

Lundbeck teleconference H1 2020

Operator

Ladies and Gentlemen. Welcome to the H. Lundbeck Q2 2020 conference call. For the first part of this call, all participants will be in listen-only mode and afterwards there will be a question and answer session. Today I am pleased to present Deborah Dunsire, President and CEO, Anders Götzsche, Executive Vice President and CFO, Johan Luthman, Executive Vice President of Research and Development. Speakers please begin.

Deborah Dunsire

Thank you very much, operator and thank you all for your interest in Lundbeck. We want to welcome you to this teleconference covering our financial report for the first half of the 2020. As you have heard, together with me are Anders Götzsche and Johan Luthman but I am also joined by Jacob Tolstrup, Head of Commercial Operations, and calling in from Chicago, Peter Anastasiou, Head of North America. On slide 2, you can see the company's disclaimer and I know you have read it many times before so I am not reading it out, I am sure you will be glad to hear.

On slide 3, the first thing I want to say is something I already said last quarter, I am very proud of the way Lundbeck employees have responded to the immense challenges of the COVID-19 pandemic. They continue to put patients first while embracing and delivering on our Expand and Invest to Grow strategy. The pandemic has affected the delivery of health care in many, many ways. In the first quarter, we saw major discontinuities. Physician-patient interactions were severely interrupted as people sheltered in place and health care providers' capacity was redirected. Our market facing employees were also completely out of the field. We saw people stocking up on medicines across all parts of the chain from patients in their homes to the distributors. As the situation has slowly begun to return to somewhat normal in the second quarter, we have seen the stocking effects unwind. Overall, I would say that the first half in totality is a more balanced reflection of the underlying performance of the business than either quarter alone. We are pleased with the development of the business in the light of the challenges delivering overall growth in revenue of 5%. Our strategic brands continue to show remarkably strong growth both in volume and value across all regions. In total, our strategic brands grew by 25% and now constitute 60% of our revenue. In April, Vyepti was launched in the US. As you can imagine, that launch needed to be significantly adapted given the pandemic limiting patients' ability to see their physicians. Even so we have seen patients treated and they have had very good responses. We are acutely aware that 2020 is a year with more than usual uncertainty but in the first half, the business has delivered solid performance in the markets and costs have come down given the inability to conduct business in the normal way. Anders will elaborate on the financials in detail but I will simply state that we are reaffirming our revenue guidance and upgrading our EBIT guidance.

With that please turn to slide 4. Front and centre for all of us in the first half has been the impact on all aspects of life from COVID-19. Our priorities at Lundbeck have been and will remain preserving the health and safety of our employees as well as continuing to supply all our medicines to the millions of patients around the world who depend on us. We successfully implemented and embraced new ways of working, switching to virtual interactions internally and externally around the world. The COVID pandemic continues to impact clinical activities and while we are seeing some sites opening again slowly in the last weeks, it is still affected and Johan will elaborate on this in a few minutes. Currently we have not observed a meaningful impact to our business from increased unemployment but we don't yet know the longer-term implications if unemployment remains at elevated levels and a significant number of patients lose their commercial health insurance, particularly in the United States. We know that this continues to be a fluid and rapidly changing situation in different countries and regions and we will continue to adapt our work to local needs to best drive the business as we have done successfully in the first half.

Next slide, please. Our five major strategic brands generated substantial growth up 25% in aggregate adding more than a billion kroner in sales compared to the same period last year. There is healthy volume growth for all our strategic brands. These growth products constitute 60% of Lundbeck sales. I am going to touch on each of them individually. But overall, we expect these strategic brands to continue their double-digit growth in 2020. A testament to the value these products provide as well as to the excellence in execution by our organisation around the world.

Next slide, please. Starting with Brintellix/Trintellix, the revenue has reached DKK 1.6 billion in the first half of 2020, growth of 21%. If we only look at the second quarter, the reduced promotional activity combined with the stocking in the retail channel has muted the growth versus what we have seen in Q1. Beginning in mid-March, COVID-19 significantly reduced patients' visits to health care providers across psychiatry and primary care and that has impacted new prescriptions as the health care providers are most comfortable starting a new patient on medication or changing an existing patient's medication when they can see the person face to face. This has led to a flattening of even slight reduction in total prescriptions for major depressive disorder medications in the first half when compared to the end of last year. I will note though that the product continues to increase its market share and we are confident that we will see continued solid demand growth driven by an increase in new patients as well as improved persistence on therapy in the balance of the year.

Next slide, please. Rexulti is still mainly a US franchise although we are planning additional launches throughout 2020. The brand achieved close to DKK 1.4 billion in sales for the period and that represents impressive growth of 35%, particularly impressive given this is its fifth year in the market. The main driver of growth is increased volume demand in the US major depressive disorder market.

Next slide, please. Northera grew 19%, finishing the period just about DKK 1.2 billion. We continue to expect good volume and value growth for this product in 2020.

Next slide, please. Abilify Maintena which was launched in 2013 grew by 24% to close to DKK 1.2 billion. In many markets, Abilify Maintena is the second most prescribed long-acting injectable treatment for patients with schizophrenia. In the UK, it is actually the most prescribed brand and in the Nordics, it ties for first position. We continue to see solid growth in the overall LAI market and Abilify Maintena maintains its 19% market share.

