

Lundbeck Q3 Results
5 November 2019

Operator

Hello ladies and gentlemen and welcome to the H. Lundbeck third quarter results. 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. So today I am pleased to present Deborah Dunsire, President and CEO, and Anders Götzsche, Executive Vice President and CFO. Speakers, please begin.

0.00.21

Deborah Dunsire

Thank you operator and thank you all for your interest in Lundbeck. We welcome you to this Lundbeck teleconference covering our financial report for the first nine months of 2019. Together with me today I have CFO Anders Götzsche, Johan Luthman, the Head of R&D, Jacob Tolstrup, the Head of Commercial Operations, and Peter Anastasiou, the 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 going to read it out I am sure you will be glad to know. Let us go directly to slide 3. In the first nine months of 2019, Lundbeck has continued to deliver strong momentum on our promoted brands around the world. We are therefore increasing our financial guidance for the year. Anders Götzsche will elaborate on the solid financial performance later in the call. During 2019, Lundbeck has made significant progress against our Expand and Invest to Grow strategy. Our strategic brands continue to show remarkably strong growth both in volume and value across all regions. We have made two important acquisitions which significantly supplement our pipeline and expand the range of brain diseases that we address. As you know, we closed the acquisition of Abide Therapeutics in June and on 22 October this year, closed the acquisition of Alder BioPharmaceuticals. We have also made important progress in our internal pipeline finishing Q3 with 11 compounds in clinical development. Our financial position is sound despite the several major payments through the first three quarters. This gives us some headroom to make continued progress on Expand and Invest to Grow in future years. As previously announced, Q4 will of course be impacted by the execution of the Alder transaction which brings us into a net debt position. With that please turn to slide 4.

Our four strategic brands are generating substantial growth. Up 29% in aggregate adding DKK 1.5 billion in sales compared to the first nine months last year. These growth products constitute more than half of Lundbeck's sales. Each of the brands has achieved double-digit growth and is growing in all regions. The continued growth in these strategic brands is a testament to the value these products provide to patients as well as the excellence in execution by our organisation around the world.

Next slide please. Revenue from Brintellix/Trintellix reached DKK 2 billion in the period. Growth of 31%. 54% of the revenue was generated in North America. In the US, Trintellix continues to increase its market share. We saw strong demand growth in the first nine months driven by an increase in new patients as well as improved persistence on therapy. I am very pleased to see that this brand is growing dynamically at 30% in its 6th year on the market reflecting the patients' and physicians' appreciation of the benefits it provides in treating depression. Trintellix is the biggest branded anti-depressant by value with the US market share exceeding 25%. Demand growth was 22% in the third quarter. In the major European countries, Brintellix is approaching a 10% market share. In China, we are encouraged by the progress but it is still early days given that we launched last year and are still awaiting public listing for reimbursement. We are happy to report that Trintellix was approved in Japan in September this year and together with our partner Takeda, we will launch once pricing is finalised later this month. Depression affects approximately 2.5% of the population in Japan. Over 3 million patients. We firmly believe that Trintellix will be an important new treatment option

for patients and healthcare professionals in Japan. We foresee this brand continuing to grow well into the future.

Please turn to slide 6. Rexulti is still mainly a US franchise. In Europe, the product has been launched in Denmark, the Netherlands, Norway and Switzerland. Additionally, outside of Europe, it is launched in Australia, Chile, Mexico and Saudi Arabia and more countries will launch in the coming year. As you can see from the graph, the significant uptake continues. Rexulti achieved more than DKK 1.6 billion in sales for the period representing impressive growth of 35%. The demand growth is a healthy 22% in the third quarter impressive in its fifth year on the market. Rexulti's US value share has increased from 13% to 15% since January of 2018. Johan will elaborate on the progress with additional indications for Rexulti in a minute. Let me just say that we continue to have high expectations for this product as Rexulti has an attractive profile and is highly valued by the medical community.

Please turn to slide 7. Abilify Maintena grew 23% approaching DKK 1.5 billion for the period with strong double-digit growth in all regions. Abilify Maintena was launched in 2013 and volume share approaches or exceeds 30% in markets such as the UK, Italy, Canada and Switzerland and it is continuing to gain market share. In many markets, Abilify Maintena is now the second most prescribed long-acting injectable treatment for patients with schizophrenia. At the American College of Neuro-psychopharmacology Conference in Florida in early December, data from the so-called PRELAPSE study led by doctor John Cain will be presented. This study included patients early in the course of their disease and demonstrates the feasibility of engaging the overwhelming majority of early-phase patients in the use of LAI when the clinical staff are appropriately trained. The use of LAI in this population produced a significant delay in time to hospitalisation.

Turning to slide 8. Northera grew 25% finishing the period above DKK 1.5 billion. There have been quite a few moving parts for this product in the last 12 to 18 months. In this quarter, we see good volume growth of 18% against the lower quarter last year where we experienced a temporary backlog based on moving the patient hub. We do continue to expect good volume and value growth for this product in 2019 and beyond.

Next slide please. Our North American region is overall impacted by the expected generic erosion of major brands such as Onfi and Sabril. In spite of this, we are very pleased with the strong growth of our strategic brands which now constitute more than 70% of the regional revenue. Actually, if one takes out Onfi from the equation, then growth is 13% for the period and a very strong 15% for the third quarter. North America constitutes 56% of our revenue.

