

H. Lundbeck A/S

Transcript: H1 results 2017

9 August 2017 at 11.30 CET

Operator

Ladies and gentlemen. Welcome to the H. Lundbeck Q2 results 2017. Today I am pleased to present President and CEO Kåre Schultz. For the first part of this call, all participants will be in a listen-only mode and afterwards there will be a question and answer session. Speakers, please begin.

0.00.19

Kåre Schultz

Thank you very much operator and thank you all for your interest in Lundbeck. Welcome to this Lundbeck teleconference covering our financial report for the first half of 2017 released early this morning. With me I have our CFO Anders Götzsche and our head of R&D Anders Gersel Pedersen.

On slide 2, you can see the company's disclaimer which I, as always, presume you have seen many times before and I will refrain from reading it out loud.

So we will go directly to slide 3. We will elaborate on the key performance measures in a minute, but please allow me to summarise on the strong financial performance we have had through the period. Revenue in the first half of the year was the highest in the history of the company. Based on the strong performance, we are raising our financial guidance for the full year 2017 and we are well on the way to achieve Lundbeck's best ever financial results.

We have continued previous quarters' significant improvements in our profitability as well as shown solid growth and revenue. We are very satisfied with the progress of our operational performance. Revenue grew 13% in the half year thereby reaching DKK 8.5 billion. Our key products have continued their strong growth and sales of these products have grown 44%. In general, all key products are performing well and especially Northera, Rexulti and Trintellix are growing fast.

I would also like to point out that in the second quarter of the year our key products constitute more than half of our revenue so the past year's journey to replace lost revenue from generic competition is well on track and is expected to continue going forward. In parallel with the sales growth, we have managed to bring down our cost and have reached an EBIT margin of 24.3% for the period. Therefore, we are well on track to achieve our long-term target of an EBIT margin of 25%.

As our tax rate is declining, we see very strong growth in earnings per share of 186%. Our business is in such good shape that we have improved our cash position and since last year we have increased our net cash position by close to DKK 3 billion.

Anders Gersel will revert with a pipeline update but let me just say that we are satisfied with the progress in our development and registration work, most recently leading to the approval of Abilify Maintena for treatment of bipolar disorder in the US and the approval of Azilect for treatment of Parkinson's disease in China.

Anders Götzsche will revert with a financial update so let me just conclude the highlights by saying that we have lifted our revenue range for the full year and raised our EBIT guidance with DKK 500 million based on the underlying operational performance and the gain from divestiture of properties.

2017 is therefore expected to provide Lundbeck with the highest sales and profit level ever.

Please turn to slide 4. I think it is important to continue to point out that we have a portfolio of mature and relatively stable products and we have a portfolio of key products which generate substantial growth. During the first half we realised revenue growth of 13% despite the continued generic erosion of products, such as Xenazine in the US.

To pre-empt questions, we have not yet seen any changes in the market dynamics of Sabril. It is our North American region that delivers most of our performance and the foremost products like Northera, Rexulti and Trintellix. The region is up 22% for the period and constitutes 61% of our sales. A second point to note is that the international market is going up 8% and is beginning to show growth even though Europe is negatively impacted by generic erosion, the region is turning the corner and isolated for the second quarter we have also seen growth in Europe. That means we now have growing sales in all regions.

Finally, I think it is worth mentioning the very strong improvement in our profitability which follows the quarterly improvements we have seen in the past year or so.

Please turn to slide no. 5. International markets, which besides our emerging markets also consist of countries such as Japan, Korea and Australia, grew 8% in the first half of the year and constitute 22% of our revenue. An important point is that emerging markets are a dominant part of the region and a key growth driver, especially driven by Brazil and China. It is my view that this region will become increasingly important, especially following the upcoming launch of Azilect and the expected approval of Brintellix in China around year-end combined with strong underlying growth.

Please turn to slide no. 6. We continue to execute on our strategic growth platforms and we have seen continued significant sales increases in our key products. In the first half of 2017, our key products generated revenue of DKK 4.2 billion corresponding to 49% of total revenue. We expect continued high growth for these products.

Please turn to slide 7. We will now look at our key products individually and let me start with Rexulti. As you can see, the significant uptake continues and the momentum looks solid after the normal volatility seen around the turn of the year. We continue to have high expectations for the product, as Rexulti has an attractive profile which is highly rated by the medical community. The week-over-week growth continues to outpace the branded market in general and the uptake is strong relative to prior competitive anti-psychotic product launches. Rexulti has so far achieved more than 13% branded total script market share and some 15% branded new script market share. In terms of revenue, Rexulti achieved DKK 574 million in sales in the quarter, which represents growth of some 85%. We expect to see the effect of the first launches outside the US during 2017, starting with Canada where Rexulti was launched in the private market in April. Additionally, Rexulti was recently approved in Australia and launch is expected later in the year. Finally, we have filed the product for schizophrenia in Europe.