Next slide, please. As you know, we filled the first orders and infused the first patients with Vyepti in April. It is very clear that the pandemic has significantly limited patients' ability to receive infusion products across all categories. Additionally, normal launch promotional activities could not happen during the shelter in place. The revenue for Vyepti is therefore not surprisingly below our original expectations. With that said, we are very encouraged with how the product is delivering for patients. Based on early feedback from both patients and their health care providers, Vyepti is fully delivering on its fast, powerful and sustained promise. We do see good progress in the number of practices ordering vials. 80% of the accounts purchasing are buy and bill for Vyepti which is consistent with our internal expectations. We are encouraged to see that accounts that are high volume anti-CGRP writers but who do not choose to buy and bill are able to refer to infusion centres when they prescribe Vyepti. On the market access side, we have made strong progress in obtaining coverage in both regional and national plans. Last week, the seventh largest plan – the Federal Employee Program – issued their policy for Vyepti and we now have access to more than 100 million patient lives without needing to go through a branded step edit. I will now hand the microphone over to Johan Luthman to comment on the R&D efforts.

Johan Luthman

Thank you, Deborah. Please turn to slide 11. The disruptions from COVID-19 impact our portfolio differently in different programmes and regions. The broad life cycle management programme on Brexpiprazole is heavily affected, although we are now beginning to be able to recruit patients in these trials again. In particular, the phase III study in agitation in Alzheimer's disease is impacted as a significant part of the patients enrolled are institutionalised and recruit most patients from the United States.

The timelines for our trials will be reassessed once this situation stabilises but the situation is improving as restrictions are being lifted. We have been able to initiate the DELIVER study with Vyepti and the VIVRE study with Vortioxetine and our early programmes are also starting to show good momentum. Importantly for Vyepti, we will substantially enlarge our R&D effort including several indication expansion studies. The first new indication will be a phase III studying cluster headache with some 300 individuals that is planned to start later this year. Vyepti has also been submitted for approval in six countries during the quarter, which makes a total of seven submissions beyond the US for Vyepti so far. The Canada submission previous quarter.

In our early development stage portfolio, I would like to mention that the lead campaign in our MAG lipase programme is planned to enter into four new Phase Ib studies from late 2020 and into the beginning of 2021.

Additionally, we have recently started phase I with the second programme from this platform. Finally, I would like to remind you of our communication last week of an early termination of the Proof of Concept study with the PDE 10 inhibitor AF11167 in negative symptoms of schizophrenia based on hitting the fertility boundaries in an interim analysis.

Next slide, please. All medical conferences since March this year have been virtual and American Headache Society conference in June we had several poster sessions including one demonstrating subgroup data in patients with medication overuse headache. Medication overuse headache usually coexists with chronic migraine or chronic tension type headache and is most often associated with overuse of medication to treat acute migraine attacks. Of the 1,072 patients in PROMISE-2, 431 patients equivalent to about 40% had a dual diagnosis of chronic migraine and medication overuse headache at screening. In patients with medication overuse headache, Vyepti 100 mg and 300 mg demonstrated a similar reduction in days of triptan use over 24 weeks of treatment which was greater than the reduction observed with placebo. Vyepti reduced mean days acute headache medication use including triptans specifically by around 50% over weeks 1 to 12 in patients with chronic migraine and medication overuse headache compared with about 25% with placebo. End results sustained were further decreased our weeks 13 to 24.

Next slide, please. The RELIEF study with Vyepti has finalised recruitment approximately two months ahead of time. The study was initiated in November last year in order to characterise the profile of Vyepti more detailed in the first 24 hours after infusion and to underscore its fast onset of action. The study has enrolled 485 individuals with migraine or eligible for preventive medication. The co-primary endpoint is to evaluate the effect of Vyepti compared to placebo with respect to time to headache pain freedom and time to absence of most bothersome symptoms during the current migraine. Included as key secondary endpoints are patients achieving freedom from pain and absence of most bothersome symptoms measured two hours after initiation of treatment. We expect to see headline data during the second half of this year.

Next slide, please. In June we also managed to initiate the DELIVER study, the phase IIIb study for European market access. The purpose of this study is to evaluate Vyepti in the prevention of migraine in patients whose treatment with other preventive therapies has been unsuccessful. The patients must have documented evidence of treatment failing in the past 10 years of 2 to 4 different migraine preventive

medications and to have a history of either previous or active use of treatments for migraine. The study is planned to recruit around 840 individuals. With that I turn over the presentation to Anders for a financial update.

0.15.22

Anders Götzsche

Thanks Johan and please turn to slide 15. Lundbeck's strategic brands have shown very robust double-digit growth for several years now. The compounded growth for the past 6 years shows impressive 90% growth. Further the compounded growth for the total revenue has been 4% for the last 6 years also supported by 5% growth in the first half of 2020. It is important to highlight that there has been no disruption in the supply chain or in the production which has secured that patients have had availability and access to their medicine.