Next slide please. International markets increased 8% reaching DKK 3 billion for the period or 24% of our revenue. This region is still in the early part of the roll-out of our strategic brands which show growth of 38%. 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 and we have now established our own commercial organisation for the planned launch of Trintellix in the coming months together with our partner, Takeda.

In China, our second largest market overall, we are progressing the launch of Azilect and Brintellix. It is early days for both products as it takes time to obtain national reimbursement listing in China. We did obtain this in September for Azilect.

Next slide please. Europe is delivering strong growth with revenue increasing 7% to DKK 2.4 billion. The European region is an important part of our overall performance and is driven by our strategic brands which grew 27% and now constitute more than 50% of the sales in the region. Rexulti is launched in

Denmark, the Netherlands, Norway and Switzerland. The launch of Rexulti in some of the larger countries in Europe will take place in 2020 so we look forward to continued growth in this region.

Next slide please. As announced on 22 October we have now successfully completed the acquisition of Alder BioPharmaceuticals and the integration is progressing rapidly. The acquisition of Alder brings the exciting investigational drug Eptinezumab into our pipeline expanding the breadth of our portfolio into migraine. This represents a major step in the execution of our Expand and Invest to Grow strategy. Lundbeck can now take part in helping the migraine community where so much unmet medical need remains. I assume you are all aware of PDUFA action date on 21 February for Eptinezumab. We are also working on the Canadian submission planned for Q1 next year as well as the European submission which will likely be towards the end of 2020.

Next slide please. Migraine is a serious neurological disease and according to the UN's Global Burden of Disease Survey, it is the most disabling of all diseases for people under the age of 50. There is a high unmet need for new, effective and well tolerated prevention options. According to the Chronic Migraine in America survey, 9 out of 10 patients don't use preventive therapies or discontinue its use within 6 months to a year because they experience a lack of efficacy or develop side effects. And even for those patients where the treatment is effective, it can take weeks or months to achieve meaningful clinical benefit. The results of the pivotal programme for Eptinezumab in the PROMISE I and PROMISE II trials clearly demonstrated a powerful, fast and sustained response to Eptinezumab. Patient-reported outcomes were also significantly improved. We believe Eptinezumab will offer a unique and differentiated value proposition to patients and those that care for them. Our market research has uncovered that symptom relief and quality of life measures are extremely important to migraine patients and that most patients will choose a product based on its effectiveness and speed of prevention effect. Given Eptinezumab's clinical profile, IV-administration is not a barrier for them. We also note that in the US, most of the specialists treating migraine patients have ready access to IV-delivery capabilities. I will now hand over the microphone to Anders Götzsche to expand on the corporate financial picture.

0.13.40

Anders Götzsche

Thanks, Deborah. Please turn to slide 14. I will turn to our financial numbers but firstly conclude on the Alder transaction. The financing of the deal is complete. We are financing the deal through existing cash reserves plus bank financing. I think it is important to reiterate that we expect the transaction to be core EPS accretive in 2023 and that we expect to stay within our current financial policy being investment grade. However, you will see us invest significantly into this asset in order to get the full value out. We are currently establishing the commercial infrastructure in the US for the planned launch next year. We are starting programmes to expand indications and we are also initiating a phase III b study to support the European market access process following approval. For 2019, transactions costs are expected to reach around DKK 200 million and there will also be integration and retention costs which we expect to reach between DKK 400 and 500 million of which DKK 50 to 100 million will hit the profit and loss in 2020. Additionally, we recognise some two months of operating expenses totalling DKK 325 to 400 million.

Next slide please. Deborah has already elaborated on our performance for the strategic brands so no need for me to do that as well. In the first 9 months of 2019, we saw a decline in our sales from Onfi in line with our expectations. Onfi will continue to decline and we have previously guided a decline around 70% versus last year. Revenue declined 9% reaching DKK 12.6 billion. This is driven by the loss of exclusivity for Onfi and Sabril which is partly mitigated by the strong growth from our four strategic products. Please also note that the effect from hedging has moved from a gain of DKK 308 million in 2018 to a loss of DKK 194 million in 2019.

Total costs are unchanged so we continue our disciplined cost spending and we even have DKK 55 million in transaction cost which is recognised under SG&A in the quarterly release. Cost of sales declined 7% to DKK 2.4 billion in the period. Our gross margin therefore reached 80.7%. This is fully in line with our expectation and we still expect the gross margin for the full year to be in the range of 80-82% of revenue. Based on non-GAAP numbers, the gross margin is unchanged.

We maintain good control over our operational cost. The SG&A cost only increased 5% which is mainly linked to FX, investment in China and Japan as well as other growth initiatives. The SG&A ratio was 36.8% compared to 31.7% the year before. The increase in the ratio is a consequence of the decline in revenue compared to last year.

R&D costs decreased by 3% to DKK 2.2 billion representing 17.6% of revenue. Considering the strong sales performance, we have managed our costs effectively. Thus reported EBIT reached DKK 3.3 billion and core EBIT reached DKK 4 billion. The core EBIT margin thereby reached 31.8%. We see this as a solid result which also creates the basis for our raised guidance and narrowed guidance range.

The effective tax rate is unchanged and consequently, earnings per share reached DKK 12.3 per share.

Please turn to slide 16. We expect continued growth for our strategic brands, Abilify Maintena, Brintellix/Trintellix, Northera and Rexulti which only partly mitigated the generic erosion on our mature portfolio. We have raised our expected revenue range to DKK 16.7 to 16.9 billion, which should be compared to our initial guidance in the beginning of the year of DKK 16.1 to 16.7 billion.

