Lundbeck Teleconference Q1 2016

11 May 2016

Operator

Hello and welcome to the H. Lundbeck Q1 report for 2016. Throughout this call all participants will be in listen-only mode and afterwards there will be a question and answer session. Mr Kåre Schultz. Please begin.

0.00.19

Kåre Schultz

Yes thank you all for your interest in Lundbeck. Welcome to this Lundbeck teleconference covering our financial report for the first quarter of 2016 released 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 presume you have seen many times in the past, and I will refrain from reading it out aloud. So we will go directly to slide 3.

We will elaborate on some of these items in a minute, but please allow me to summarise the very eventful start to the year. I would start by saying that the complete response letter we received back in March from our sNDA on Brintellix not mentioned on the slide was a disappointment to us and Anders Gersel will get back to this. Our restructuring programme, which we announced back in August last year, is well on track. And the savings might even come faster than anticipated. I am therefore very comfortable with the improvements we have already been seeing on our profitability and which we expect will continue. Additionally, we see continued very fast growth in our key products as well as our US operations in general. Also adjusted for the tail wind currencies are providing for us. Therefore, we are able to raise our full-year guidance. Lundbeck now expects revenue of around DKK 14.2-14.6 billion and EBIT is expected to reach DKK 1.3 to 1.5 billion for 2016 compared to previously DKK 13.8 to 14.2 billion and DKK 1.0 to 1.2 billion, respectively.

Please turn to slide 4. In the US, the strong uptake of key products more than mitigated the Xenazine erosion and this region has therefore grown 32 % in local currency and constitutes some 50 % of our sales. International markets show decent growth in local currencies but is negatively impacted by Venezuela and the hand-back of Azilect in selected markets in the region. Europe shows substantial negative growth, primarily as a result of the Azilect hand-back and timing of market access on our new products.

Please turn to slide no. 5. We continue to execute on our strategic growth platform. We have seen significant sales increases in our key products, which we are very happy about. For the quarter, the key products generated revenue of more than DKK 1.3 billion corresponding to 36 % of total revenue. We are expecting continued high growth for these products.

Please turn to slide 6. We will now look at our key products individually and let us start with Rexulti. As you can see, the significant uptake continues and as we are now some 9 months into the launch, I believe that the momentum looks solid and sustainable. The week over week growth continues to outpace the branded market. And the competition and the uptake relative to prior analogue anti-psychotic launches is strong. Rexulti has so far achieved more than 6 % branded TR_x market share and some 8 % branded NR_x market share. In terms of revenue, Rexulti achieved DKK 116 million in sales in the first quarter compared to DKK 58 million and DKK 59 million in sales in the third and fourth quarter, respectively, last year. I am therefore very confident in Rexulti as a growth driver for Lundbeck.

Please turn to slide 7. Revenue from Brintellix reached DKK 238 million in the first quarter of the year. The growth was primarily driven by the continued sales growth in the US, however, also from launches in countries such as Canada. In the US, Brintellix or Trintellix, as it will be called in the future, reached revenues of DKK 138 million for the quarter. Trintellix volume share of branded total prescriptions currently stands at 20.5 % and the share of branded NR_x volume stands at 23.6 % by the end of April. In general, Trintellix is the only branded anti-depressive which shows growth. Anders Gersel will get back to the disappointing feedback from the FDA concerning our sNDA.

We have recently launched Brintellix in Brazil and some smaller Asian markets but it is still too early to assess the progress. We do, however, see substantial opportunities for the product in Latin America. In Europe, market access remains a constant key challenge and most European markets are still minor. We have recently launched Brintellix in Spain and Italy but it is still very early days. Germany on the other hand is more difficult. Brintellix has shown negative growth in Germany and price negotiations with the German authorities have ended without reaching an agreement. In general, however, we continue to see market shares in markets with market access which are substantially higher than seen in the US.

Please turn to slide 8. If we turn to Abilify Maintena our long-acting antipsychotic this is doing very well in most if not all markets. Sales grew 113 % or 110 % in local currencies and reached DKK 255 million in the first quarter. For this product, US and Europe are almost of equal size and both regions see substantial growth.

Please turn to slide 9. Onfi just continues to impress. The product reaches sales of more than half a billion kroner following growth of 39 %. We continue to see increased demand but the product is also benefiting from positive currency and price development.

Please turn to slide 10. Northera was launched some 1½ years ago. The product reached sales of close to DKK 200 million. Also in this case, we continue to see increased demand but the product is also benefiting from positive currency and price development.

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

0.07.14

Anders Gersel

Thank you, Kåre. Please go to slide no. 11. I will first mention that we recently submitted Rexulti to the authorities in Canada and Australia. So far, only with the indication schizophrenia as additional indications depend on outcome from clinical trials. I will come back to the complete response later on in my presentation. Finally, we have just received the first data on a study using Abilify Maintena for the maintenance treatment of patients with bipolar disorder. And I am pleased to tell you that the study made the primary end point and we look forward to presenting the data at future medical conferences.