Please turn to the next slide. We have seen 5% growth in net sales in the first half driven by the resilient Lundbeck product portfolio. Please recall that in the first quarter, we showed 8% growth benefiting from stocking and slightly increased demand and in the second quarter, we realised 3% as the positive stocking effect had been washed out. Cost of sales increased by 5% which is in line with the revenue growth and the gross margin is therefore unchanged at 80.7%. In the gross margin is included amortisation of product rights which was DKK 560 million for the period compared to DKK 424 million in the same period last year. SG&A costs for the period were DKK 3.4 billion compared to 3 billion in 2019. The SG&A ratio for the period was therefore 37.8% compared to 35.8% for the same period last year. The increase is mainly due to investments in the commercial organisation in the US, China and Japan to support the continued growth of Brintellix/Trintellix and Vyepti. Research and development costs increased to DKK 2.7 billion for the period. R&D costs are impacted by increased clinical activity for Vyepti. Cost related to the impairment of Foliglurax around DKK 800 million as announced in March 2020. R&D restructuring costs related to the changes in the R&D organisation announced in June this year. Adjusted for the impairment of Rexulti or Foliglurax and the restructuring cost, the R&D ratio was 20.6%. Core EBIT reached DKK 2.5 billion and the core EBIT margin faced a modest decline from 32.2% to 27.8%. It should be mentioned that the COVID-19 pandemic has also impacted the company's cost spend, which has led to a reduced operational cost of 6-7% compared to our expectations. The effective tax rate for the quarter is heavily impacted by the Foliglurax impairment, focusing on the core tax rate, it has actually declined to 17.5%. Finally, our net financials have benefited from a re-evaluation of Lundbeck's shares in the biotech company Imara due to the company's US IPO. Core earnings per share reached DKK 10.3 per share.

Please turn to slide 17. In North America we are very pleased with the continued strong growth of 26% for our strategic brands which now constitute more than 80% of the revenue. The strong growth of the strategic brands led to total revenue growth of 5% for the first half of 2020. International markets increase 11% reaching DKK 2.2 billion or 25% of our total revenue. This region is still in the early part of the rollout of our strategic brands which showed growth of 26%. We expect significant long-term growth for these products in the region. Despite continued pressure on prices in China, we also continue to see growth in this important market. Europe is delivering solid growth with revenue increasing 4% to almost DKK 1.7 billion. The main driver is volume growth which to some extent has been offset by destocking and slightly reduced demand in the second quarter. The European region had strong growth mainly driven by our strategic brands which grew 20% and now constitute more than 58% of sales in the region.

Please turn to the next slide. As you can see from the slide, free cash flow was solid and grew versus last year. On the right part of the chart you can see that the acquisition we made last year increased the net debt which was at DKK 6 billion at the end of June but the net debt to EBITDA is still at a healthy level of 1.3 times. We expect net debt to be in the range of DKK 5.5 to 6 billion at the end of 2020.

Please turn to the next slide. Based on the solid performance in the first half, we today have confirmed the revenue guidance that we provided in May with the expected growth in revenue of 2 to 6% corresponding to a revenue range of DKK 17.4 to 18 billion. We expect continued growth for our strategic brands which will more than offset the impact from the continued generic erosion on our mature portfolio. Included in the reported revenue is hedging which for the whole of 2020 is expected to be a loss of DKK 100 to 150 million. It is important to highlight that following the coronavirus outbreak, Lundbeck continues to see increased uncertainty for the remaining part of 2020. The financial guidance for EBITDA, core EBIT and reported EBIT for the year has been increased due to the one-off cost savings mainly within promotional activities and travel spend as a consequence of the COVID-19 pandemic. Core EBIT is expected to reach a range of DKK 3.9 to 4.3 billion which is a margin of at least 22%. Reported EBIT is expected to reach between DKK 1.8 and 2.2 billion for 2020. For the full year, you should expect financial items to be a net expense of DKK 100 to 200 million depending on currency development. Now I will hand over to Deborah for the final remarks.

0.22.00

Deborah Dunsire

Thanks, Anders. Please turn to slide 19. Lundbeck continues our long-standing commitment to serve societal needs where we can make a difference as we focus on supporting the UN sustainable development calls. We support societal needs in multiple ways in our business but most recently have added support to patients and communities with respect to COVID-19. We are also proud to sign on to the AMR Action Fund, a \$ 1 billion fund raised by 20 pharmaceutical companies partnered together with WHO and some other agencies with the goal to create 2-4 new antibiotics by 2030 to address the rising threat of anti-microbial resistance. While we are not directly involved in antibiotic research, we view it as a societal obligation to join this initiative since antimicrobial resistance bacteria pose a rising and unmitigated threat to health worldwide. Lundbeck is committed to achieving zero carbon economy and setting science-based targets. In May, Lundbeck joined with more than 150 global corporations to encourage governments around the world to align their COVID-19 economic aid and recovery efforts with ambitious climate action. This initiative amplifies our participation in the global movement business ambition for 1.5°C where companies align with business actions with the Paris agreement. Lundbeck's actions to reduce energy consumption and CO2 emission by optimising our facilities and replacing conventional fuel with biofuels continue. In the next wave, we will extend our goals to include emission reduction from our entire value chain. These so-called scope 3 emissions represent the largest proportion of our total climate impact as a company.

Next slide, please. It has been a very busy period. That is rather an understatement and I am sure that the rest of 2020 will continue to challenge our creativity and resilience as we work to mitigate the effects of COVID-19, continue the phased launch of Vyepti in the US and drive our current business forward as we continue to execute on our Expand and Invest to Grow strategy. With the strength of our organisation and the momentum of our growth brands, Lundbeck will continue to be a robust and sustainable company in the months and years ahead. The outstanding operating results over the past years give us a strong financial foundation to continue to drive our Expand and Invest to Grow strategy and deliver a sustainable company into the decades to come as we focus on restoring brain health so every person can be their best. With that I would like to thank you for your interest and open up the Q&A session. Operator.

0.25.11

Operator

Thank you. If you do wish to ask a question, please press 01 on your telephone keypad. If you wish to withdraw your question, you may do so by pressing 02 to cancel. And our first question comes from the line of Trung Huynh of Credit Suisse. Please go ahead.