We will continue to be disciplined in our cost spend in 2019 but margins will be impacted by the closing of the Alder transaction as well as the impact from erosion of Onfi sales. EBIT is expected to reach between DKK 3.4 and 3.7 billion for the year which indicates a margin of at least 20% and for core EBIT, the implied margin is at least 28%. Please note that in the fourth quarter, some of the transactions, integration and severance costs will be recognised in other operating items, net. We expect this to be in a range of DKK 400 to 500 million and the remaining cost of DKK 400 to 500 million will be recognised in the individual cost lines.

For the financial items, you should expect a net amount of DKK 0 to minus 100 million depending on the currency development. The reported tax rate will be slightly impacted by the Alder transaction and will probably be in the high end of the range of 26 to 28% this year. It will also be slightly elevated in the next couple of years. It is important to note that the cash tax rate is somewhat lower and we expect it to be around 19-23% for the following years. However, be aware that due to utilisation of NOLs, there will be swings between the years.

We are currently early in our budgeting process for next year so I will refrain from being too specific on the cost ratios for 2020 but we will invest in building a strong Eptinezumab franchise and just to give you some input to your modelling, you need to include some DKK 2 billion in additional operational expenses for 2020. Amortisations regarding these assets will furthermore amount to around DKK 0.5 billion.

Next slide please. Lundbeck continues to generate a solid cash flow, although the period has been impacted by some major payments which certainly also will impact Q4. Cash flow from operations has declined from DKK 4.6 billion to DKK 2.2 billion first and foremost as a result of the lower profit following Onfi erosion and a decline in working capital as a result of the payment of the settlement with the Justice Department and fluctuations in other short-term liabilities. The net cash outflow reached DKK 632 million compared to a cash inflow of DKK 694 million last year.

We expect the net debt position by the end of the year to be around DKK 7 billion, mainly as a consequence of financing the Alder acquisition. With that I would like to hand over to Johan to provide an update on our R&D pipeline.

0.21.53

Johan Luthman

Thank you Anders. Please turn to slide 18. This is our current R&D pipeline and you will note it looks materially different from the beginning of the year. Around half of these products were not included in February. We are continuing executing on the Expand and Invest to Grow strategy by carefully adding external products to the pipeline. Also, we continue to aggressively move early stage products forward. While being disciplined to close down less attractive products as early as possible.

Next slide please. As you know, we have a comprehensive life-cycle management programme ongoing for Brexpiprazole. We have begun the first of two planned pivotal studies in PTSD. PTSD is the constellation of symptoms that emerge following traumatic life events causing significant impact and disability. Currently there are only limited treatment options and therefore a substantial unmet medical need. The first trial initiated tests of flexible dosing schedule while the second study which also commences soon tests a fixed dose schedule. In total, we expect to recruit some 1,250 patients in the programme. We expect to finalise these studies during 2022.

Next slide please. Last quarter we told you that we would begin a proof of concept trial with Brexpiprazole in borderline personality disorder. And this trial is now underway. BPD is another serious psychiatric condition with substantial unmet medical need. There is no drug approach for this challenging condition. We believe that Brexpiprazole with its multinodal mechanism action may well have the ability to address a range of the symptoms of this serious condition. The study will be a two-armed flexible dose study and it is expected to enrol some 240 individuals. In October, FDA designated this programme as a fast-track development programme.

Please turn to slide 21. In June last year, Lundbeck and Otsuka started a third clinical phase III study of Brexpiprazole in the treatment of agitation in Alzheimer's disease. More than 220 patients are expected to be enrolled in the trial and patient recruitment progresses as planned.

Next slide please. As I said in the beginning, we continue to move early-stage products forward and during the third quarter, we had included three first-in-human products in our pipeline. We have replaced our former PDE1-inhibitor product which we terminated in the beginning of the year with 88434 which has a specific inhibition profile of the PDE1b subtype of the enzyme. PDE1b is highly expressed in brain regions involved in cognitive processing and we believe inhibition of this enzyme may have a potential in addressing cognitive impairment in conditions such as schizophrenia and Alzheimer's disease.

We have also begun a phase I study with an antibody targeting Tau, a protein that plays a role in Alzheimer's disease. This antibody targets species of Tau that are believed to be implicated in so-called tau seeding, a process that is thought to be critical in the spreading of the tangle disease pathology in the brain.

Finally, Lu AG09222, which we have acquired through Alder, has also recently commenced phase I. 09222 represents the potential new therapeutic option for migraine prevention. This monoclonal antibody inhibits pituitary adenylate cyclase-activating polypeptide (PACAP) binding to its receptor a mechanism that is distinct from inhibition of CGRP. PACAP and its receptors have been found across the pain processing pathway and increased levels of PACAP have been found in blood samples of patients experiencing a migraine attack. In pre-clinical studies, 09222 has been shown to be selective, high-affinity antibody to PACAP that are demonstrated in vivo engagement of the target.

In phase 1 programme of O9222, we will enrol approximately 100 healthy volunteers to assist in safety, tolerability and pharmacokinetic profile at various doses.

Initial results are expected in the second half of 2020. With that now back to Deborah.

0.26.45

Deborah Dunsire

Thanks, Johan. Looking at slide 23, 2019 has been a busy and exciting year so far. This is the list of selected deliverables we set up in February and we have actually delivered on most of them although I recognise that the outcome of Brexpiprazole in bipolar mania was a negative surprise. Unfortunately, we also experienced delay in the finalisation of the Phase II study with foliglurax and now anticipate this being completed in the first half of 2020. We will continue driving our current business forward as we execute on our Expand and Invest to Grow strategy.