Please to slide 8. Revenue for Brintellix/Trintellix reached DKK 778 million for the period of which 56% was generated in North America. However, countries like Brazil, Canada, Italy, Spain as well as France are beginning to make valuable contributions to the total Brintellix revenue. In Spain and Italy, Brintellix continues the encouraging start. In December last year, we were also able to launch it in France and even though it is early, we see an encouraging performance. In these markets, we see volume market shares exceeding 1%.

For Trintellix, we did receive a complete response letter from the FDA regarding cognition. Takeda and Lundbeck will determine next steps following an end-of-review meeting with the FDA. However, as you have seen, we had a great quarter on Trintellix and the CRL has

had absolutely no impact on current performance. As the leading branded anti-depressant, Trintellix is poised to continue the impressive growth achieved last year as adoption continues to steadily increase with psychiatrists and general practitioners and physicians. Expanded clinical experience further strengthens prescriber appreciation of Trintellix long-term efficacy and favourable tolerability profile to maximise further potential. This sustained growth trend reflects the significant unmet need that continues to exist for MDD patients and a strong appreciation of the benefits Trintellix can offer to patients who are struggling with symptoms beyond mood.

In the past 3 years, since its launch in the US, more than 575,000 patients have been prescribed Trintellix. In the US, over three quarters of all anti-depressant prescription volume flow through commercial and Medicare Part D channels. Trintellix coverage continues to strengthen and is supported by strong growth in patient and prescriber demand. Trintellix is covered without prior authorisation for roughly 80% of commercial insured patients and over 97% of Medicare Part D patients.

Please to slide 9. If we turn to Abilify Maintena, our long-acting anti-psychotic drug, this product is doing well in most if not all markets. The product has more than 15% of the total atypical LAI market worldwide. In the first half of 2017, sales of Abilify Maintena grew 23% and reached DKK 659 million of which close to 60% was generated outside North America. The long-acting injectable market remains strong, especially outside the US. The double-digit growth rate supported by a shift from all to long-acting antipsychotics as well as new product offerings. We were also able to strengthen the overall product profile in the US with the expanded label which now also includes bipolar 1 disorder.

Please turn to slide 10. Onfi reached sales of close to DKK 1.5 billion in the first half of 2017 following growth of 28% and we expect to see continued increased demand for this product.

Please turn to slide 11. Northera reached sales of DKK 716 million following growth of 60% and also for this product we expect to see continued increasing demand.

I will now hand over to Anders Gersel to go through the latest in the pipeline.

0.10.13

Anders Gersel Pedersen

Thank you very much, Kåre. Please go to slide 12. I am satisfied with the progress in our development and registration work leading first and foremost to the approval of Abilify

Maintena for treatment of bipolar disorder in the US. We have also reached an important milestone with the approval of Azilect for the treatment of Parkinson's disease in China leading to an important first step in expanding our presence with our newly registered products in this region with importance for us.

Regarding the FDA process around the sNDA for Trintellix, I do not have much additional information. Takeda and Lundbeck are in the process of reviewing our positions following the end of a review meeting that we have had with the FDA. Concerning Rexulti and Alzheimer's agitation, a Type C meeting request has been submitted to the FDA to discuss the findings but no date has yet been set for a meeting. Additional analyses on the completed studies are ongoing. The results of these studies will obviously be presented at a future scientific congress and we will be discussing the data with the FDA at the Type C meeting.

We will, together with the Otsuka, following that meeting decide on the potential path going forward with this product and the FDA.

Regarding the early pipeline, I can say that the Lu AF 20513 – our anti A β vaccine, we have completed the enrolment of all the patients into the last cohort and all have had their fourth and last immunisation so we just have to wait for the maturation of the data to decide when to move on with this project.

This is all from my side at this meeting and I will pass it on to Anders Götzsche to go through the financial performance.

0.12.14

Anders Götzsche

Thank you very much, Anders. Please go to slide 13. In the first half of the year, revenue increased with 13% and reached DKK 8.5 billion with limited impact from foreign exchange rate movements. It is also worth mentioning that in the second quarter the growth reached 14%. Our gross margin has improved considerably following improved product mix with reduced royalties and reached 77% in this period compared to 72% in the same period last year. Furthermore, our EBIT exceeded DKK 2 billion for the first half and has therefore more than doubled. This is partly driven by the top line performance and partly driven by the positive effect from product mix as well as the restructuring programme which we initiated in 2015.

In the second quarter, EBIT grew from DKK 469 million last year to slightly more than DKK 1 billion. The EBIT margin has significantly improved from last. The margin has improved from 13% to 24% for the quarter. This means that the positive development we have seen in the last few quarter continues.