0.25.31

Trung Huynh

Oh hi thanks for taking my questions. Trung Huynh from Credit Suisse. I have got three, if I can. First you upped your core EBIT guidance on the cost savings from the pandemic. But next year could you give us some help about your costs? You continue to invest in Vyepti to make a global brand. You are still very much active in R&D... (sound falling out)... 2021 core EBIT on 2020?

My second question is on China growth. That seems to be doing quite well but perhaps can I get your thoughts on the impact of the VBP next year? We see that Lexapro and Ebixa are on the VBP list. What impact could this have for 2021? And then finally just a modelling question, the level of other revenue was impacted by a one-off this quarter. Do you have a guide for the second half of the year and how should we think about this going forward? Thanks very much.

Deborah Dunsire

Thanks a lot and it is an easy one for me. I am handing over the EBIT question to Anders along with the modelling on other revenue and Jacob will take the China question. Do you want to start, Jacob?

0.26.44

Jacob Tolstrup

I can start yes, so Trung thanks for the question. Absolutely right so a new policy for the VBP, the third round has been announced where Ebixa is included, also Cipramil. And there are still some uncertainties here. What we try to model after is what we have seen in the past and the further policies will come out later with a timeline of you could say bidding and announcement towards the end of this year in November. Cipramil is a fairly small product for us in China and it is handled by Xian Janssen. So the impact that we will have potentially is on Ebixa. Ebixa is our second biggest product in China so there will be an impact. How large, how much to quantify that I don't think I will do that on this call but there will be an expected impact on Ebixa that we would have to account for for next year.

Trung Huynh

Sorry, can you remind me how big China sales are for Ebixa?

0.27.57

Jacob Tolstrup

I don't think we have spelled it out. Overall China is around a billion kroner in sales to give you that and then remember it is a broad portfolio in China where we promote all our brands so that is both Cipralext, Lexapro in China it is ??? 0.28.17 handled by CMS. It is Ebixa, it is Cipramil and then it is Azilect and Brintellix and out of those, Ebixa is the second biggest product today in China but I don't think we have spelled it out.

0.28.34

Anders Götzsche

And Trung, you asked about other revenue about one-offs. I don't think there is any kind of one-offs in other revenue. What we have said is that compared to when we started the year, we anticipate it to be a bit lower than the beginning of the year due to some of the contracts we have with external supply have been more muted so we anticipate it will be a bit lower and compared to cost, it was difficult to hear all that, you were falling out from the line but with regard to 2021, it goes without saying that we will – as Johan alluded to, we will continue to invest in Vyepti and that will of course be part of R&D costs next year with additional indications and then we will hopefully at the end of 2021 get approval for Europe and then we will start pre-launch activity for Vyepti and then during 2021, we will also hopefully launch in some countries with Vyepti which will of course increase cost.

0.29.49

Deborah Dunsire

The specific guidance will only be given in February.

Thanks Deborah for clarifying.

0.29.59

Operator

Thank you. Our next question comes from the line of Wimal Kapadia of Bernstein. Please go ahead.

0.30.05

Wimal Kapadia

Great, thanks very much for taking my questions. I am Wimal Kapadia from Bernstein. Could I firstly just push a little bit more on Rexulti and Alzheimer's agitation and the trial there. So firstly just to confirm that the trial has restarted and secondly you know while you said you were reassessing time lines any comments on whether Lundbeck plans to use the statistical modelling to maintain the 1H 2021 timeline or could details actually be delayed in the second half or beyond?

And my second question is just on OPEX and the DKK 2 billion incremental spend for Alder in 2020 I guess just some context on whether we shall expect that DKK 2 billion to be in 2020 or could we see a delay so some of that spend occurs in 2021? So any colour there would be great. And then the final question is just on Vyepti coverage. Thank you very much for the details on the greater than 100 million lives access without the need to step through a branded product. But just to confirm, do you actually have greater access but with step restrictions? And then just any comments on how you expect that access to evolve. That will be great. Thank you very much.

Deborah Dunsire

Okay perhaps we will start with the Rexulti AAD trial and Johan can talk about that.

Johan Luthman

Yeah there were kind of two parts of the question. The model, the impact. But let me mention on the execution of it a little bit so obviously this is as I said a US study primarily, we have sites outside the US and obviously when you run these trials, you have sites that are heavily affected right now. It is in dementia and institutionalised people so people that are really very much affected by the COVID-19 pandemic. Which means that it is almost impossible to predict how the trial will progress. You are correct. The trial has restarted. Many sites are open but the amount enrolment will be very, very hard to predict going forward. It is a very fluid situation so we cannot comment on timelines for this study right now.

0.32.05

Deborah Dunsire

Yeah and I think all sites that may be open may need to pause if COVID-19 in their particular local area flares up again and we have certainly seen some of that. With respect to the guidance we have given on investment behind Vyepti, I think that we have seen savings in the first half and we have recognised those in upgrading our EBIT guidance. We hope that we will be able to invest everything we thought we could in the second half if the world opens up and we can make those, the type of investments but we will see it continue into 2021 and there are other regions that might launch so we could see slight increases in 2021. For the coverage question, I am going to hand it over to Peter to give you more colour.

