies. Please go ahead, Peter, your line is now open

0.43.47

Peter Welford

Hi, thanks. I have got a couple left actually. First of all just on 06446 I think it is, the Abide product. I just wondered if you had the initial data that I think may be coming in house from the neuropathic pain trial. I appreciate this is very speculative but I just wondered if there is anything you could infer out of those data. Secondly then just because the net debt coming back to a comment Anders made before just with regard to your assumptions there so does the DKK 6-6.5 billion assume both the 25 million I think it is payout to ??? 0.44.16 on epti as well as success on Foliglurax presumably not necessarily the full 100 million and then what about also on the Abide drug? I don't think we were aware of the milestone, the precise milestone that could be paid on that but I guess could you tell us is this trial probability adjusted or how should we think about net debt and the sensitivity to those various events? And then finally just with regard to the comment on it being an investment year in 2020. That is, I guess, fairly obvious to all but I guess it is just thinking ahead to 2021 for a minute. I mean presumably 2021 again will have yet more investments as we start thinking about epti in Europe together with potentially preliminary AD agitation expansion by the

sound of it. But equally as well we will have Lexapro in Japan losing exclusivity I think and also we should see the initial decline of Northera in all likelihood so I guess if you think about 2021, are there any other factors we should be thinking about? How should we sort of frame the shape of the P&L going into next year, please? Thank you.

0.45.18

Deborah Dunsire

Johan, on the 06446

Johan Luthman

Yes, thanks for the question. This as you may know is the same molecule we have for a Phase IIa study in Tourette's so this is another indication that the study started under the guidance of Abide and it continues under us. It is a Phase Ib study. It is a small study with about 32 subjects. And it is primarily looking at safety tolerability. The aim is just to have a look at safety tolerability in the neuropathic pain population. We are finishing off that study and it is really only guiding for how we position the molecule for further development.

0.45.54

Deborah Dunsire

Anders, would you like to take the...

0.45.56

Anders Götzsche

Yes. What we have.. it is pretty straightforward, we have included DKK 800 million in milestone payments and approximately DKK 500 million is related to Abide and to Foliglurax that we hit the first endpoint. And then from an investment point of view in 2021, then it goes without saying that approval in Europe as we have said before we would probably need around the same size of sales force on top of the European organisation as in the US, around 100 people. Most of the back office functions, support will be done with the existing structure so what we assume is around 100 people, it is around \$ 25-30 million in cost.

0.46.52

Deborah Dunsire

Jacob, do you want to supplement?

0.46.53

Jacob Tolstrup

Yes, I have something to say to that, also remember Peter that you are obviously a lot more phased when it comes to the launch of new products so it will not be all 100 that will come on board in 2021 so they will be phased over even years in Europe as it normally goes before you have market access in place in several markets and then I just also want to point out I think you made a comment around Lexapro Japan. We do not expect generics on Lexapro Japan before towards the end of 2022 so no impact of that in 2021.

0.47.28

Peter Welford

That is great, thank you.

0.47.32

Operator

We have some more questions joining the queue. The first is over to the line of Jannick Denholt at ABG. Please go ahead Jannick. Your line is now open.

0.47.41

Jannick Denholt

Hi, thanks for taking my questions. Just a quick one as we are approaching the PDUFA for epti obviously. Just any thoughts on what you have seen on the migraine market development as it has gone along obviously when the first CGRPs they were approved and came to market, there were a lot of discussions on the rebating and the pricing policies and so forth. Are there any dynamics that so far have been a surprise to you when you observe the market or anything that you see as encouraging or just any thoughts on where you see this? Thanks.

0.48.13

Deborah Dunsire

Thanks for the question, Jannick. I will start and then Peter will take it from there. I think that this is the first new class of therapies for migraine in multiple decades and it is highly effective and very specific in migraine so we see that over years the class will grow. There is a lot of people who have the type of migraine that requires preventive therapy that are not currently getting treated and so not only are those who are in treatment with relatively ineffective therapies going to be brought into effective treatment with the CGRPs over time but the population who has migraine that needs prevention that are diagnosed but not treated will also come into effect so I think with any new thing it takes time to build so we are looking at the growth in the market and saying, yes it is continuing to grow and we see a huge opportunity still down the line in the future. Peter?

0.49.21

Peter Anastasiou

Yeah, well said and I would just emphasise a couple of the points that Deborah mentioned. First 85+% of the market for prevention treatment are older therapies that either have a poor evidence base or are not very effective or have significant tolerability issues and so that opportunity exists as Deborah was describing for the CGRPs to become the predominant class of migraine prevention treatments and so our main focus is to really, once approved, to come out into the market and really help grow the class and certainly help differentiate epti versus those older therapies and then also I will emphasize the point Deborah mentioned that about 25% of the migraine prevention market are people who are diagnosed but are not currently treated because they have been dissatisfied with the efficacy or the tolerability issues with those older therapies that I mentioned that 85% of the market is older therapies so they have just fallen out of treatment and so I think the CGRPs among them certainly give new hope to those patients and we will hopefully bring them back into the market and into treatment and really modernise their therapy.