Please go to slide no. 12. While we are pleased that the FDA recognises cognitive dysfunction in depression as a valid treatment target and that they also recognise the DSST scale as valid and relevant measure, we are obviously very disappointed about the FDA's current position giving us the complete response letter rather than an inclusion in the label, especially in the light of the positive voting from the AdCom meeting earlier this year. The process from here would be that we would be requesting a meeting with the FDA which they also invite us to do in the complete response letter and then we will have to decide what the next steps are from here. Therefore, you should not expect any concrete update on the process before we are well into the third quarter of the year.

Please go to slide no. 13. Lundbeck has a long history in the four chosen therapeutic categories and we have solid disease biology understanding which together with our experience in running clinical trials in these areas make us better able to translate data into clinical relevance here. I believe we have a solid pipeline with a maturing early-stage portfolio and products although we are not very communicative about that part of the earliest pipeline.

I will, though, highlight here that a change from before is that Lu AF35700 is now actually in Phase III and actually recruiting patients into a Phase III study. We have additionally a broad portfolio of life-cycle management projects to choose from. Therefore, to put it bluntly we have almost had more projects than we are able to handle at this stage in the R&D organisation.

With this I will hand over to Anders Götzsche to go through the financial performance.

0.10.03

Anders Götzsche

Thank you very much Anders and please turn to slide 14. As you have seen from the release in the first quarter revenue increased by 6 % and reached DKK 3.8 billion and the impact from loss of effectivity was more than mitigated by the growth in the key product. However, the growth is of course partly offset by the decline in mature product portfolio in Europe and in international markets as well as we handed back Azilect to Teva in the beginning of the year for certain areas.

The EBIT margin increased by more than 12 percentage points and has therefore continued the positive development that we already saw in the fourth quarter of last year and I know that many of you are still focused on core EBIT and I can explain that the only difference between EBIT and core EBIT when you look into the full year numbers is around DKK 1 billion in product amortisations – or amortisation of product rights. We, of course, see continued room for margin improvement in the longer term following the continued effect from the restructuring programme and of course also combining with the growth in the key products with higher margin improving our gross margins.

For the remainder of the year, it is however likely that the expected erosion of Xenazine could put slight pressure on margins, at least compared to the level reached in the first quarter 2016. I also think it is prudent to comment on our net financials as well. In February 2016, the Venezuelan government devalued its currency and based on this and combined with a decline in transactions that have been settled at the official exchange rate we have assessed our receivables and consider it to be highly unlikely that we will receive settlement at the official exchange rate. Consequently we have recognised in the net financial expenses an exchange rate loss of DKK 125 million which has been taken into – so we have taken a full write-off of all receivables in Venezuela in the quarter.

The tax rate is around 49 % and it is a higher tax rate compared to the Danish corporate tax rate and that is caused by a couple of factors. One is the amortisation of the Northera product rights which is not deductible for tax purposes and then it is the increasing activity in the US where the tax base is in the US

with the higher tax rate multiplied by the tax paid. And that results in the higher tax rate. Of course, we have a loss in Denmark but as it is taxed at a lower tax rate then the totality of the tax rate is 49 %.

Please flip to the next slide. As you can see then all cost ratios have improved compared to the same period last year and it is a substantial improvement. When you look at the cost ratios, we still expect our cost of sales to reach a level of around 25 % for the year and we expect that the R&D percentage will stay around 20 % for the full year 2016. The SG&A margin is likely to end the year in the range to 40 to 45 % so that is the guidance we can give for our cost ratios for the full year.

Please turn to the cash flow statement on page 16. The solid improvement in our cash flow is obviously a reflection of the improved profitability but we have also seen improvement in working capital, we have seen reduced provisions as we are spending costs for the restructuring programme. When we finish 2016, we expect that our net interest-bearing debt will have been reduced to a level between DKK 1.2 and 1.4 billion.

Please go to the next slide, slide 17. Based on what Kåre also explained we have had a solid start on the year. We believe it is prudent to raise our financial forecast for the year. We expect the continued growth for the key products and the outlook for 2016 now indicates a revenue range of DKK 14.2 – 14.6 billion and that is also resulting in a significant improvement in our profitability and we now expect an EBIT of DKK 1.3 to 1.5 billion for the year which indicates a margin around 9 %.

I have already gone through the expectations for the cost ratios so we are now down to the financial items and based on the situation in Venezuela we expect that net financials will be a loss around DKK 200 million. It is of course still difficult to provide a specific guidance for the tax rate as it very much depends on how much revenue we have in the different regions, but currently based on our expectations for now we expect a tax rate slightly above 50 % for 2016.

The outlook we have presented today is based on unchanged exchange rates by the end of April and going forward for the remaining part of the year. And with that I will now hand back to Kåre for the concluding remarks.

0.16.01

Kåre Schultz

Thank you, Anders. Before I hand over to the operator for our Q&A session, I would like to say that Lundbeck stands in front of exciting times. We believe that 2016 will be a year where we will see continued positive results of our actions. With that I would like to thank you all for your interest and open up for the Q&A session. Over to you, operator.