0.33.00

Peter Anastasiou

Yeah, hi Wimal. Thanks for the questions. Yes in terms of I heard you mostly want to focus in on what steps are involved so just like most highly generic markets there are generic steps that most plans have in place, 1 or 2 generic steps for some of the older preventatives like beta blockers, old antidepressants etc. That is not unusual. We see that in the antidepressant market, we see that in the antipsychotic market. But importantly, those more 100 million covered lives that have no branded steps is very important and that is what we have mostly been working towards is to avoid the branded steps and so far of course not all plans have made their coverage decisions. It's a fluid process you know every day more and more plans are making decisions but so far, we have been pleased with the progress that we have made in terms of getting a significant number of patient lives that don't require any branded steps.

Deborah Dunsire

I think Wimal's question went on to say if there is further access with some branded steps added and Peter I think it is true to say that there are a couple of plans where there are branded steps added.

Wimal Kapadi

Yes exactly.

0.34.25

Deborah Dunsire

One thing we should clarify is the J code situation, Peter?

0.34.31

Peter Anastasiou

Yes we were guiding that it could take up to a year for the J code but the CMS did roll out a new process but because it was so new, we weren't sure that it would materialise as advertised, but we are very pleased that it did and so in July, we were notified that the J code has been issued but it will not take effect until 1 October but that is certainly something that has happened ahead of where we have guided in the past.

Wimal Kapadi

Thank you.

0.35.04

Operator

Our next question comes from the line of James Gordon of J.P. Morgan. Please go ahead.

0.35.09

James Gordon

Hello this is James Gordon from J.P. Morgan. Thanks for taking my questions. The first question was just about COVID-19 pressures and the pace at which they bake. When we look at Trintellix, it looks like there was a bit more deceleration observed for this product than some other products, the outpatient products, even like Rexulti, I think maybe it seems like sales reps haven't been interacting with doctors so there has not been much promotion going on. Are those issues all resolved? And do you think you're going to see a rapid acceleration to Trintellix now going into Q3 or could it take a while for Trintellix to get back to normal? And maybe more generally on COVID pressures. So cost savings, you made some cost savings because of COVID-19. It looks like maybe it looks like some DKK 400 million is going to be total saving. That's how much EBIT guidance has gone up by. Have you had all of that benefit already in Q2 or is there still a bit more cost savings to help you in the second half as well, maybe another DKK 100 million? So that is the first question, please.

And the second question was a little bit further out. So just more generally for 2021 so it is good that you don't have the COVID-19 pressures but you are going to have Northera ??? 0.36.15 probably and some more back to launch cost. So just how to think a bigger picture about 2021? Is it more likely to be a growth year or is it more of like a sort of transition year and an investment year when we think about core EBIT level before we are returning to growth in 2022?

0.36.30

Deborah Dunsire

Okay, so I think Peter will start on discussing Trintellix and the COVID-19 pressures. Anders you will take the cost savings and I will take the last.

0.36.42

Peter Anastasiou

Hi James, thanks for the question. Yes so you compared Trintellix and Rexulti for example and the dynamics there are different so Rexulti is very heavily driven by psychiatrists by specialists whereas Trintellix is driven certainly by psychiatrists but also a heavy influence by primary care physicians. And so some of the effects that you are describing with Trintellix relate to really two things. The PCP presence, they were quicker to close during the pandemic, they were slower to open, slower to go to a TeleHealth and that sort of thing where we were seeing psychiatrists were already moving to TeleHealth before all of this and certainly were more open and accessible. But the second piece is also promotion so we have a partner in the US, Takeda, the way we have responsibilities is both of us call on psychiatrists but Takeda takes exclusive ownership of the PCPs so I think the lower promotional efforts that were observed during the quarter also impacted Trintellix as well, particularly in the primary care segment.

Deborah Dunsire

Anders on the..

0.38.02

Anders Götzsche

And from the cost savings, the cost savings that we have baked into the guidance upgrade is more or less already realised in the first half so what we anticipate is that we see that the reopening is continuing and that we are able to invest behind the products to drive the growth that we have signalled, the continued growth of these strategic brands in the second half.

0.38.27

Deborah Dunsire

Then lastly on Northera obviously the exclusivity or patent lapses in February of 2021 and I think a lot about whether it is a growth year or a transition year depends on what happens in the second half of 2020. If the COVID-19 impact continues to be strong and patients really can't get out to physicians and there is a drag factor on NRXs and new patient starts as well as an impact on Vyepi where patients are getting the infusions then we may see a bit more of a transition year. If the second half things resolve and we can get back to you know fully executing on our business then it would be less of a bump. So I think the uncertainty in the second half makes me a little cautious about giving a very directive answer to that question.

0.39.36

James Gordon

Thank you.

0.39.38

Operator

Our next question comes from the line of Emily Field of Barclays. Please go ahead

0.39.44

Emily Field

Hi, thank you. I know you touched on the unemployment situation in the US briefly and that it has not impacted your business but I guess just for the sake of argument, if unemployment were hypothetically to stay at current levels, what kind of impact would that have on your US business Y/Y just if you could frame sort of an order of magnitude? Then also on Vyepti, have you started any in-person promotional efforts as of yet? And then also I was just curious if some of the scripts for the oral CGRPs have looked somewhat strong during the pandemic. Do you suspect that there has been any share shift to oral just given the challenges that lockdown presents? Or are these being viewed by providers as very discreet markets between acute and preventative? Thank you.

0.40.39

Deborah Dunsire

Thanks Emily. Peter is closest to the market where all of those questions are directed so why don't you take that, Peter?

