

H. Lundbeck A/S**Transcript Q1 2017**

Operator

Ladies and gentlemen. Welcome to the H. Lundbeck Q1 2017 financial results. Today I am pleased to present President and CEO Kåre Schultz. For the first part of this call, participants will be in a listen-only mode and afterwards there will be a question and answer session. Speaker, please begin.

0.00.16

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 quarter of 2017 released this morning. With me, as usual, 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 achievements in a minute, but please allow me to summarise on the solid financial performance we have had through the quarter. We have achieved a significant improvement in our profitability as well as growth in revenue and we are very satisfied with the development. Revenue grew 12% in the quarter thereby reaching DKK 4.2 billion. Our key products have continued their strong growth and sales of these products have grown 46%. In general, all key products are performing well and especially Northera, Rexulti and Trintellix are growing fast. The products are, however, negatively impacted by a typical first quarter weakness which we also have seen in past years.

In parallel with the sales growth, we managed to bring down our cost and have reached an EBIT margin of 24% for the quarter, but it does mean that 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 (EPS) of 217%. Our business is in such good shape that we have improved our cash position even further

and since last year we have increased our net cash position by DKK 3 billion and just since year end added an additional 600 million in net cash.

Anders Gersel will revert with a pipeline update and give you more insights into our Phase III data on Brexpiprazole in Alzheimer's agitation but let me just say that I am encouraged by the totality of the data in the studies.

Finally, we have raised our financial guidance for 2017 with DKK 200 million based on the solid operational performance. 2017 is expected to provide Lundbeck with the highest sales and profit level ever.

Let me also point out that the expected gain from the divestiture of property announced last week is not included in this guidance.

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 quarter, we realised revenue growth of 12% despite the continued generic erosion of products such as Xenazine in the US. It is our North American region that delivers most of our performance and foremost products like Rexulti and Northera.

Please note that from this quarter we have moved Canada from International Markets into a North American region to reflect our organisational setup. The region is up 21% for the quarter and constitutes 59% of our sales.

It is also relevant to mention that close to half of the growth in the US is driven by increased demand. And if one excludes Xenazine where demand obviously is declining, then demand actually drives close to 70% of the growth.

A second point to note is that International Markets are now starting to show growth again and Europe seems to be stabilising though still negatively impacted by generic erosion.

Finally, I think it is worth mentioning the very strong improvement in our profitability which follows the quarterly improvements we saw in 2016.

Please turn to slide 5. International Markets which besides our emerging markets business also consist of countries such as Japan, Korea and Australia, grew 6% in the quarter and constitutes 24% 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 China. It is my view that this region will become increasingly important, especially following the expected approvals of Azilect and Brintellix in China towards the end of the year.

Please turn to slide 6. We continued to execute on our strategic growth platforms and we have seen continued significant sales increases in our key products. In the first quarter of 2017, the key products generated revenue of DKK 1.98 billion corresponding to 47% 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, at least until the beginning of 2017 from when you see a slowdown which then also impacts the quarter, at least when it is compared to the fourth quarter.

This is an anticipated quarterly fluctuation which we also have seen in prior years and also with other product categories. We believe that the product will get back to growth as Rexulti has an attractive profile which is highly rated by the medical community. The W/W 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 around 12% branded total script market share and some 13% branded new script market share. In terms of revenue, Rexulti achieved DKK 271 million in sales in the quarter, which represents growth of some 130%.

Additionally, we expect to see the first launches outside the US during 2017 starting with Canada where Rexulti was approved in February. Pending approval, we expect to launch in Australia later in 2017. Additionally, we have filed a product for schizophrenia in Europe.

Please turn to slide 8. Revenue from Brintellix/Trintellix reached DKK 367 million in the quarter of which slightly more than half was generated in North America. However, countries like Brazil, Italy and Spain 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 the past three years since its launch in the US more than 517,000 patients have had the opportunity to benefit from Trintellix. That represents 2.8 million prescriptions from approximately 90,000 unique prescribers.

In the US, over three quarters of all anti-depressants prescription volume flows through commercial 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 about 80% of commercial insured patients and over 90% of Medicare Part D patients.

Finally, let me just pre-empt questions regarding the CRL (Complete Response Letter) and say that the dialogue with the FDA remains ongoing and we will of course communicate the feedback upon conclusion of these discussions.