The effective tax continues to decline and as a result we see very strong growth in our net profit and subsequently our earnings per share, which has grown by close to 200%. Please also let me repeat what I said last quarter regarding our forecast for the tax rate going forward and please aware that it is very dependent on our geographical mix as well as our product mix. The reported tax rate is expected to be around 40% in 2017 and then decline in the following years and by 2021 probably end up around 30%. Beyond 2021, the long-term reported tax rate is expected to decline to a level between 23 and 25%.

It is also important to note that the cash tax rate is somewhat lower from being around 38% in 2016 to around 30% in 2017 and 2018 and from 2019 the rate is expected to decrease to a level between 23 and 25%.

Please turn to the next slide. The successful execution of the restructuring programme is best illustrated by the continued reductions in the number of FTEs which is now at the lowest level for 15 years so we are back to 2002-2003 where we had the same number of employees. We have seen a positive effect on sales costs due to a low number of FTEs following the restructuring including finalisation of the European negotiations.

Cost of sales declined from around DKK 2.1 billion to just below DKK 2 billion while at the same time growing the top line. The gross margin has therefore improved from 72.1% to 76.9%. sDNA costs increased from DKK 3.1 billion to DKK 3.2 billion driven by a 6% increase in sales and distribution costs, which is less than the growth in revenue.

The SG&A ratio for the period was 38% compared to 40.8% in the same period the year before.

Please turn to the next slide. Lundbeck continues to generate a very strong cash flow but remember that in the second we had cash outflow from dividend payment and tax. Furthermore, we have invested in securities and repaid a large portion of our debt. We ended the quarter with a positive net cash position of DKK 1.1 billion. The strong improvement in our net cash of close to DKK 3 billion from last year is obviously a reflection of our improved cash flow, mainly driven by our improved profit. We expect our net cash position to be around DKK 3 billion by the end of 2017.

Please turn to the next slide. We assume that the remaining part of 2017 will be somewhat impacted by introductions of generic versions of Sabril and the continued generic erosion of Xenazine. We also expect continued growth for our key products and higher sales for the year. However, that is partly offset by the current trend of a declining main currency. For 2017 we expect higher revenue and have updated our revenue outlook to be in the range of DKK 16.7 to 17.5 billion.

We expect to see a continued significant improvement in our profitability in 2017 and EBIT is now expected to reach between DKK 4.1 and 4.5 billion for the year. The revised EBIT guidance includes DKK 200 million in gain from the divestiture of properties here at the Valby site, which was not included in our previous guidance, and of course the improvement of DKK 300 million from our better performance.

For the financial items, you should expect a net loss around DKK 50-100 million for the year, which is unchanged from previous guidance.

And now I would like to hand back to Kåre for the concluding remarks.

0.17.53

Kåre Schultz

Thank you Anders. With that I would like to thank you all for your interest and open up for the Q&A session.

0.18.03

Operator

Thank you. Ladies and gentlemen. If you wish to ask a question, please dial 01 on your telephone keypads now to enter the queue. Our first question comes from James Gordon of J.P. Morgan. Please go ahead, your line is open.

0.18.16

James Gordon

Hello, thanks a lot for taking the questions. Two questions please. One on Alzheimer's agitation which should just be: At which conferences are you targeting presenting the data

subject to being accepted and what is your confidence on being able to get an approval on the existing data? How confident are you that further data won't be required? Then the other question is just on margins. You mention being on track for 25% EBIT margin. But actually you got there today for the quarter and the mid-point of the guidance for the year gets you there as well. So when could we see a higher margin target be set? Could we get something like a 30% margin by the end of the decade or are there headwinds that mean that might not be possible? Thanks.

0.18.57

Kåre Quist

Thank you James. The first question I will pass on to Anders Gersel.

0.19.02

Anders Gersel Pedersen

Yes, concerning the Alzheimer's agitation, we have not yet decided exactly which conference to send it to but they will come out and we will let you know as soon as we have that clarified. And with respect to the upcoming strategy for the filing with the FDA I will refrain from commenting specifics on that until we have had the meeting with the FDA because that obviously has a huge bearing on that.

0.19.29

Kåre Schultz

Thank you Anders. With regard to the margin question, I will address that. It is correct that we are very close to the 25% long-term EBIT margin target. As I have said before, we will not comment on any new targets until we have actually reported and reached in our reported numbers the target we have so that if everything goes well might be some time next year but until we reach it we won't start to speculate about what we and the Board could potentially set as new targets.

0.20.06

James Gordon

Thank you

0.20.08

Operator

Thank you. Our next question comes from Michael Novod of Nordea Markets. Please go ahead, you line is open.

0.20.14

Michael Novod

Yes, thank you very much. A few questions as well. So looking at the full-year guidance and also Sabril generics bearing in mind that the first generic rarely sets a very aggressive price, doesn't the full-year guidance still look a bit conservative, also based on, Kåre, your comments in media around they are expecting the same growth in Q3 and Q4 as you have seen in Q2 and then secondly on Rexulti, if you look at the gross sales in the US, it seems like there is additional discounting taking place on Rexulti or is this just a matter of quarterly fluctuations between Q1 and Q2 and how rebates are paid? Thank you very much.