0.40.50

Peter Anastasiou

Yes, I will try to address those and please Emily tell me if I forget to address any of your three questions. The first one, Vyepti in the field. Yes, we are back in the field basically with all of our sales forces. As you can imagine, it is very regional in terms of the degree of openness so while our reps are out, almost all of them both with Vyepti and the other products, not all doctors are seeing reps and certainly the levels of call volume is certainly not at pre-pandemic levels but people are back out in the field where it is safe to do so in various parts of the country. In terms of your question about oral CGRPs it is tough to speculate exactly what is happening of course they are – I do believe that customers think about them differently acute and maintenance, or excuse me acute and prevention. Also the price points for some of the oral CGRPs probably are prohibitive to using them on a regular basis with regard to prevention. So I think most of the use that we are seeing is in the acute setting and so I think those are separate markets in the eyes of customers and I think the dynamics of course in terms of prescribing an oral or being able to do TeleHealth and making a prescription versus an in-office infusion certainly creates a different dynamic between the two categories. And was there a third question?

0.42.29

Deborah Dunsire

I think the unemployment the US and an order of magnitude. We haven't specified an order of magnitude but if you have a comment, Peter, on you know the commercial lives?

Peter Anastasiou

Yeah it is tough to speculate, I mean, each one of our categories, each one of our markets has a different payer mix. Some are more dominated by commercial than others and I think the insurance issue mostly relates to, the unemployment issue relates to commercial insurance. So what we could see in a lot of companies could see although we haven't observed it yet is a mix shift with commercial potentially decreasing as people lose their job and lose their benefit to something like Medicaid but we have not yet observed that as it is kind of tough to speculate on what impact that would have if it did happen.

Emily Field

Great, thank you.

0.43.23

Operator

Our next question comes from the line of Martin Parkhøi of Danske Bank. Please go ahead.

0.43.30

Martin Parkhøi

Thank you very much. Martin Parkhøi, Danske Bank. I have got three questions and one for almost each. I will start with Jacob. Just because now there is a lot of focus on US and unemployment rates in US but I guess you have business outside the US as well. Can you talk a little bit about one of course the possibility of you know government cost measures and the product areas. What are you experiencing with diseases within great disorders and also any impact on what product are sensitive to out-of pocket spend which of course also occurs in this could it be recession.

And then secondly to Anders just on the top line guidance what would the top line guidance of these DKK 17.4 to 18 billion have been if you had used the same spot rates as you used in connection with your first quarter results? And then a final question, I think it is for Deborah and maybe also Johan can chip in. Just to get a complete overview because we talk about Northera patent expiry next year, but if you look over a 10-year horizon for Lundbeck, where do you actually see the challenges? What years and what time do you see the challenges of the current portfolio and how do you believe that your current pipeline actually addresses these challenges?

0.45.04

Deborah Dunsire

Okay, perhaps Jacob you will start.

Jacob Tolstrup

I can definitely start. Thanks Martin. I would say overall on the government initiatives we haven't seen anything at this point in time. It is something that we live with all the time in I would say especially in Europe where you know we have always government initiatives. We have ongoing price pressure on all our brands in Europe every year. We have not seen any new or exceptional initiatives anywhere in Europe at this point in time. You could say that the – all the international markets I would say outside of China/Japan basically Australia are more or less out of pocket markets and there of course there could be an impact if you see prolonged unemployment rates on the purchasing power for some of our brands but it is too early to speculate in. Right now, up to this point, we have not seen an impact. If we go back and model what it looked like during the financial crisis in those days and I know this is different but in those days, we also did not see an impact so you have different dynamics that come into play here for a number of patients coming in and then an economic crisis at the same time so it is too early to speculate in.

0.46.32

Anders Götzsche

And with regard to the top line guidance as compared to previous years, it is a pretty broad guidance we have and that is of course also reflecting that there are uncertainties but you are of course right that FX especially US has been declining and if the level has kept the same in the first half as it or compared to what you are seeing now then of course revenue would be 100 to 200 million higher but I am not saying and speculating in that the guidance would have been different because the guidance is based on multiple factors.

0.47.11

Deborah Dunsire

Great and then your overview question in the 10-year time frame where do we see the challenges? Well, it goes without saying that any time a great brand which has been so valuable to patients growing with great momentum goes off patent or exclusivity, it is a challenge. We do see the strong momentum in the growth brands and then the momentum that will come in with Vyepti in migraine prevention will help us through those years. Of course we have got 2021. Vyepti will still be a small brand at that time. Big brands, Rexulti, Trintellix and Abilify Maintena will be the drivers for us weathering Northera. By 2024 in Europe and a bit later in other markets, Abilify Maintena patent is the next one to go and by then we will have Vyepti growing strongly around the world and potentially bringing in other indications from both Rexulti where we have life cycle management ongoing with AAD, PTSD in phase III and borderline personality disorder coming up and there are some interesting programmes in our phase I portfolio that could potentially have opportunity to accelerate but of course it is much too early to tell with those and then we will keep looking externally for products that can fit in with our capabilities and be growth drivers for Lundbeck.

0.48.51

Martin Parkhøi

Thank you very much.

0.48.53

Operator

Our next question comes from the line of Michael Novod of Nordea Markets. Please go ahead.