Please turn to slide 9. If we turn to Abilify Maintena, our long-acting antipsychotic drug, this product is doing well in most if not all markets. The product has close to 14% of the total atypical LAI market worldwide.

In the quarter, sales of Abilify Maintena grew 22% and reached DKK 312 million of which close to 60 % was generated outside North America. The product has been negatively impacted by quarterly fluctuations and a slight increase in the gross/net deductions in the US.

The long-acting injectable market remains strong with double-digit growth rates supported by a shift from oral to long-acting anti-psychotics as well as new product offerings.

Please turn to slide 10. Onfi reaches sales of DKK 690 million in the first quarter following growth of 27%. Northera reaches sales of DKK 340 million following growth of 70%. For both products we expect to see continued increased demand.

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

09.43.00

Anders Gersel Pedersen

Thank you very much Kåre. Please go to slide no. 11. First, I would like, on this slide, to comment a bit on the Lu 35700 which we have in active Phase III for treatment-resistant schizophrenia. We are currently recruiting patients and are also still opening recruitments centres and enrolment is progressing nicely. We therefore currently expect that we will need to recruit patients for the next 12-18 months before we complete these important studies.

Regarding the Trintellix and the FDA discussion, I do not have much to add to what Kåre has already said. The dialogue is actually ongoing with the FDA and we will communicate the feedback upon conclusion of these discussions as already mentioned.

Please go to slide no. 12. Brexpiprazole data were announced early in May where we had the top line results from two Phase III studies evaluating Brexpiprazole for potential treatment of Alzheimer-related agitation.

Both studies showed improvement in symptoms of agitation relative to placebo and one of the two studies met the primary end point. In the first study, the primary end point was statistically better than placebo and more robust than the key secondary end point which was not meeting the pre-specified P values.

In the second study, the primary end point was not met. Yet, the secondary key end point shows statistical significance against placebo.

In both studies, there was variability in the data from different countries, perhaps associated with different standards of care of the underlying support of patients. Both studies are undergoing extensive additional analysis to better understand the data and the geographic variability that was observed. When analyses are complete, we will meet with the FDA to discuss the results and the next steps. I think it is important to frame the

condition of this disease here. Agitation is a leading cause of institutionalisation for patients with Alzheimer's dementia. With no currently approved treatment specifically for agitation associated with dementia in Alzheimer's.

It contributes to the roughly \$250 billion cost of burden of Alzheimer's disease alone in the United States and underscores the importance and urgency of the work in this area. More than 50% of all patients living with Alzheimer's will experience neuropsychiatric symptoms such as agitation at some stage of their disease. Symptoms of agitation place a serious burden on the people afflicted with the disease and their caregivers significantly affecting the quality of life for all of the affected individuals.

Please turn to slide no. 13. We believe a long-acting formulation of Brexpiprazole could add significant value to patients and could be an important treatment option in the market. Therefore, Lundbeck and Otsuka have recently initiated a Phase I open-label trial to determine the pharmacokinetics safety and tolerability of Brexpiprazole Long-acting Injectable (LAI) administered subcutaneously or intramuscularly in adults with schizophrenia. The trial is expected to recruit about 110 patients and will likely finalise in the second half of 2018.

This was all from my side today and I will now hand over the presentation to Anders Götzsche to go through the financial performance.

13.36

Anders Götzsche

Thank you very much Anders. Please go to slide 14. In the first quarter, revenue increased by 12% and reached DKK 4.2 billion. The impact from loss of exclusivity was therefore more than mitigated by the growth in other products. Our gross margin has improved considerably following improved product mix with reduced royalties and reached 77% in this quarter compared to 72% the year before and 75% in the fourth quarter 2016.

Furthermore, our EBIT reached DKK 1 billion for the quarter and has therefore improved substantially. 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 initiated in 2015.

The EBIT margin has significantly improved from last year. The margin has improved from 13% last year to 24% for the quarter in 2017. That means that the positive development we have seen in the last few quarters continues.

The effective tax rate continues to decline and as a result we see very strong growth in our net profit and subsequently also in our earnings per share which has grown more than 200%.