0.50.36

Jannick Denholt

Thanks

0.50.38

Operator

Okay, we go over to the line of Peter Sehested of Handelsbanken. Please go ahead, Peter. Your line is now open

0.50.48

Peter Sehested

Yeah, hi, it's Peter, thank you for taking my questions

Operator

Sorry, Peter you are sounding very, very quiet. Could you please sit closer to the phone?

Peter Sehested
Is it better now?

Operator
That is better, thank you. We can hear you now.

0.51.02

Peter Sehested

I have two questions. The first one relates to the coding, the billing codes for epti. Allergan provides some very detailed instructions for physicians. What to do. They have 3 different kinds of codes. Drug codes, procedure codes, diagnosis codes. Instead of me doing sort of you know all the dirty research into this, could you just basically give us a run-down on the economics behind each of these codes and what an average physician can earn from making a – treating a single patient with epti.

The second question relates.. more high-level perhaps for Deborah, and that relates to sort of how you are thinking about filling the patent gap which is still there in 2027. Are there any sort of particular drugs in your pipeline that you are awaiting the readout of before let's say pulling the trigger on the next wave of M&A and going to the next wave of M&A if there is any? Could you elaborate a bit on how you see the timing of this ahead of 2027-2028? Should we see you pull the trigger before, up to, I guess it all depends on what kind of opportunities you have. But sort of in general, just to give us an update on how you think about this at this point in time. Thank you.

0.52.37

Deborah Dunsire

Starting with a general description of the market in the US for buy and bills from Peter

0.52.46

Peter Anastasiou

Yeah and codes of course. There is no specific code for epti yet. At the time of launch, physicians will be using a not otherwise classified code and then within a year of approval or less we expect to have eptinezumab specific codes that of course will be published and available and then we can certainly provide it to all of you once they are out there so that you can look them up and learn more about them but those are not yet available and they won't be for like I said a year or less after the approval so I think that is pretty much all I can say right now.

0.53.23

Deborah Dunsire

I think that the general in the infusion market, physicians gain a small fee for the actual administration of the drug and those that choose to buy and bill are also reimbursed for the drug, currently at ASP + 6% and there are physicians who choose not to do that and who will buy through a specialty pharmacy and will be able to provide it in both directions but the administration fee is pretty much constant if you are doing an IV whichever kind of IV it is depending on the length of time of the infusion or injection so I think that is as much general background as we will give now.

With respect to thinking about broadening the pipeline. As we pointed out during our presentation, we do have the potential for multiple launches and one of the great things about eptinezumab is that not only do we have a near-term launch in the prevention of chronic and frequent episodic migraine ahead of us but the mechanism can have application in other forms of headache and we will be able to expand the

indications over time with this drug. It is patent protected up till the mid 2030s so over time, this brand will be driving growth for Lundbeck. We do see of course the expansion of indications into agitation in Alzheimer's disease and post traumatic stress disorder with Brexpiprazole, both in Phase III, and the potential in another indication, borderline personality disorder, where we have a proof of concept trial running so those will continue to drive growth into the future and then within the earlier-stage pipeline there are a number of different interesting mechanisms that could progress reasonably quickly. Some of them will have a longer development time, some of them shorter so they are just too early to really comment on as yet. We have always said that our strategy will include both the internal innovation coming from our own pipeline as well as things that we can bring in from outside and that we would look at external innovation across all phases of the pipeline so for instance in the Abide acquisition we now have molecules in the MAG lipase pathway which could go into some rarer diseases or some broader diseases and then a serine hydrolyse platform behind that that could yield some very interesting molecules. We also have the PACAP inhibitor which came in from the acquisition of Alder Bio Pharmaceuticals that is in Phase I that will help broaden the migraine franchise so there is a lot of different potential growth opportunities in the pipeline and then we will be selectively looking outside to supplement in areas that leverage us strength in neuroscience where we feel we can develop the assets and where they fit with our commercial footprint so that strategy will continue to be a mix and we will take the actions at the time that the right assets show up and in the form that is best for Lundbeck and whoever the partner is at the time, be it partnership, licence, M&A.

0.57.01

Peter Sehested

Okay, that was helpful. Thank you very much. Bye-bye.

0.57.04

Operator

Okay as that was the final question in today's queue, I will just pass it back to you for any closing comments.

0.57.09

Deborah Dunsire

I think we have had a tremendous year in 2019. I am very proud of what Lundbeck has accomplished around the world and we look forward to an exciting 2020. Thank you for your interest.