Michael Novod

Yes, thanks a lot, just two questions. One regarding Japan. So in Q1 you noted that the launch of Trintellix in Japan had sort of been depressed given that it was difficult to go out fully and also with the prescription limitations there are in Japan in initial days. How does that sort of pan out right now and what do you expect for 2021? And then secondly, on Abilify Maintena and the two month formulation. We are awaiting some data and then you will file. Maybe you could just confirm to us when you are expecting to file for approval and when you will be able to launch and how fast do you expect that patients can be able to get switched to the once monthly to the two-month formulation. Thanks a lot.

0.49.53

Jacob Tolstrup

Yeah I will be happy to start on Japan. Absolutely right, we did see an impact on Japan Trintellix launch. We had a very strong uptake in the very early part of 2020 and then we were impacted by the situation and as you are pointing out, the biggest issue we have is the traditional two-week prescription ban we have for the first year on a new medication in Japan so it is difficult to get traction when you are not out there and being able to talk about your product. At the same time, it is only for a two-week prescription so what we have seen lately is that we are coming back. We have had a higher share of voice during the period including all online activities and now we are getting out more together with our partner in Japan and seeing physicians face to face so we have since April started to see good uptake of Trintellix. We are still behind plans but we do see an uptake and then sort of the real change in that uptake will happen once the ban is being lifted towards the very end of this year.

Deborah Dunsire

Johan on Abilify Maintena

0.51.08

Johan Luthman

Yes I can probably not comment so much because obviously this is based on a number of pharmacokinetic parameters and those are still being explored so obviously with the label on this it can progress very well but right now it is too early to tell.

Michael Novod

And what about, just follow-up on that. What about sort of the commercial side of this two months versus one month and is this all about a very aggressive switching strategy or how should we think about this because there is of course a patent expiry coming up?

0.51.46

Jacob Tolstrup

Yeah, I can say from my market, I see this actually as a very interesting opportunity and of course it will be helpful to have it out as soon as possible so that we have that differentiation between the different formulations. I think it is a great offering to patients that using long-acting injectables that they will also have an offering that goes up to two months. So certainly we will see a cannibalisation and we will also see generic competition coming in on the one month but I think the two months will offer an additional benefit for patients that are already now also have that same opportunity for other brands even going up to three months so I think a very interesting opportunity, they will of course be patent protected for a longer time for us in Europe.

0.52.37

Deborah Dunsire

We have seen in this pandemic time groups coming out in the US to say it would be valuable to have your patients on the longest possible acting, long acting and so two months fits right into that target recommendation.

0.53.02

Operator

Our next question comes from the line of Michael Leuchten of UBS. Please go ahead

0.53.09

Michael Leuchten

Thank you very much. Three questions please. One just a clarification on the VBP Ebixa answer. Is Ebixa positioned differently to Lexapro where it is my understanding in the past you haven't participated in some of the tenders because you had enough volume and growth elsewhere. So should we think about the trajectory here differently for the two products?

And second question on the Northera erosion for next year. I guess Sabril is a product that again in Q2 was a lot stronger than expected I guess the function of the distribution channels. How should we think about the speed of the Northera erosion? Can you give us any commentary at this point?

And then a question on R&D on the phase II failures. Is there anything to read into the latest round of failures? You have in the past commented on how too much risk was taken later in development so in that spirit, how do you read the phase II failures the last three that we have seen? Any comments would be helpful. Thank you.

0.54.19

Jacob Tolstrup

Yes on Ebixa in China overall you could say dynamics are similar. That means that already today we have generics on the market that has a relatively sizeable portion of the in-market sales for memantine in China.

We have several CQCs so you can say quality generics in the market that could go into the bidding and that is why we also estimate that we will see significant price bidding going down and we do not participate, we do not anticipate to participate in that so we will not go in and bid to win so in that sense it will be similar you could say to what happened to Lexapro in China.

Deborah Dunsire

Peter, would you like to comment on the erosion we anticipate?

0.55.17

Peter Anastasiou

Yes I will. Thanks for the question. With regard to Northera when I think about comparison to our previous three LOEs I would think that it would look more like Xenazine or Sabril than Onfi. For one main reason and that is because Northera like Sabril and Xenazine has been distributed through specialty pharmacies, it is not a retail product like Onfi. And so I won't give the specific about what we expect in terms of percentage erosion that sort of thing. Those numbers of course will be embedded in our 2021 guidance that we issue in February. In general, if you are trying to assess how we think about it, it would be more in the Xenazine/Sabril camp than Onfi and of course the other thing I have to say is erosion always depends on the number of generics at the time of LOE. And that is of course something that is tough to speculate on.

Deborah Dunsire

Johan would you like to comment on the phase II?

0.56.20

Johan Luthman

Yeah, thanks for the question, so obviously we are trying very hard to put our efforts where .. and risk where it is the right place for it. The most recent announcement with PD10 that was early interim analysis in a smaller phase II proof of concept study. First time this molecule met efficacy evaluation so that is the place where you would rather like to have them than later in the development. But obviously, we have a strategy now where we are trying to really put as much of de-risking efforts as we can in early development and that is really the strategy to make sure that we are not having late stage failures and that is indication and mechanism of action dependent so we are moving forward much more carefully in picking the indications and the mechanism we are going to work on so we get much more early answers before we make those big investments.

0.57.18

Deborah Dunsire

I think it is important to say that you will see us do that more with these phase II proof of concepts and trying to make sure we have got the right indication. I still remain happy that we were prepared to try in negative symptoms in schizophrenia. These patients have no approved therapy and there were indications from the early phase I and the pre-clinic that there may be a possibility so it was worth trying in a measured way and that is what we did. Unfortunately for patients, it did not deliver.