0.21.03

Kåre Schultz

Thank you Michael. I will handle these questions. So with regard to full-year expectations and guidance and Sabril it is a peculiar situation that we have one product that is completely approved by the FDA – one generic product – and it is also included in our shared REMS so theoretically nothing should hold back apart from whatever – I don't know – competition from launching the first generic. At the same time, we now have four companies who have asked to opt into the shared REMS so I do expect that we get generic competition. Should we not get any generic competition whatsoever this year, it will be a surprise and it would of course lead to a higher performance than what we are including in the guidance so we are assuming that we will see generic competition on Sabril during the next couple of months. With regards to what I have said to the media, I haven't said that we expect exactly the same growth in our top line in the second half of the year as we saw in the first half. We do have a combination of better organic growth in local currency than we expected a quarter ago but also a headwind from some of the currencies including the dollar and the guidance you see now is a combination of these two effects as I just mentioned before. With regard to Rexulti, you are absolutely right, it is just – I would say – random quarterly fluctuations. There is no change to the very positive trend in the scripts and there is no change in the gross to net position on Rexulti so it is just those quarterly fluctuations that we will continue to see basically on all our products in the US.

0.22.49

Michael Novod

Thanks

0.22.52

Operator

Thank you and our next question comes from Jo Walton of Credit Swiss. Please go ahead, your line is open.

0.22.58

Jo Walton

A few questions, please. I apologise I did not quite catch it. Could you reiterate the financial guidance for the year? And also tell us what the size of the one-off mortgage repayment – early mortgage repayment was so that we can get a sense of the underlying net financials in Q2 and could you also tell us a bit about your expectations for R&D expenses going forward? It has been coming down as a percentage of sales and it is now in the sort of 15-range, looking at the projects that you have in development, would it be reasonable to assume the same sort of 15-16% range for the next couple of years when we are thinking about margins? I appreciate you don't want to give us a full margin breakdown but something to help us on the R&D would be helpful and finally I wonder if you could tell us just a little bit more about your early adoption in Europe. You gave us some volume market shares for Trintellix in Europe. Can you tell us a bit about the pricing that you are managing to achieve? Just some more colour on that European take-up, please.

0.24.12

Kåre Schultz

Yes, thank you very much Jo. For the first question on financial items I will hand that over to Anders Götzsche.

0.24.20

Anders Götzsche

The guidance upgrade, if I understand your question right, we have upgraded our EBIT guidance with DKK 500 million and we had a divestiture of buildings which –

Kåre Schultz

The question was very specifically on financials

Jo Walton

It is just the financials

0.24.37

Kåre Schultz

and the breakage cost on the mortgage

Anders Götzsche

Okay, okay – sorry for that – the financial items: you should expect it to be around DKK 50 to 100 million for the year and the cost this quarter is a bit high due to the repayment of the mortgage debt and we now have a debt of around DKK 900 million and we expect to repay that in the beginning of 2018.

0.25.07

Kåre Schultz

And then on the R&D percentage, Anders Gersel, would you comment on that?

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Anders Gersel

We have previously stated that we expect to have an R&D percentage around 15-16 in 2017-2018 and it may increase slightly up until 2020 but we are going to stay at that level of magnitude of R&D expenditure.

0.25.29

Kåre Schultz

And then I will comment on the launches of Brintellix in Europe and it is correct, we see a very positive uptake of the product and we have seen in countries such as I said Spain, Italy, France a very positive volume share development. The pricing is sort of around the €

1 per day, some are a little higher, some are a little lower, but that is the pricing we have seen for the product so overall we are very optimistic that with the previous launch of Ability Maintena in Europe and now with the launch of Brintellix in Europe we will in the coming years see net growth in sales, of course still being influenced a little bit by continued decline of Cipralex and Ebixa but that decline has sort of slowed down dramatically and now we are seeing the positive effects of selling both Abilify Maintena and Brintellix in most European markets.

0.26.29

Jo Walton

And within the DKK 55 million of net financials that you had this quarter, how much of that was just the one-time early repayment of your loan mortgage?

0.26.43

Anders Gersel Petersen

Most of it is currency fluctuations.

0.26.48

Jo Walton

Okay, thank you.

0.26.51

Operator

Thank you. Our next question comes from Martin Parkhøi of Danske Bank. Please go ahead, your line is open.

0.26.59

Martin Parkhøi

Yes, Martin Parkhøi, Danske Bank, actually it is only for Anders Götzsche, it is regarding hedging because could you try to elaborate a bit on the fact that you take your underlying sales forecast up by DKK 200 million but your underlying EBIT up by DKK 300 million? How much of that is due to hedging because as I understand it you take a beating on sales in 2017 but you put up the hedging gains on your cost side so is this the driver of the

difference, DKK 100 million, or is there actually also a relatively cost-saving effect? Then the second question. If we look at the current situation we have right now, how significant a beating do you actually think you will take on the EBIT line in 2018?