Please also let me repeat what I have said last quarter regarding our forecast for the tax rate going forward and please be 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 we will end up around 30%. Beyond 2021, the long-term reported tax rate is expected to decline to a level between 23 and 25% but it is also very important to note that the cash tax rate is somewhat lower. From being around 38% in 2016 and around 30% in 2017 and 2018 from 2019 you should expect that the rate will decline to a level between 23 and 25%.

Please go to slide no. 15. The successful execution of the restructuring programme is best illustrated by the reduction in the number of FTEs from more than 6,000 people to less than 5,000 people, which is the lowest FTE level in more than 10 years.

Cost of sales declined from around DKK 1.1 billion to DKK 965 million for the quarter and remember at the same time we grew the top line by 12%.

The SG&A cost increased from DKK 1.5 billion to DKK 1.6 billion driven by a 10% increase in sales and distribution costs but it is also worth looking at the SG&A ratio for the period which was 38.5% compared to 39.6% in the same period the year before.

Please turn to slide no. 16. We ended the quarter with a positive net cash position close to DKK 1 billion. The strong improvement in our net cash of around DKK 3 billion is obviously a reflection of our improved cash flow mainly driven by the improved profit.

Please turn to slide no. 17. Lundbeck returned to positive net cash position at the end of last year and in this quarter you can also see from the graphs that we have realised a further improvement in our net cash position. Our free cash flow for the quarter is impacted by changes in working capital driven by quarterly fluctuations in the inventories and short-term liabilities but of course we will continue to deliver a strong cash flow in the remaining part of 2017.

Please go to slide 18. 2017 will likely be impacted by the loss of exclusivity on Sabril and also the introduction of generic versions during the middle of the year and continued generic erosion on Xenazine.

However, with expected continued growth for our key products, the outlook for 2017 indicates revenue in the range of DKK 16.5 – 17.3 billion. We expect to see a continued significant improvement in our profitability in 2017 and EBIT is expected to reach between DKK 3.6 and 4 billion for the year, which indicates a margin between 21 and 24%.

Please note again, Kåre said it in the beginning, but please remember that the revised guidance provided does not include the possible gain from the divestiture of the property of some DKK 200 million which we announced last week.

For financial items, you should expect a net loss of around DKK 50-100 million for the year and now back to Kåre for the concluding remarks.

0.19.21

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. Back to you, operator.

0.19.38

Operator

Thank you. Ladies and gentlemen. If you have a question for the speakers please press 01 on your telephone keypad. Please hold until we have the first question. And our first question comes from James Gordon from J.P. Morgan. Please go ahead, your line is now open.

0.19.43

James Gordon from J.P. Morgan

Hello. Thanks a lot for taking the questions. One question is just on Rexulti and the Alzheimer's data. What had the FDA previously said about the possibility of pooling the two studies? And what is the precedent in terms of whether you can pool the studies when they don't agree on the primary and secondary. One question is just on R&D whether it is fair to assume it can stay at this low level based on what is going on in the

pipeline at the moment or other reasons R&D can tick up in the remainder of the year and then the third question just Sabril. What is your expectation in terms of how many other generics can launch this year and the impact on the product this year? Thanks.

0.20.17

Kåre Schultz

Thank you very much James. Anders Gersel will take the two first questions and I will take the third one on Sabril so over to you, Anders, for Rexulti.

0.20.26

Anders Gersel Pedersen

Yes. With respect to the FDA what you are alluding to is what the FDA actually does look at, what they call a totality of evidence that you present and that means not only what happens in the individual studies but also what is the underlying consistency between the various parameters they are looking at in the single studies and also across studies. We have not been in any sort of dialogue up front with the FDA concerning outcomes of these two studies as such and we need to look further into the details of the study before we have these discussions, but there is a precedence for having discussions with the FDA and actually get approvals without having hit the primary end point on the a priori situation but that depends on the underlying reasons for that to occur.

With respect to the R&D percentage or expenditure, then we are at the run rate that we have currently, is what we expect to have for the rest of the year and we do not expect to see any significant ramp-ups over the coming quarters or years for that matter. We think we can manage the portfolio within that range that we are having here.

0.21.45

Kåre

And with regard to Sabril, one generic version has already been FDA approved and we expect that to launch within the coming months and then we do not know exactly, of course, what will then happen but my guess would be that there will probably be one more coming before the end of the year.