0.57.58

Michael Leuchten

Thank you very much.

0.58.00

Operator

Our next question comes from the line of Marc Goodman of Leerink Partners. Please go ahead.

0.58.09

Marc Goodman

Yes, just a continuation of the R&D discussion. Can you talk a little bit about the MAG lipase and these programmes that you are working on? There is obviously a new one, 06479. What indication goals are you pursuing there? How are the other studies going? The other assets? And then just second of all on business development. I was curious if you just the next deal that we see is it more likely to be a late stage asset versus something that is you know pre-clinical or phase I? Because of the phase II losses that occurred over the past six or so months. I was just wondering if you were changing your strategy at all to kind of boost that you know. Phase II, phase III you know area up more? And then lastly, if you could just take a look at the phase I assets that you list here in the press release. Which one of these will we see some real proof of concept data first? Thanks

Deborah Dunsire

Okay Johan

0.59.16

Johan Luthman

Yeah let me start on the programme questions so first of all the MAG lipase platform that we acquired through the Abide acquisition is really a very promising platform. We remain extremely confident that this will play out as an interesting class of molecules in the future but obviously it is early stage and that is why we are playing in that space very early development space exactly to the point I addressed before. We would like to find the right indications. We have not gone public yet which kind of indications we are going in but we are going into those that are for some manner is supported by exocannabinoids but also some with more innovative ideas around this so we will gradually tell you where we are working on this. If it delivers and looks fine, we like to have very directed small studies that can be conclusive but we are not going to reveal at this stage which indications.

In terms of phase I assets and which ones are closest to get to proof of concept again. That is really based on that whole idea. We would like to get the information content very early but we do have a number of late-stage phase I assets. We have our antibody AsimAb for Synuclein which has been in phase I for a while and it is progressing. That is of course a disease modifying mechanism so it takes a bit longer to get to a proof of concept if we progress into phase II the MGLLi I already commented upon so I would rather see the molecules mature in the phase I space before we progress and derisk before we go into bigger phase II studies. Like I always say: Let the molecule speak. And that is what we should do in phase I.

Deborah Dunsire

Yeah and the second MGLLi?

1.01.06

Johan Luthman

The second MGLLi, yeah that is an interesting one. They are all differentiated. They are follow-up molecules not back-up molecules so it definitely has its own space. It has some improved pharmacokinetic properties in terms of target action it is about the same. I would like to mention that we have a whole flow of follow-up molecules that we are working on at the pre-clinical space. This is not probably the last molecule we take into this space because we really like to see the different pharmacokinetic properties also play out with this target biology.

Deborah Dunsire

And then on the BD question, Marc, I think that we are looking at filling and we have said across all stages of the pipeline and so we would be opportunistic in late stage if there was a deal that fit with Lundbeck at

the right price. Many of those are not at the right price so I would not hold your breath for that but we are active in looking across all stages of the pipeline. The great thing about Lundbeck is that we have five brands that are continuing to grow strongly and that gives us a great foundation to be able to be thoughtful and disciplined on price as we do our business development externally. We only unfortunately have time for one more question.

1.02.30

Operator

Our last question comes from the line of Carsten Lønborg of SEB. Please go ahead

1.02.38

Carsten Lønborg

Excellent. Thanks a lot. I actually just had, yeah, then one question I guess. Peter, you mentioned on the oral CGRPs that you did not think their pricing level was sustainable for preventive use. Do you mind telling us how do you actually benchmark pricewise to the orals if it came to preventive use with Vyepti?

Peter Anastasiou

Yes so what I meant there is that daily preventative treatment of 30 pills a day or 30 pills a month I should say or whatever the paradigm would be in clinical trials of course, it could be prohibitive but I was telling you what I hear from our customers not necessarily our own belief. I don't like to speculate about other products. I am just telling you what we typically hear. And at the current price point I believe it is roughly \$ 80 per pill if I am correct. You will have to fact check me on that. But that is at least in the eyes of our customers we have been told could be prohibitive. But I certainly can't speculate what plans would do and what any of those companies would do in the future.

Carsten Lønborg

So it is a list price you talk about, yeah, I guess.

Peter Anastasiou

Yeah I certainly have no visibility to what their gross to nets are and things like that.

Carsten Lønborg

Okay and then just one quick follow-up. Just listening to your Vyepti with the sales force being back on the ground again where are you in terms of commercial posture right now? Are you exactly where you would like to be or are you at 50% capacity, 80% capacity? Where are you?

1.04.21

Peter Anastasiou

Yeah, I would be surprised if anybody on the planet said that they were right where they want to be given the current situation. So now we definitely are – I won't get into the specific number because I think, you know, that also gives away what we are doing in terms of competitors and that sort of thing that may be listening in on our calls but I won't say what percentage that we are at but we are certainly back at full capacity but we are – our team is in the field not just as I mentioned with Vyepti but others. Almost everybody is able to make calls with our customers and in every part of the country, it is different in terms of customers receptivity based on the local situation with the pandemic and hot spots and things like that and certainly a blend of virtual and face to face calls are growing rapidly every single day but certainly we are not a pre-COVID levels but I won't give a specific number of where we are at in terms of that as a percentage.

1.05.22

Carsten Grønberg
Okay thank you very much

Operator
I will now hand back to our speakers for closing comments

Deborah Dunsire
We would like to thank you all for your attendance today and we look forward to talking with many of you over the next few days on the virtual road shows. Thank you.