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Anders Götzsche

I can start by saying that the decline in the USD for the last three months of course has been pretty significant and that is of course eliminating some of the over-performance we have had for our key products and especially for Sabril and Xenazine so that is the reason for only moving the range DKK 200 million on the top line and you are fully right, going into 2017 we have had our net exposure and therefore there is basically no FX impact on the profit. So we have a...

0.28.25

Martin Parkhøi

Okay, so how much hedging gain do you have in your profits?

0.28.30

Anders Götzsche

I don't have the specific number here but of course due to the fact that until, I don't have the exact numbers, but until February or so, the USD was beyond DKK 7. Of course, we have hedged, we took a favourable position at that point in time and of course that has been included in the guidance. But you have had a very positive effect on performance and in local currencies and then you of course have a negative effect on the USD. And you will also see that in the second half. You will see that we will report higher growth in local currencies and then there would be lower reported growth.

0.29.18

Martin Parkhøi

Yes because I guess that the margin is positively impacted by the declining sales due to the USD but EBIT being flat due to hedging so my understanding is just how much EBIT impact you actually, margin impact you actually see from that thing and how much we will see into 2018. But I guess I can get the numbers from Palle offline then.

0.29.41

Kåre Schultz

And then just one comment here from Kåre Schultz on the margin and it gets a little technical and we shouldn't get into all the details now but of course there are two different effects. One effect is if you have your positive hedging recorded on your sales line and you have a drop in your cost because you don't put the hedging there, then that in isolation for the USD amounts improves your margin. However, we also have a lot of cost in DKK and the DKK cost stays firm versus the top line which goes down in USD which sort of goes the other way. So the net effect on the margin from the change in currency when the USD drops is relatively complex to estimate precisely.

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Martin Parkhøi

Yeah but the question was just that the difference between the sales upgrade and the earnings upgrade is DKK 100 million. Is that solely FX, hedging gains related or are there also underlying improved cost effects?

0.30.44

Kåre Schultz

I would put it this way, Martin, the key reason for it is that sales in local currency are doing significantly better. But from that effect you have to then subtract the negative currency effect, which we have done, in our top line guidance. And that means that less of the local currency improvement drops down to EBIT. So we see probably a, let's say, DKK 200 million of the local currency effect, which is significantly higher, dropping down to EBIT and then we probably see around DKK 100 million in improvements on the actual cost. And then we have the DKK 200 million from the property which we can keep separate.

0.31.29

Martin Parkhøi

Okay. Thank you very much.

0.31.32

Operator

Thank you. Our next question comes from Carsten Lønborg Madsen of SEB. Please go ahead, your line is open.

0.31.38

Carsten Lønborg Madsen

Thank you very much. Carsten Madsen, SEB. Of the 14% reported top line you have in this quarter, could you talk about how much of this comes from pricing? And then also in line with the many other pharma companies, I guess you have been in discussions about 2018 access and pricing levels in the US market. Do you mind trying to give us some sort of feeling for how we should think about 2018 for Lundbeck in the US? Thank you.

0.32.08

Kåre Schultz

Yes, so I will try and handle those. In terms of our growth in sales and how much of that comes from pricing, I can say that the majority of the growth comes from increased volumes, so more patients being treated by our really good products. So as you know, the world's best antidepressant and the world's best antipsychotic, they are both growing prescription numbers in the US and that volume is driving sales higher and that goes for all our key products. So the key driver is volume. That being said, we do take price increases in the US at a sort of normal level and on most products we take the high single digit price increases and then of course through the contracting a part of that price increase is then sort of not resulting in increased net pricing but we do have increasing net prices in the US. With regards to 2018, we are not seeing any significant change in the peer landscape. Our negotiations with various PBMs and so on have not really resulted in any significant change for 2018 so we expect to see a stable pricing environment for our products in the US.

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Carsten Lønborg Madsen

Okay. Thank you very much.

0.33.30

Operator

Thank you. Our next question comes from Tim Race of Deutsche Bank. Please go ahead, your line is open.

0.33.34

Tim Race

Hi there. So a couple of R&D questions and then one financial question. So on R&D, just looking at the pipeline for the long-acting Brexpiprazole, can you just remind us of the timelines here to get this to phase III and to market? And also what the target for the profile of this in terms of duration of long-acting or whatever.. subcutaneous or intramuscular? Then just maybe a follow-on question on that, just in terms of you state that 80% of your sales of Rexulti today are in MDD. Just what is your experience in research suggestion of the demands for MDD in terms of long-acting injections as such and how long do patients typically take an antidepressant for? And then just perhaps moving on to cost, obviously very good cost control on SGNA and in terms of the number of employees. Just wondering how much further you can go in terms of that outside of the current programme? And in terms of when we are looking at like the upcoming sort of expiries of Sabril is there any further cost where you can take out there or is that already done? And then in terms of Europe with the Rexulti you allow in various countries and Trintellix, do you need to add any extra costs? Or employees? Thank you.