0.22.03

James Gordon

Thank you

0.22.07

Operator

Thank you. Our next question comes from Carsten Madsen from SEB. Please go ahead. Your line is now open.

0.22.12

Carsten Lønborg Madsen

Yes, thank you very much. Carsten from SEB. A follow-up question to the agitation data, just to understand sort of your view better. When you look at the adjustments you are kind of probing to make or at least you suggest could be made with these Russian patients, do you consider that a big adjustment because from our side I think removing 20% of the patients in one of the trials it sounds like a pretty high adjustment to the trial data. And as a follow-up on that, the primary end point in study I was positive for the P value below 0.05. Can you tell us how much below because 0.05 is maybe not the most challenging P value to present, at least not when the second study was not significantly positive on the primary end point. Thanks.

0.23.03

Kåre Schultz

Thank you Carsten. Two questions again to Anders Gersel on Rexulti and agitation in Alzheimer's.

0.23.12

Anders Gersel Pedersen

First and foremost, the P values are what they are. I mean, I think we have a general sort of notion that P values less than 5% are what we consider significant in these discussions. However, as you know, they are just – it is an arbitrary number and one needs to discuss with the FDA and the set of evidence how does that come forward. In terms of whether it had to be 0.02 or 0.01 that is usually if you go for a single approval for a single study as your strategy that you would normally entertain that discussion.

With respect to the number of patients that you need to exclude, I think I will not get into any detailed discussion about it until we have had the chance to get much more in depth with that but it is quite clear that when we look across the geographic spread then taking out some entire geography that has an obvious different outcome than some of the others we need to understand the reason behind that and find out if there is a good medical explanation that will justify doing that.

0.24.29

Carsten Lønborg Madsen

And when do you expect to or hope to present the detailed data?

0.24.35

Anders Gersel Pedersen

For the public? We haven't discussed that in detail. I think the first step is that we need to understand the data ourselves first and then we need to discuss with the FDA and that is sort of the imminent work that we are doing right now.

0.24.51

Carsten Lønborg Madsen

Okay. Thanks.

0.24.55

Operator

Thank you. Our next question comes from Trung Huynh from Credit Suisse. Please go ahead. Your line is now open.

0.25.04

Trung Huynh from Credit Suisse

Hi, it is Trung from Credit Suisse. I have a couple of questions on Brex and one on Northera, if I can. Firstly, can I push you on the geography of the trial? You note in your slides that the US was a main recruitment centre in both trials. Can you tell us what proportion of patients in the studies were from the US? And how did the US subgroup

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perform? And finally on Northera, quarter on quarter the growth seems to be plateauing. Is there still an effect of seasonality there or is this, you know, is the 1Q level what we should expect going forward? Thank you.

0.25.38

Kåre Schultz

So, Anders, if you will take the first question on Rexulti, then I will address Northera.

0.25.43

Anders Gersel Pedersen

Yes, I am not going to great detail about the total geographic spread, but it is obvious that for us to have a sensible discussion with the FDA, they need to feel that the US constituents are doing quite good.

0.26.00

Kåre Schultz

With regard to seasonality in Northera, then it is correct that we have seen seasonality since the launch of Northera. Typically, we have seen the winter months showing slightly less growth than the summer half of the year. We expect that also to be the case this year, so we expect to continue to see overall growth of Northera going forward.

0.26.26

Trung Huynh from Credit Suisse

Thank you

0.26.30

Operator

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

0.26.38

Michael Novod

Yes, hello, it is Michael from Nordea. Just a few follow-up questions also to the seasonality because when looking back it actually seems that both Abilify Maintena, Trintellix and to some extent also Rexulti has actually been growing from Q4 to Q1, so are the comments more related to the Lundbeck business starts to look more like say general pharma which sees the slowdown in Q1 or could there be any, say, underlying other drivers in Q1? And then secondly also a follow-up to Alzheimer's agitation. You write that if Russian sites are excluded from both studies, the P value is significant. Is that the combined studies or is it significant in each of the studies when you adjust for Russia? And then lastly on Sabril. Would it be fair to assume that given a very solid Q1 that Sabril sales at worst are flat this year?

0.27.38

Kåre Schultz

Thank you very much Michael. I will address the seasonality. Then Anders will get back on the Alzheimer's and I will take Sabril in the end.