Next slide please. To summarise, leveraging our deep neuroscience expertise to restore brain health 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 for your interest and open the Q&A session.

0.28.04

Marc

Deborah, obviously, Alder and Abide are two deals this year, just curious what your thoughts are on business development and how active you guys are behind the scenes – you know what kind of deals you are looking at, how things have changed and if you will, you know, give us a sense of just how many deals you are looking at just so that we have an understanding of when to expect something else and then you talked about doing a study for Alder for Europe. Can you tell us a little more about that study and what needs to take place before that project can move into Europe? Thanks.

0.28.41

Deborah Dunsire

Thanks, Marc. First of all, we have made two acquisitions this year, we are supplementing our pipeline, we are executing on Expand and Invest to Grow. In the next couple of months, what we need to do first and foremost is make sure that we support the approval and launch of Eptinezumab and really get this integration done effectively. We do of course continue to scan the environment and look at things that will fit with Lundbeck's strategic capabilities in neuroscience and sometimes opportunities present themselves either for partnerships or licences or even acquisitions and you need to act when the opportunity arises. And so we continue that work, ideally I would love to keep us focused right now, we have got a big job at hand, but we will not overlook opportunities should they come our way. And it will across all phases of the pipeline and across all deal types that we would be examining. So I will stop there with that and then hand over to Johan to comment on what is required for Europe.

0.29.51

Johan Luthman

Yes, thanks Mark. So we are planning to do something we call a phase III b study for Europe to make sure that we have the optimal package basically for the European environment to optimise for market access and also include the current therapy landscape with a preventive therapy so that is the idea with this study

so we are expanding a little bit on the previous good ideas by Alder but we need to have a more comprehensive study in Europe going forward.

0.30.30

Operator

Next question is over the line of Wimal Kapadia of Bernstein. Please go ahead, your line is now open.

Wimal Kapadia

Okay, thank you very much for taking my questions. Wimal Kapadia from Bernstein. So you guided to an incremental DKK 2 billion in spend next year for Alder, so firstly how should we think about the split between SG&A and R&D? And secondly how should we think about the trend moving forward, is DKK 2 billion a fair reflection of incremental cost over the long term or should we expect that to reduce over time? My second question is on CipraleX. Clearly had a strong quarter by benefiting from some of the inventory stocking in China. Can you quantify should we expect a similar benefit in Q4 and then is China enough to actually grow international sales for CipraleX in 2020? And then my final question is on the pipeline, there is currently lots of activity with multiple trial starts in recent months and you were expecting multiple readouts in 2020 so which data sets are you most excited about in 2020? And why? Thank you very much.

Deborah Dunsire

Wimal, that was a lot of questions. Anders is going to start. The Jacob will address China and then Johan will address the pipeline and then I will finish up.

0.31.44

Anders Götzsche

Okay what we tried to do in this quarter was to give you early heads-up on what we expect for 2020 from a cost perspective taking the Alder cost base into Lundbeck. But of course also what we are doing now is we are reviewing the business. We are reviewing how much cost will be – you know, make a more precise estimate so what we know for sure is that next year will be the US launch and then we will start the European launch and the Canadian launch after so we haven't finalised the numbers and what we of course need to do is to go through each and every country and see what is needed of additional costs. Will it be incremental? Will it be possible to utilise the existing infrastructure and sales force so it is too early to speculate about that. The split will be more or less that you could say more or less 50/50. 40 to 50% will go into R&D, 40 to 50% will go into Commercial and then we will have some additional cost for our hub in Seattle so that is more or less how you should think about it.

0.33.07

Jacob Tolstrup

And regarding China. Absolutely correct that we have some timing and some phasing. I think you have to look towards last year when we had stocking in the first half of the year going to our partner at the time which was C.N. Jensen, so absolutely correct that China is delivering more growth now because we are getting into the second half and we have more you can say traditional distribution of our revenue in China for this year. And that also means that the fourth quarter will be strong for CipraleX in China also. I think also for your last question, China alone will not be able to drive growth for CipraleX, but we also have other markets where we do see growth for CipraleX/Lexapro so that also means if we look for Europe International Markets for the full year, I do expect the flattish to slight growing CipraleX for this year.

Deborah Dunsire

Johan would you like to comment on what is most exciting about the readouts in 2020 and beyond?

Johan Luthman

Yes, so obviously we have a number of activities going on across the portfolio but when it comes to the bigger programmes, we have the agitation in Alzheimer's disease coming up which is the – as you know- very, very high medical need so that is one of the most exciting and of course with established brands we are really looking forward to get that third trial readout. We have of course in the pipeline some smaller read-outs in phase 1 and 2 but I probably will not go into those right now, those are more forward-looking programmes that we come back to in more detail in the future.

0.34.45

Deborah Dunsire

I think what I am pleased with, with the pipeline, is that the shape we now have more in later stages than we have at the beginning of the year. We have got four trials in phase II – three of them will read out in 2020 and then a good amount, five new programmes into the phase I pipeline this year, which gives us the opportunity to be disciplined and taking forward only the best ones down the line so I like the balance that is developing in this portfolio.

Wimal Kapadia

Great, thank you very much.