0.34.56

Kåre Schultz

Thank you very much, Tim. I will hand the two first questions to Anders Gersel.

0.35.02

Anders Gersel Pedersen

With respect to the Brexpiprazole long-acting injectable, the target is to go for a two-monthly injection for this molecule and then to have both the opportunity for a subcutaneous and an IM formulation of that preparation. We will know more about that by 2018 and then we would immediately roll into a phase III programme, expecting us to be able to conclude that in 2020.

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Kåre Schultz

And with regard to MDD, the 80% of Rexulti that is currently on MDD, how do you see that for LAIs?

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Anders Gersel Pedersen

I think the LAI is going to be, if you have a subcutaneous formulation, it is going to be more attractive to use for particularly severe patients in this area so I will not preclude

that there will be a use of that here, which is something that we have not seen widely being done for the intramuscular formulations so far being available.

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Kåre Schultz

Thank you, Anders. Then I will hand the last question on cost to Anders Götzsche.

0.36.23

Anders Götzsche

I think you should expect that the level we have of FTEs is the level that we will continue to see because we do not have any, you know, we have finalised our restructuring plans, the last plans we had to execute on were in Europe and we have done that and in the second quarter we also saw a decline in our sales cost but we saw also a slight increase in our promotion and that is primarily due to the fact that we continue with DTC in US for Brintellix and Rexulti and we have the upcoming launches or the on-going launches for Brintellix in Europe. So you should expect kind of the same level and for Sabril, of course, we have a sales force behind that, still have a sales force, but of course the number of people and the cost for that is on a minimal level so the profitability for that product is very high.

0.37.21

Kåre Schultz

And maybe I would just add, with regard to a launch of Rexulti in Europe, once we hopefully get that approved, then there is a very, very big overlap between the target group for Abilify Maintena and the target group for Rexulti so we would not expect to see any increase of the European organisation in connection with a launch of Rexulti in Europe.

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Tim Race

Perfect, thanks.

0.37.48

Operator

Thank you. Our next question comes from Emma Newey of Bank of America Merrill Lynch. Please go ahead, your line is open.

0.37.55

Emma Newey

Hi, thanks for taking my questions, a couple, please. Firstly, does the second CRL for Trintellix cognition change your long-term expectations for the product? And secondly, I was told that eight-weekly dosing was approved in June. How is this affecting Abilify Maintena?

0.38.13

Kåre Schultz

I think I can answer both those questions. So we have not seen any effect whatsoever from any of the two CRLs on Trintellix in cognition. So we see a very steady positive momentum on TRx and NRx for Trintellix in the US and we are of course disappointed that we didn't make it with the FDA to get some kind of text included in the label but we are of course encouraged by the fact that we have scientific data that we are allowed to discuss with experts at congresses and so on. So we are very optimistic about the future progression of the Trintellix market share and the script numbers in the US. With regard to Abilify Maintena and the competition from Aristada, we don't see any change in the sort of curves for Aristada or for Abilify Maintena for that matter so we continue to take market share on a global basis with Abilify Maintena and we are of course very happy about the bipolar approval that we just received from the FDA for Abilify Maintena in the US. So again there we see a very positive momentum that we expect will continue.

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Emma Newey

Great, thanks.

0.39.28

Operator

Thank you. Our next question comes from Marietta Miemitz of Prime Avenue. Please go ahead, your line is open.

0.39.34

Marietta Miemietz

Thanks for taking my questions. The first one is on the sequential sales development from Q1 to Q2, specifically in the international region. So you reported slightly lower sales in Q2 than Q1, even for Brintellix and Abilify Maintena just because currency worked against you. But can you please give us any feel for the local currency growth trajectory or any other granularity on the momentum for Brintellix, Abilify and international as a whole from Q1 to Q2? Because it is really difficult to work out that number from the Y/Y local currency growth rates. And then on the AF35700, the new patient study population, can you just explain some of the thinking behind enrolling early- and late-end disease patients and what screening criteria you are using to exclude middle-end disease patients? Because based on the limited-information clinical trials, the inclusion criteria don't actually look that different from those in the DayBreak trial. And then just quickly on Brex and Alzheimer's agitation, I mean at the last update you were still in the middle of your analysis. Can you actually now say whether the pool data from the two studies is statistically significant? And just also a quick one on Trintellix cognition in the US, is it a fair assumption that it won't be included in the label based on any of the clinical trial data you have got now that you won't be doing any further re-analysis and you either need a new study or more real-world data to have a chance to get it on the label? Thank you very much.