You are absolutely right, the seasonality we are seeing is more getting in line with the general pattern that you see for many prescription drugs in the US where you, due to high deductibles in many plans, you see this effect where scripts increase in the fourth quarter above trend and then they slow down in the first quarter below trend and you need to sort of average it out on an MAT basis in order to get the steady underlying growth number. So that is absolutely correct. That is what we are seeing for, for instance, for Trintellix, for Rexulti and other products so that is the seasonality. Then could you address the thing about the sites and excluding Russia data, Anders?

0.28.33

Anders Gersel Pedersen

Yes it is correct that if you exclude the Russian sites each of the studies is significant so and that is obviously what drives us to look further into understanding what is the particularities around these sites and what are the underlying explanations for this other than just a coincidental finding.

0.28.56

Kåre Schultz

And then with regard to Sabril sales, it is correct that we had very strong Sabril sales in the first quarter. It is also a fact that we have had the first generic product approved by the

FDA. It is also a fact that they need to comply with a REMS most likely, a shared REMS with us and we have agreed that REMS with the FDA and we have to wait and see when that gets fully implemented by the generic manufacturer and we have to wait and see exactly what the timing will be of the product actually getting into the marketplace. Then after it gets into the marketplace we have the whole uncertainty about the speed of the generic erosion. We have the fact that we have two different product versions, one is sachets, one is tablets. The approval that we have on the table now is for the sachets so it is hard to predict exactly how it is all going to work out. My guess right now, which can be as good as yours, is that we might see a slight decline based on a decline in the third and fourth quarters but we have to get closer and see what actually happens before we can say anything precisely about it.

0.30.07

Michael Novod

Super. Thanks

0.30.10

Operator

Thank you. Our next question comes from the line of Marietta Miemitz from Prime Avenue. Please go ahead. Your line is now open.

0.30.17

Marietta Miemitz

Yes, good afternoon, thanks for taking my questions. The first one is on Brintellix outside of the US. Can you somehow split out the sequential growth how much of that was driven by sort of new launches in new markets or markets getting access that previously did not have proper reimbursement versus actually sort of steady growth in the markets where the drug was quite entrenched and then just generally trying to get a feel for what is the actual underlying growth rates in those markets where the drug had previously been available. Is there any risk in any of the major markets that you could be reaching an early plateau or do we still just see continued solid uptake? And then I just wanted to come back also to Trintellix and Rexulti in the US since both products' sales were sequentially and I mean I think you know obviously we have seen that in other pharma categories but I always thought that the depression category was pretty immune to the sort of incremental rebating that we have maybe seen in other categories to secure access further along so I was just trying to get a feel for, you know, how did the pricing actually stack up in Q1? Is there any sort of change in the rebating dynamics, even in depression? And when do you really think we could get – we could expect to return to sequential growth for these products in the US? And then I just quickly wanted to follow up on the

R&D spend so can you just give us some of the reasons why the run rate seems to have come down from last year – has that anything to do specifically with the trials that you are running or have R&D rates just become structurally lower across the industry? Because that really seems to be a pretty consistent finding across this earning season that R&D spend from a lot of companies was actually much lower than we had expected so it would just be really good to understand the dynamics behind that. Thank you.

0.32.26

Kåre Schultz

Thank you very much, Marietta, I will address the two first questions and then I will ask Anders Götzsche to address the last ones about R&D spend in general and our ratio as well. If you look at Brintellix/Trintellix, overall sales growth then you could say that in the US it is growing very steadily because we have, you know, Y/Y we have strong increased uptake. Outside of the US we have had launches coming in later so outside of the US it is a combination of markets that are growing and then markets where we have new launches but what is important and what I would like to point you to is that in terms of volume market share we continue to see on a moving annual total a nice development in the US. We are sort of around 0.6% in TRx so not much in reality in volume share right now. But if we look to the new markets where we are launching, so a lot of European markets for instance, but also markets such as Mexico, Brazil and so on then in general we see within the first year shares moving up very close to 1 percentage point in volume and keep on moving so we are very optimistic about the volume share trends that we are seeing in markets outside the US. And it is of course also based on the fact that the branded part of the market outside the US is slightly higher than is the case in the US. So overall very good momentum outside the US, also for Brintellix.