Operator

Our next question is over the line of James Gordon at J.P. Morgan, please go ahead sir, your line is now open.

0.35.24

James Gordon

Hello. Thanks for taking the questions. James Gordon from J.P. Morgan. I have two Alder-related questions, please. The first one would just be on CGRP sampling and discounting. If we look at the ramp-up of the products that have already launched, it looks like quite a lot of free products sampling and more recently some very heavy discounting or rebating particularly we saw that for IVIVC, So how do you think the US market might play out in that regard? Are you likely to have to do very heavy sampling as well and is there a reason to think that you would not have to talk about the same sort of discount so are you protected from that in some way? Or long-term is this likely to be a very competitive space with lots of rebating for a long time and we need to bear that in mind when we are thinking about the net price you might achieve for a product like that. And my second question will also just be on Alder and CGRPs. How competitive do you think the oral products are going to be? Are they a big competitive threat? And is that something that Lundbeck is going to pursue and are you going to do an oral approach as well?

0.36.15

Deborah Dunsire

Okay, I will ask Peter to start on the first part of the question and maybe Johan can comment on the second part.

0.36.22

Peter Anastasiou

Yes, James, this is Peter. As we look at the CGRP market and the migraine market in general, I think it is a market that is revealing itself to be quite dissatisfied. There is a lot of interest despite the fact there are many treatments and now new treatments in the marketplace we see the uptake and adaption of some of these therapies as a sign that the Alder therapies just aren't meeting patients' relief. There were some stats in the manuscript that Deborah and Johan have described around migraine that reveals a very dissatisfied market because of the lack of efficacy and because of tolerability issues. In terms of your question with

regard to discounting and that sort of thing, we certainly won't get into as in the past with any of our products we don't talk about our discounting strategies in gross to net. I will say that it is important for all of you to consider the difference in administration of Eptinezumab and other products whether they be oral or subcutaneous, this is an infusion therapy that is typically paid out of the medical benefit. It is a medical procedure and so there are key differences in the way it is administered that I think will lead to some differences from a reimbursement perspective but the other thing I would highlight is the clinical profile as Deborah has mentioned and Johan has mentioned. This is a strong clinical profile with powerful results, fast results and also sustained being only once a quarter administration.

Deborah Dunsire
Johan

0.37.57

Johan Luthman

Yes if I may just expand on a little bit first. I mean, obviously, the CGRP mechanism is a very powerful mechanism that has been explored by various approaches as you know. Small molecules and monoclonals and we have a very good position here with the IV-treatment. Peter mentioned the rapid onset which obviously is one advantage with the IV-approach. We have, looking at this at a little broader level also, we are going to work in this field also with the new entrance that we have – the 09222 compound which is a take-up molecule so we are going to approach this biology also with other mechanisms that we believe will take some of those that are a little more treatment-resistant to the current CGRP therapies.

Deborah Dunsire

And the question was around orals.

0.38.47

Johan Luthman

Yes, and the orals, as you know, they are primarily progressing with acute treatment. Now that is the first wave. Then they come after with later trials in more preventive space. The oral drugs have of course a little different mechanist action. They block the receptor. We are now locking the ligand and there is a little bit of different biology when you deal with this and the perceived effect of taking out the ligand is actually somewhat stronger than what you see with blocking the receptor.

Deborah Dunsire

Thanks. Next question.

0.39.27

Operator

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

0.39.34

Emily Field

Hi, yes, a few more questions on Alder. I was just wondering how much of the incremental R&D spend is going to be allocated to the advancement of 1910 versus additional spending on Epti and just how long you would expect this European phase IIIb study to take just given that the CDR has some timing constraints and then also regarding the planned acute study for Epti, I am just kind of curious what the incremental benefit would be of having this inclusion on the label given that it seems like the plan is already to promote for the faster onset of action and assuming orals are approved in the acute setting, I am just wondering if you could expound on what you see the benefit of running this study would be. Thanks.

0.40.21

Anders Götzsche

I can start with the R&D spending. Most of the additional R&D spending will go into Eptinezumab. It will be the trial to support the market access in Europe. It will be the treat and prevent study and then of course if you look more ahead in the future, then of course other life-cycle management initiatives will also be taking some R&D spending but of course, PACAP is in the early stage. It is phase 1 programme so therefore it goes without saying that the majority of the spending is in Eptinezumab.

0.40.57

Deborah Dunsire

Great and then Peter would you like to comment?

0.41.00

Peter Anastasiou

Yeah, with regard to the treat and prevent study, Emily, you know first of all with the launch promotion of the label we can't speculate on what will be in the final label but clearly we have some nice data from the PROMISE I and PROMISE II trials but we believe that this is one of the strong benefits and we have got some evidence to support it now but we want to bolster that evidence base about this very important concept of rapid onset of prevention and so we believe that making the investment will be something that will help us continue to bolster that claim and let us not forget that we have exclusivity for many years with this asset going into the mid-2030s so you should expect that we will continue to invest in a strong life-cycle management programme and probably the first steps in that life-cycle management programme are these studies that we are talking about for Europe and also the treat and prevent study.

0.42.00

Deborah Dunsire

Can I just amplify that by saying when you think about PROMISE I and PROMISE II, we know already on the day after infusion that you get more than a 50% reduction in the number of patients experiencing a migraine. The treat and prevent study will characterise the slope of that curve, if you like. How fast does the migraine get controlled in the setting of delivering 12 weeks of preventive therapy. So that will finish up there. Next question. No sorry, Emily, did you want to say something more?