0.41.16

Kåre Schultz

Thank you very much, Marietta. So that is basically four questions. I will handle the first one together with Anders Götzsche and then the last three ones I will ask Anders Gersel to answer. I will just give you a brief comment on international markets and then Götzsche might comment a bit further. In international markets we have a combination of markets of which some are quite traditional with normal sales on an on-going basis where you have prescriptions and you have wholesalers and the whole thing but we also have tender markets where we have huge shipments in one quarter or in one month and then basically no shipments for a specific product in the following quarters because government organisations are sometimes buying huge quantities. So that is just a general comment on international markets, that in the emerging markets there is a lot of tender business and that swings a lot. If I should comment on the more traditional sort of launch performance of products like Abilify Maintena and Brintellix, then both these products are performing extremely well, also in all the international markets where they have been launched. So we see very, very nice launch uptake curves for both Abilify Maintena and Brintellix in all markets with steady growth quarter by quarter but of course we do have some of these swings on both currencies and on shipments. But Anders Götzsche, do you have further comments?

0.42.41

Anders Götzsche

And it is fully right, what Kåre is alluding to is that we have had launches in Egypt and Saudi Arabia, we also have a continued uptake and we saw some stocking in Brazil and that is impacting, making fluctuations between the quarters. So it is exactly as Kåre explained, that we see nice growth but we are also launching in these regions and that might give some bumps because we have some pipeline filling.

0.43.09

Kåre Schultz

Then on to Anders Gersel, three questions for you.

0.43.12

Anders Gersel Pedersen

Yes. The first question on the new study on 35700, it is a study where we try to get more insights into the range of effect we may see in different types of patients with TRS. As you are maybe aware then there are some patients who very early on in their disease basically have features of TRS and then there are some who don't get it until quite late and then there is obviously a group in the middle who are difficult to say if they are one or the other. And we are trying to see if there is a difference in terms of how the two categories of patients are responding to 35700, even if they are all classified as TRS patients, merely based on the timing of the TRS condition to emerge in these patients throughout their disease lives. In terms of the Trintellix data, if we are going to try to incorporate the currently available data into the label, we are actually discussing what we can do currently with Takeda in terms of do we need something additional or what do we make out of the second TRL discussions that we have had with the FDA. I think the bottom line here, why I cannot be very precise on that, is that it is our clear understanding that even within the FDA there is not a clear position on this and that is why we need to have some further discussions about how to approach that. If we look at the agitation data then we will not discuss details of this data until we have had the meetings with the FDA so I will not go into further discussions on that but we will have the meeting, as I have said, we have requested a Type C meeting with the FDA, submitted that to them.

0.45.09

Marietta Miemitz

Just to clarify the 35700 so do you actually have specific screening criteria where you say okay, an early disease patient is somebody who got it within the first, I don't know, one year of this disease and the late disease patient got it at like 10 years of this disease and those are the only patients we take into the study, we analyse them separately and that really informs the second phase III trial? Because I mean it is really not very clear on the clinical trials what the inclusion criteria are.

0.45.38

Kåre Schultz

We are specifically asking for a group of patients to be amongst the early ones that have not had disease for a prolonged period of time, that is correct. So we are trying to separate them out as much and it simply has to do with the fact that we want to get a sense of what impact does prolonged exposure to the two treatments have on the pathology of these patients in itself but also when you subsequently treat them with a 35700 which has a different receptor profile.

0.46.09

Marietta Miemitz

Okay, great. Thank you.

0.46.12

Operator

Thank you. Our next question comes from Jacob Lademann of Carnegie. Please go ahead, your line is open.

0.46.18

Jacob Lademann

Yes hello, thanks for taking my questions. Just briefly on Xenazine, I mean the result here in Q2 looks perhaps a bit surprising, given the sharp erosion in Q1 so I am wondering if you could break down for the full year update of the sales guidance how much of the Xenazine performance during Q2 is carried forward as expectations for the rest of the year? And basically also the same question for other pharmaceuticals, is this the category that you expect to be quite strongly performing and what would the contribution be to the full-year sales guidance? And finally just a question on AF35700, is it correctly understood, just a clarifying question actually, that the new DayBreak studies are the only planned pivotal trials because the Anew study is actually registered as a phase II study so I am just wondering if you expect to make your submission based on that data alone or perhaps there will be a second phase III trial later? Thanks.

0.47.21

Kåre Schultz

Thank you very much, Jacob. I will try and answer the first two questions and then Anders Gersel will answer the last one. On Xenazine there are some, you could say, also here some quarterly fluctuations but the way we look at it is that the decline we have sort of on average seen over the last basically eight quarters since it got generic competition two years ago, that declined the way we have seen in the last year. We expect that to continue and therefore we expect a continued decline in Q3 and Q4 of Xenazine. In terms of other pharmaceuticals, this is a lot of different very old products that we sell in many countries around the world and basically we expect that to be sort of very close to stable but it does have products that also get sold in tenders and so on so it can fluctuate up and down but there is no dramatic change expected in terms of other pharmaceuticals in the second half compared to the first half.