Then you had the question about the phenomenon of the softness of both TRx and sales in the first quarter compared to the fourth quarter because you have to remember that first quarter over first quarter we have very strong growth both in Rexulti, like 130%, and in Brintellix/Trintellix also had very high growth in the US. But it is a fact I think for many categories that you see a slow-down in TRx in the first quarter. This is not specific to the depression category but on the other hand the depression category is not protected from this trend and it is really not to do with any price negotiations or changes in gross to net and so on. It is much more to do with the fact that we many high deductible plans and people on these high deductible plans in managed care for instance they try to get some more scripts filled in the fourth quarter when they are not paying that deductible any more then as of 1 January they have to start repaying the deductible and therefore they hold back so this is a phenomenon we see across many different disease categories and it is a phenomenon we expect to continue to see but it is really driven – at the end of the day - by patient behaviour and not by pricing. With regard to pricing, we have not seen any dramatic changes in our rebating schemes, in our sort of agreements with the PBMs. We have taken sort of average price increases in line with what we have seen earlier in

the market which are high single-digit and we did take that on Rexulti and some other products here in April 2017.

With regard to the R&D spend I will ask Anders Götzsche to answer that.

0.35.46

Anders Götzsche

Yes you should expect the R&D spend to be around 15% for 2017. You need to remember that last year we also had the Idalopirdine studies and so forth and we also had some write-offs, and then we have also been – the restructuring of course also has an impact on the capacity costs in R&D and you should expect, if you look at years to come, that our R&D ratio – you should expect it to be between 16 to 18% on a – you know, it will swing between the years because it will also be due to the portfolio we have on the activity level so that is the level that we anticipate going forward.

0.36.28

Marietta Miemitz

Okay, thank you.

0.36.30

Operator

Thank you. Our next question comes from Emma Newey from Bank of America. Please go ahead. Your line is now open.

0.36.37

Emma Newey

Hi, it is Emma Newey from Bank of America. Two questions please. Firstly, could approval for Abilify Maintena in bipolar disorder be so Abilify Maintena grows again? And secondly, what approximate discount to Sabril's net price do you believe it is possible for generics to launch up? Thank you.

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0.36.56

Kåre Schultz

So, thank you very much for that. With regard to approval for Abilify Maintena, I will ask Anders to comment on that.

0.37.04

Anders Gersel Pedersen

We have a PDUFA date late July on the Abilify Maintena bipolar so that is where we expect to hear back from the FDA.

0.37.18

Kåre Schultz

With regard to discounts on generic versions of Sabril, it is really, really hard for me to predict since we are not directly involved and since we see that there might be, you know, one discount for the list price but other discounts being given to the pharmacy chains so I will rather refrain from that and refer to the fact that in general in the marketplace when you have new launches you see anywhere from let us say 20 to 90% discount but we really have no qualified information on what might be the case for Sabril with the first generic launch.

0.37.54

Emma Newey

Okay.

0.37.58

Operator

Thank you. Our next question comes from Jacob Lademann from Carnegie. Please go ahead. Your line is now open.

0.38.03

Jacob Lademann

Hello, thanks for taking the questions. A couple of questions regarding AF35700. The recruitment update that you gave indicates to me quite a significant delay of around 6-12 months in terms of finalising the study so two questions. Could you talk a little bit about what drives the delay if I am correct in assuming that delay? And also, does it change your plans at all in order to - the timing of the potential or the planned second Phase III trial that you likely expect to run? Thanks.

0.38.38

Anders Gersel Pedersen

In terms of the recruitment, we see that the recruitment on the sites that are open they are going pretty much the way that we expect them to do. What we have been slightly delayed on in some countries has been sort of the regulatory approval process of getting the sites opened in all of the countries at the same time. So you are right there is somewhat of a delay in that. I don't know where it is going to end up. As you can see from the indication here that we are basically talking about a recruitment scope of 12-18 months so we are still quite wide in that recruitment scope. It is a difficult set of patients, a difficult study to run to take them through that process so that is the main driver that change in getting sort of both the sites up and running and then making sure that we cannot just boost the recruitment as you might be able to do with some other simple indication. This is not an easy set of studies to run so we are more careful about making sure we get the right patients than that we get the fast patients.