0.42.38

Emily Field

Oh no, that's helpful, but just on just on the timing of your European phase IIIb expectation if you can comment on that?

0.42.47

Deborah Dunsire

I think we expect to start the phase IIIb trial in the middle of the year and deliver results towards the end of the year or early 2021.

Emily Field

Thank you.

Operator

Okay, in that case, our next question is over the line of Danske Bank and Martin Parkhøi, please go ahead. Your line is now open.

0.43.00

Martin Parkhøi, Danske Bank

and I actually also have a couple of questions on the Alder. Just coming back to the US pricing discussion, I don't expect you to give some kind of net price guidance but anyway that if you listen into the conference call of the players which have launched in this space so far, then it appears that then the pricing has been somewhat lower than even was suggested in the ICER review so have you changed your assumption to the net pricing in US during the process? Then secondly, if we look into 2020 and you expect a launch in Q1 but what kind of uptake should we expect because on the contrary to the existing products in the market then I guess you need a J code for your product but how does that impact uptake? At least the speed of uptake. And then thirdly, should we actually regard this more as a non-US opportunity? As I see it, the price that Novartis has obtained for Aimovig in Europe is probably more favourable than the price that ??? 0.44.22 has for the same product in the US.

0.44.25

Deborah Dunsire

Great, so thank you for the questions. On US pricing I think our assumptions when we went into the deal are consistent with our assumptions now and we don't speculate on pricing. Peter, do you want to comment further and comment on the J code and then Jacob, you can talk about ex-US.

Peter Anastasiou

Yeah there is nothing further to add on pricing. On J code, you are correct because this is a medical procedure. There is not a product-specific code that will be available from day one. The CMS has changed how rapidly they turn around J codes so we believe it will be a year or less in having that J code. There are temporary J codes that we can access at the beginning, but clearly having the permanent J code is what we will be working towards but our launch expectations that we have internally in uptake we are taking that into consideration.

Jacob Tolstrup

So just to add, Martin, on the ex US. Of course the US is the most important market for us due to its size obviously but I think like you we are very encouraged about pricing levels that we see for ex-US in Europe and one thing with the phase IIIb study that we are doing is that it is going to support us going into those discussions so the plan is that we have that study once we are ready to have those discussions with the authorities in Europe but you are right, very encouraged at this timepoint but we have maintained that price assumption throughout the whole deal, transactions with Alder when we started that some time ago.

0.46.03

Deborah Dunsire

And just circling back to our strategy Expand and Invest to Grow encompasses the world and one of the things that we have always liked about the Alder transaction and the Eptinezumab launch is that it will be a global launch for Lundbeck. Our colleagues at Alder have done a great job building the brand but we really have the global reach to make this a global brand for patients.

0.46.34

Martin Parkhøi

If I just can follow up with respect to the J code. Just to make sure that so if before you have a permanent J code, then don't you expect any kind of material sales and I allude to 2020. I see from the schedule 14D9 from Alder. They have some quite substantial sales in all their scenarios but does that include that J code impact?

Peter Anastasiou

We won't speculate on our projections for the product certainly for the first year but we do have that built into the temporary and then permanent J code into our own expectations, but even with a temporary J code, of course sales are able to take place and clinicians are able to utilise the product and get reimbursement for it. It is a little less clean of a process that when we have a product-specific permanent J code, but all of that has been built in and this is not unique to Eptinezumab. Any product that is infused in an out-patient setting or for that matter any product that is administered as a procedure has the same exact issue. And all of that is built into our expectations.

Martin Parkhøi
Thank you very much

0.47.57
Operator

Our next question is over the line of Philippa Gardner at Jefferies. Please go ahead, sir. Your line is open.

Hi, it's actually Peter Welford at Jefferies. A few questions left, please and firstly just with regard to the OPEX build around DKK 2 billion during 2020 of which I think around half would be on the commercial side. I guess we are returning to some extent to Vimal's question. Can you give us some sort of an idea that in terms of that 2 billion or I guess 1 billion of commercial spend, how far along is that in the US roll-out and is that basically then a full sized US infrastructure we should be thinking about or is there still further US investment that will be required beyond that to maximise the potential in the US market? Secondly then just on the financial expenses. I wonder if you can give us any sort of idea for 2020 what we should be thinking about ex-FX obviously or alternatively some sort of idea for what the average financing cost is for the net debt. Do you believe to the year-end of this year and then finally just briefly on China – just with regard to you said you got reimbursement in September for Azilect, I wonder if you could give us a timeline perhaps for some of the products? And also, if possible, any commentary on whether or not Cipralext could or when it could perhaps be considered in a 4+7 or value type programme in China, how we should think about that? Thank you.

0.49.19
Deborah Dunsire

Okay, so thank you for questions. Regarding the US infrastructure, we will be hiring in a sales force to support the launch of Eptinezumab and making the appropriate investments to support the brand in the market, which includes additional further studies so Peter, I don't know whether you would want to comment? We are not specific for each year. Anders, do you want to?

0.49.45
Anders Götzsche

Yes I think it is a great question because of course what we will do is we will hire in the reps from the beginning of the year so in that respect, we actually have a fully fledged commercial organisation but of course the launch will first take place in the beginning of April and therefore you could foresee in the years to come that we will invest more in promotional activities but you also need to take into account that what we are also facing in 2021 is a loss of exclusivity for Northera so of course we will make a balancing act about securing that we have the right cost balance and utilising the very strong sales force we have for all the US products to create the optimised or make synergies between these sales forces so that is of course what you cannot – we are not going to predict today, but so you need to say 2020 as an isolated year and then when we move ahead as I also said or told you about Europe before, we would also look into Europe as we have been doing in the past. How can we optimise and structure all the sales forces at the right level to secure the right push in the market? And that is how we will approach it.