0.48.27

Anders Gersel Pedersen

And this is Anders. I will just comment on the DayBreak and the Anew studies, the two 35700 studies. They are the only studies currently on-going and obviously we will not decide on the additional phase III study until we have seen the results of the 35700 study in terms of what it is going to look like and how we are going to size it and position it. The current Anew study is not what we have previously commented on as a second phase III study just so that you are aware of that.

0.49.15

Operator

Our next question comes from Peter Welford of Jefferies. Please go ahead, your line is open.

0.49.20

Peter Welford of Jefferies

Hi, yes, thanks, I have got two questions left. Firstly just on the margin trend, I appreciate you don't want to provide any sort of targets for the margins longer term at this point in time but are you confident you can continue to see margin improvements in the EBIT line during 2018-2019, given some of the headwinds you face or should we be thinking about margins perhaps stabilising for a while and then picking up again longer-term once we are beyond some of the current headwinds that you are facing in the, I guess, all the portfolio? And then just on the pipeline question on 20513 I think that's on the Alzheimer's vaccine I just wondered if you could give us some sort of insight into what we should be looking for when we see those data next quarter in terms of I guess both the immunogenicity and of the safety but also whether we should be looking for anything else

potentially in the data that will give you some insights into future development plans?
Thank you.

0.50.19

Kåre Schultz

Thank you very much, Peter. I will try and answer the first question and then I will leave the second one for Anders Gersel. So as I said before, we won't comment on a new target for our longer-term financial targets before we reach the ones we have right now. And as you rightly say, we are close to reaching the 25 % target but we haven't actually reached it yet. Once we reach it, we will discuss with the board of directors and look at the whole situation in order to assess what our new long-term financial target should be for the EBIT margin. All that being said, of course personally I would be disappointed if at some point in time we were not able to improve that margin further, but it is too early to comment on exactly with what speed and magnitude that can happen.

0.51.10

Anders Gersel Pedersen

With respect to the Vaccine programme, what we expect to see out of that is obviously if we are raising antibodies of the kind that we would like to see and of a magnitude that we would like to see using this kind of vaccine. And it will as such not be expected in any way that we will get any sort of, if that was what you were asking, any effect results on patient response or anything like that because that is clearly not possible with such a small study with so few patients. We basically are doing it as a way of understanding if we with the vaccination that we are giving, with the magnitude we are giving, are able to raise antibodies at a level and of a nature that we think are appropriate for us to move on with.

0.52.06

Peter Welford

Sorry, I appreciate that efficacy was not likely but I guess with regard to the nature of the antibodies, I guess what I am trying to tease out is what is it you are trying to get specifically in terms of the type of antibodies that you are looking to generate, and I guess the persistency as well, are you looking to see?

0.52.26

Anders Gersel Pedersen

Well, first and foremost, as you know this is a vaccine that generates internal antibodies and therefore you are not getting a monoclonal response antibody-wise here and we need to make sure that the antibodies that we do raise are targeting the right types of A β position that we want it to be so that we see that we are getting a possible effect on different aspects of A β accumulation either as monomers or polymers or whatever and see that they are hitting the right places. So it is rather complex to decipher that and that is what we need to know upfront because if we, let's say we get a profile that is closer to a profile resembling a Sulesomab , it would be different in terms of strategic decision as to if it was someone that looked more closely to an Aducanumab, for example, in its antibody profile.

0.53.25

Peter Welford

That's great, thank you.

0.53.27

Operator

Thank you. The final question in the queue so far is a follow-up from Michael Novod at Nordea Markets. Please go ahead, your line is open.

0.53.37

Michael Novod

Yeah, just a follow-up on 35700, you talked about on the call after Q1 that the enrolment was perhaps a bit slower and we now see you moving the trial completion into 2019. Are you certain on that timing or do you continue to see some enrolment challenges in terms of timing?

0.54.06

Kåre Schultz

Thank you for that question, Michael. I will pass that on to Anders Gersel.

0.54.10

Anders Gersel Pedersen

Currently, the enrolment is as we expect it to be and I think the statement that I made in terms of the Q1, saying that we needed 12-18 months of enrolment, still holds true. It is, as you can imagine, it is a little difficult to be very accurate about how quickly we get these types of patients in there but so far things are looking okay and there are no expectations at all that we will see a delay in that.

0.54.45

Kåre Schultz

Thank you, Anders

0.54.44

Michael Novod

Okay. Thank you.

0.54.48

Operator

Okay, as there are no further questions, I will hand back to our speakers for the closing comments.

0.54.53

Kåre Schultz

Thank you, everybody, for listening in and thank you for your interest in Lundbeck and have a nice day. Bye-bye.