0.39.48

Jacob Lademann

Okay and maybe just a follow-up. Does it impact your plans at all for when to start the second Phase III trial? I assume that the original plan was to see the data of the first trial. I think you mentioned that a few times, but does this change anything at all?

0.40.01

Anders Gersel

No, it doesn't and I think we have in our internal plans we have already had some gap between the two studies and we still believe we have a chance to look at the data and get studies going at an appropriate time after that but we want to see the data to get a good feel for where we are heading in the next study because they are much more difficult to change if you have started them than to do them right when you start them.

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0.40.32

Jacob Lademann

Thanks.

0.40.35

Operator

Thank you. Our next question comes from Peter Welford from Jefferies. Please go ahead. Your line is now open.

0.40.39

Peter Welford

Oh, hi, yes. I have got a few questions left. Firstly, just on Sabril the solutions or sachets whether this form that has been approved, approximately what proportion of your volume is that? Secondly then, Ebixa in the ex-European market seems to be relatively strong. Do you anticipate that sort of growth to continue for the remainder of the year? And I wonder also if you could potentially give us Azilect sales if possible in the quarter? And then finally, just on the LAI tax that you are using for Brex in there, is that the same long-acting formulation that you are using for Abilify Maintena or are there any differences at all in the sachets that are being used for that? Thank you.

0.41.23

Kåre Schultz

Okay, thank you very much. I think we will start with the Sabril question. What is the split between sachets and tablets? And we on average see a 50/50 split there so you should expect that the top line we are seeing on Sabril, the sales revenue we are seeing on Sabril is split 50/50 and then I will move on to comment on Ebixa. It is correct that we see quite steady posted/post-**exit** ? business with Ebixa outside of the EU and we continue to see that as a strong business where we will be able to continue to have business throughout the coming years and also throughout this year so no real risk there.

Then in terms of Azilect, I don't think we comment on it specifically, but of course you know that we have handed back Azilect in Europe and that means that we are no longer booking the revenue directly but we have a small commission or whatever you want to

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call it, royalty that we are getting but that is relatively minimal and then on the formulation of a potential LAI formulation of Rexulti. Anders, do you have any comments?

0.42.43

Anders Gersel Pedersen

Yes it is not the same formulation as for Aripiprazole. First and foremost, the amount of drug that you need to give with Brexpiprazole is much, much smaller. It goes from the simple dosing that are in the two different drugs but there is also differences in the solubility of the two substances so it is a very different way of being able to administer it with Brexpiprazole than with Aripiprazole and that is also the reasoning for subcu(taneous) testing going on which will be an impossibility with Aripiprazole.

0.43.23

Kåre Schultz

So Peter, did we answer your questions?

0.43.25

Peter Welford

That is great, thank you.

Kåre Schultz

Thank you

0.43.30

Operator

Thank you we have a follow-up question from the line of Trung Huynh from Credit Suisse. Please go ahead. Your line is now open.

0.43.38

Trung Huynh from Credit Suisse

Hi, just two quick follow-ups, if I may. One on pricing. Can you let us know the impact of your price increases in January to your revenue growth in 1Q? And the second one is how do you think about the build up of your infrastructure in China given that it is potentially going to be a key area? Thank you very much.

0.43.58

Kåre Schultz

So I will give it a go with the pricing and the infrastructure and then I will ask Götzsche also to comment on the pricing. If I look at the pricing and I assume you are talking about the US market and the pricing we saw – what changes we have seen in the US, then of course we only in the first quarter took price increases on a few products but if you are thinking about the total effect sort of compared to last year then it sort of depends on whether you look at it including or excluding Xenazine because Xenazine of course was a drag on volume so if we exclude Xenazine where we had very big negative volume that affected total volume and just look at the rest of sales then significantly more than 50% of our sales increase came from demand from more patients using our products, which we are of course very happy about so that was positive, but I don't know, Götzsche, do you have any further?

0.44.57

Anders Götzsche

We can say that you know the average number is this 70% and then of course it varies slightly between the different products. But in general it is between 60 to 80% that is demand and the rest is price. And then of course you know the sales channels for the products are.. of course vary between the products if it is primarily commercial, if it is Medicare or Medicaid and of course the gross to net impact on the price increases coming down to the net price increase and impact, you know, it is a big landscape of calculation, so – but in general between 60 to 80% of the growth estimate.