Deborah Dunsire
Peter

0.51.03

Peter Anastasiou

Yes and I would just like to add in general in terms of launch progression and planning, the Alder team has done a very nice job and I think we are in very good shape preparing for launch and many of the Alder leaders will continue and help us maintain that institutional knowledge and that therapeutic expertise coupled with the great infrastructure and commercial experience we have had having launched 7 products in 8 years very successfully in the US and so it is a really nice marriage of their preparation and expertise and then certainly the infrastructure that we have at Lundbeck.

0.51.40

Deborah Dunsire

Would you like to comment on the cost of debt question?

Anders Götzsche

Yes we have financed the debt with RCF and also a DKK 2 billion debt facility. Our term loan. And we are now evaluating how we are going to finance and it will be partly in Euro and partly in dollars so for the Euro loan, it will be less than or around 1% in total cost but of course the dollar loan that will hedge the exposure for the US will be more expensive. It might be up to 3%. We have not finalised the split but you should expect it to be maybe between 1 and 2%, the interest rate on our debt, and we start the year with DKK 7 billion and then we will of course, then you can yourself calculate what is kind of average interest we will have for 2020.

Deborah Dunsire

And I will hand it over to Jacob to comment on your China question.

0.52.50

Jacob Tolstrup

Yes so Peter I think the first question was around the – with Azilect and you are absolutely right, we are now on the regular list for Azilect and that means that for the beginning of 2020, then Azilect will be in our deal and that still means that there is some work to do in terms of getting it into the different provinces but it is great news and a clear recognition of the benefit that Azilect also provides for patients in China. I think, I missed a little bit the second part of the question. Maybe it was a general question or it was related to Lexapro only regarding 4+7 but even before going into 4+7 with Lexapro, we had lost the majority of our sales going to generics. In the 4+7, we of course lost more due to volume as we did not go in and try to bid for the winning price and the expansion then of the 4+7 will have an impact but less so as the regions that it is being expanded to are the regions where we had already lost quite a significant portion of sales to generics. But I don't know if that was your question or it was more generally related, Peter?

Peter Welford

No, that is great. Thank you.

0.54.09

Operator

Okay, could I please go over to the line of Peter Sehested at Handelsbanken. Peter your line is now open, please go ahead.

Peter Sehested

Yes hi, thank you. It is Peter from Handelsbanken. Just a couple of questions left here. Could you please remind us about the amount that you have booked in the balance sheet for Foliglurax? Secondly, with respect to again Alder and costs, should we have any hopes for let us say synergies coming out of this acquisition on the cost side or should we basically see it as a – or should we mainly see cost relating to the acquisition or the OPEX expense as increasing for the next 2-3 years? Basically in line the scenarios which were in the 14D9 filing that Martin mentioned? Thank you.

0.55.04

Anders Götzsche

Foliglurax. We have € 100 million on the balance sheet and of course, what we need to take into account when we make our guidance for 2020 is that there is of course a risk if the data are, you know, show no signs at all and our R&D folks say this will not show any improvement for patients going forward in whatever indication we can think about, then we need to take a write-off. That is how the mechanics work but it can also be other scenarios, you know, it can be mixed data, it can be of course if it is a yes – if it is good data then we keep with the balance sheet position and then we see how the next phases are developing. If it is mixed data then we need to make an evaluation of what can it be used for so there are different outcomes but if you want it black or white then it is write-off or keep it on the balance sheet. I think, with the synergies, I think it is back to what I said before you know, we have acquired Alder because we believe that we will be some of the best in the world actually to launch this product. We are a specialised pharma company. We are extremely good working with these specialists. We have shown that over decades and therefore we also have a strong backbone platform so we will of course utilise the commercial platform, the commercial launch in the US will be driven out of Deerfield where we have our home office in the US and of course Alder will be heavily integrated into Lundbeck but we will also build on the strength that they are coming with, excellent data package, excellent knowledge about the market and therefore we are thankful that a lot of these folks will stay and be integrated into the commercial operation so there will be synergies but we are also decisive that we want to secure that this will be a blockbuster drug and we will launch it globally. And this drug can actually – will solve, hopefully if we execute well, some of the strategic challenges we had in the past. We wanted to strengthen the pipeline. We wanted to secure that we also continue growth in Europe after loss of exclusivity for Maintena. We will already from hopefully next quarter and definitely from next year start to see growth again in the most important market in the world, US, and therefore we think this is a great deal and it is a great fit for Lundbeck.

0.57.48

Operator

The next question over to the line of Jo Walton at Credit Suisse. Please go ahead your line is now open.

0.57.55

Jo Walton

Thank you. I think if we look at the consensus earnings estimates, a DKK 2 billion increase in operating expenses was not in most people's minds for 2020. You have told us about where that fits between R&D and SG&A but in order to help us understand how much of this is a fixed new incremental base level of infrastructure, I wonder if you could help particularly on the selling side, tell us a little bit more about what your investment plans are. You have talked about building more of a sales force in Japan. You have told us that you are going to be rolling out Rexulti into more EU major markets next year. I wonder if you could help us look at that perhaps ex-US infrastructure build and presumably when it comes to your migraine drug that will be able to sit on top of your existing infrastructure to a greater extent in Europe or come 2021 when you are looking to roll that out in Europe, should we see another material increase in infrastructure at that time point ex-US? Many thanks.

0.59.09

Deborah Dunsire

Thanks for the question, Jo. I will start and then pass it over to Jacob to talk a bit further. I think that first of all that the roll-out ex-US will come a bit later. We are submitting Canada in Q1, Europe towards the end of the year so we will see the European roll-out probably in 2022 and beyond and we probably will have the need for some additional infrastructure given that Abilify Maintena is still growing strong as is Brintellix but we will evaluate. I think you can count on this company to be very disciplined in evaluating what is needed and taking as much use of the resources that we have in all our markets as possible and Jacob, I will ask if you have any further comments?

0.59.55

Jacob Tolstrup

Yeah you know, absolutely correct so I think we can say for now that we expect sort of a limited increase and I think you also mentioned Rexulti as an example. Rexulti we are launching in Europe without any additional head counts utilising the infrastructure that we already have and then you are right that in Japan and China, we can build up but there are all sorts of things that have happened during 2019 and we are not planning to expand more in 2020 so I think for Epti right now, it is further out as Deborah said so 2022 and beyond but we expect a relatively limited increase.

1.00.41

Jo Walton

And could I just also ask your epti dosing frequency is every quarter. How do doctors feel about that? As I understand it, they really only look to see their patients every six months or so. Are they happy to see a patient and then say come back and you know it is two times as often as they would normally see them so it is clearly it is much easier to give them a prescription and say go away and do home administration every six months and come back six months later. Is that seen as a block that once a quarter dosing?

1.01.20

Peter Anastasiou

Yeah, the short answer is no, it is not a block at all. I will give you the physician perspective and then I will give you the patient perspective from our research and certain advisory boards and that sort of thing. The physician perspective is actually in our research that these headache clinics which is going to be most of our focus at the beginning typically see their patients every three months so it fits quite nicely with the frequency that they are seeing their patients already. They do administer other therapies once every three months like botox for migraine so that is not an issue at all. Quite frankly, it fits quite nicely with their treatment practice. From the patient perspective, we have consistently learned that the most important thing to a patient is relief. These migraines are extremely debilitating, painful and really hurt their quality of life. So for them, there is no concern about an IV. In fact, what we also see is that there is a lot of confusion and apprehension among patients with injecting themselves with the subcutaneous treatment so they worry about, are they doing it right? Have they created any kind of issue? They actually prefer physician-administered therapies in general and a 30-minute infusion for a patient who can be sitting there and simultaneously be on their phone or watching TV or reading a magazine and doing that once every quarter is actually quite attractive from a patient perspective.

1.02.46

Deborah Dunsire

I think just the last thing to amplify on that is that don't lose sight of the degree to which these migraines are happening. This is the prevention group of patients who are experiencing the episodic 4-14 migraine days a month and in the chronic migraine, it is 14 to 28 migraine days a month. These are patients whose lives are extremely impacted by migraine so getting fast relief is above all important to them.

1.03.22

Jo Walton

Thank you.

Operator

Okay, so we have time for a final question and that is over to the line of Michael Novod at Nordea Markets, please go ahead Michael, your line is open.

1.03.36

Michael Novod

Thank you very much, it is Michael from Nordea. Just two questions. One last one for Alder or regarding Alder. When you talk to European physicians treating migraines, they talk about regarding Epti that infusion equipment availability may not be that great in Europe. It is obviously not a problem at all in the US. Do you hear anything about or have any expectations around bottlenecks in Europe regarding infusion equipment? And then secondly to Trintellix and the Japanese launches. It seems like Takeda is or what is raising their expectations near-term to Trintellix and near-mid-term expecting stronger growth. Is that, you think, related to the Japanese launch or other factors where you know that they are more positive on Trintellix going forward?

1.04.30

Deborah Dunsire

Jacob will start.

Jacob Tolstrup

Yes, great. So on Alder in Europe, obviously it is a little bit of a time away but the assessment that we have at this current point is in principle you are correct Michael in the sense that this is more of a hospital-based.. looking out for Europe as a whole. It is also important to remember that there are different market dynamics in the different markets in Europe so a country like Germany is obviously very different to some of the other markets. But you are right in the sense that it is more hospital-based. I don't think we see that as any big limiting factor but it is more hospital-based than it would be for instance compared to the US.

Then on Japan, maybe I should touch upon that briefly also. So we have, of course we have the approval for Trintellix. We are awaiting price that we hope to get here in November and then we will be seeing the first sale of Trintellix in Japan at the end of November and in December. Together with Takeda, we have what we believe, a quite.. we are quite hopeful of a very good launch in Japan where I think we have a very good partner and the physician interaction that we have had so far since the approval seems like very good appreciation of the product and willingness to try the product.

1.05.57

Deborah Dunsire

Yeah and just finishing off, Michael, I think on the Epti in Europe, remember again it is these chronic migraine patients, these patients who are very, very impacted so they are.. being seen in a hospital-based setting is not as much of a challenge. With respect to Trintellix and the bullishness you are hearing from our partner, we observe that too, not only based on an expected good launch in Japan but also very strong continued growth in the rest of the world based on the profile of the drug and its benefit for patients. So I think with that, we will finish up. And thank you for all of your interest in Lundbeck.