0.45.39

Kåre Schultz

And then with regard to infrastructure in China, it is absolutely correct that since we launched the new strategy a little less than two years ago we have had the focus on growing our infrastructure both in the US and China and we are in the process of growing the infrastructure as we speak and we are also of course in the process of obtaining regulatory approval for Azilect and Brintellix in China. We hope to see approvals before the end of this year and so we have an organic model where we will on an ongoing basis be expanding our organisation in line with the increase we will expect to see in our sales.

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0.46.22

Trung Huynh from Credit Suisse

Thank you

0.46.25

Operator

Thank you. And as another reminder if you do wish to ask a question, please press 01 on your telephone keypad now. And we have a follow-up question from Carsten Madsen from SEB. Please go ahead. Your line is now open.

0.46.40

Carsten Lønborg Madsen

Thank you. Just one quick follow-up here. When you say that 60-80% is demand and the rest is prices then pure price or is it price mix? Just to understand. Thank you

0.46.53

Anders Götzsche

What do you mean with price mix?

0.46.57

Carsten Lønborg Madsen

You know, I will reformulate it and say so the rest is just basically price increases just sounds like a relatively high number that is 40% of your revenue growth in any given quarter could come from price increases alone.

0.47.12

Anders Götzsche

Yes but this is of course you know you have the demand and then of course you have the ongoing price increases – you know, the average price increase we have per year is you know high single-digit so in general you have – the demand is around the 60-80%.

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0.47.32

Kåre Schultz

So Carsten, this is because it was just, I don't know, some quick math. If you have growth of 20% in the first – we just pick a number, right. If US grew 20% in the first quarter and you had a net pricing effect of let us say 8% that would then be 40% of your growth coming from pricing. So if you have 5% growth in price on average then there will be 25% of your growth coming from pricing, so we are in that ball park.

0.48.02

Carsten Lønborg Madsen

Yes thanks, very clear. Thanks.

0.48.06

Operator

Thank you. Our next question comes from Peter Sehested from Handelsbanken. Please go ahead. Your line is now open.

0.48.13

Peter Sehested

Yeah, hi, it is Peter from Handelsbanken. Thank you for taking my question and it is also a bit of a quick math but for Anders Götzsche. Anders, looking at your midpoint sales guidance – the revised one – 6.9 billion you are guiding or hinting at the R&D cost level around 15%, SG&A around 40%, COS around 20, you know, taking that from your midpoint of guidance you get to an EBIT of around DKK 4.2 billion. I mean that is, as far as I can see, that is higher than your current high end of your range and secondly looking at the comments you just made on the conference call regarding the prospects for Sabril, I just wonder what is you know the thought behind the low end of your sales guidance? Thank you very much.

0.49.04

Anders Götzsche

I can just say that you need to remember that we say around 20%, we say around 40% and we say around 15% so the math you are doing is you take the exact numbers and then you

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take the mid-range. We have not guided that you can take the mid-range and the exact numbers and then you come down to our guidance so what we still expect is that you need to understand that we have Sabril and Xenazine, which is basically the two products that have been doing extremely well the US and we are seeing generics for Xenazine and we will probably see generics for Sabril so the growth and the revenue coming from these two products will be declining over the next three quarters. How much? We don't know and that is the reason for the guidance.

0.50.00

Peter Sehested

Okay, thank you very much, but just perhaps just a follow-up on the absolute level of the SG&A costs or these S&D costs. Could you just please explain what is driving that and whether it will drive that for the next three quarters? Thank you.

Anders Götzsche

The slight increase we have had in SG&A is of course that we have more support behind the launch of Brintellix and Rexulti in the US as well as you can see that the uptake for Brintellix in other markets is taking off and that means that of course we have more resources behind but of course it is our aim to secure that we have profitable growth and that also means that you can see that we have reduced our SG&A margin with 1 percentage point so that is definitely, you know, we think we use the resources wisely. Put pressure behind the markets where we can see growth opportunities but at the same time we are very diligent in securing that we are not using too much cost.

0.51.02

Peter Sehested

Okay, thank you.

0.51.05

Operator

Thank you and as there appear to be no further questions I will turn the conference to you, Kåre.

0.51.09

Kåre Schultz

Transcript

And I will just like to thank everybody for your attention and thank you for listening in on this conference call. Have a nice day. Bye.