0.16.22

Operator

Thank you. Ladies and gentlemen, if you have a question for our speakers, please press 01 on your telephone keypad. Our first question comes from the line of Carsten Lønborg Madsen of SEB, please go ahead, your line is now open.

0.16.41

Carsten Lønborg Madsen

Thank you very much, this is Carsten from SEB. Two questions, first on Northera where we have seen a strong launch so far but here in Q1 you actually see almost flat growth versus Q4 2015 so what should we expect for the rest of 2016 and are there any particular reasons why Q1 was a little bit to the weak side? Looking at prescription data it seems that there is an uptake again now in numbers towards the end of this quarter. And then on AF35700 to Anders Gersel, I guess, when we .. as you said you are not telling us a lot about your very early stage pipeline but you have actually also not told us a lot about 35700 but maybe you could tell us a little bit about what have you shared with the FDA and also get fast track status.

0.17.35

Kåre Schultz

Thank you for those questions Carsten. I will answer first one and then Anders Gersel will answer the second. So in terms of Northera sales, it is correct that the growth from the fourth quarter 2015 to the first quarter 2016 is not as high as the average growth we have been seeing. We have seen a phenomenon in the US over the last couple of years where the 4th quarter sales on certain products tend to be higher relative to the first quarter and there is a lot of debate whether it has some link to the whole deductible situation and to the prescription patterns up against the end of the year. We still see a continued positive increase in total scripts on Northera. We still expect to see Northera grow throughout 2016 but you are right that there are some quarterly phenomenon that probably will mean that also going forward we will see lower growth rates between Q4 and Q1 than we will see for instance between Q3 and Q4 and so on.

0.18.39

Carsten Lønborg Madsen

There is no change to for example rebates, rebate reversals or something?

0.18.44

Kåre Schultz

No anything significant and we still see a continued uptake in scripts so we are positive about the long-term outlook. And with that over to you, Anders on 35700.

0.18.55

Anders Gersel

Yes, the 35700 programme is the first one that is going to target patients with treatment-resistant schizophrenia as the primary in the case to go through and that is obviously one of the reasons why the FDA has granted us a special designation here. What we have shared with them is the phase I information we have on the drug and also some PK and dynamic data in some few patient cases where we can basically illustrate in these dosage escalation schemes that we are at an appropriate dose level with 35700 in these dose ranges that we are operating with here from 10 to 20 mg. It is a unique profile in the sense that we have a higher D1 binding relative to the D2 binding and that we are seeing effect in patients with a D2 binding which is around 30-40 % compared to where you normally would see one in excess of 70 % for most other antipsychotics. And in relation to that we also have a 5-6 active component in the molecule it has a somewhat different receptor profile than any of the other currently available anti-psychotics and because of that and because of the indication we are going for we have got this special designation by the FDA.

0.20.35

Carsten Lønborg Madsen

Okay, thanks a lot.

0.20.38

Operator

Thank you. Our next question comes from the line of Sarah Potter of Deutsche Bank. Please go ahead, you line is now open.

0.20.44

Sarah Potter

Hi there. It is Sarah Potter from Deutsche. I have three questions please. Firstly on the guidance which areas have exceeded your expectation in the first quarter to drive the guidance upgrade. Is it just Cipralex which looks to have been very strong or are there other areas? And then secondly on the Brintellix cognition data I know you have not yet met with the FDA but do you have a sense if there is going to be a pass forward in the matter or is it more likely to be a multi-year review with the FDA? And then finally on Rexulti which looks a lot stronger this quarter and is this finally the treatment showing through or do you think there might be some stocking in this number? Thank you.

0.21.26

Kåre Schultz

Thank you for those three questions. I will handle the first and Anders Gersel will handle the second and then I will handle the third question. In terms of the guidance, what has surprised us positively in the first quarter has been the total sales. Not so much driven by Cipralex where we are seeing sort of a flattening out, a plateau you could say, with a much lower drop in Cipralex than expected from our side this year compared to what we have seen in previous years. So it is reaching a more stable situation but we did anticipate that Xenazine in the same kind of situation would be dropping off slightly faster than what has happened and we are also seeing very strong growth of our core products more than doubling compared to last year, so that is on the sales side where there is a positive deviation and then there is also a positive deviation on the cost side. We are still pursuing our restructuring plan with a total settings target of 3 billion which we still plan to realise in 2017 compared to when we announced it. And we see that the cost reductions are being realised slightly faster than we were anticipating so the combination of two elements: slightly better sales than anticipated, slightly lower cost than anticipated altogether means that we see a better first quarter and that we can see that this will continue through the next three quarters and that is the reason for the upgrade of the guidance. Then on Brintellix maybe Anders you can comment on that.

0.23.03

Anders Gersel

Yes. As I mentioned earlier on the – we have not yet had the meeting with the FDA and we have requested it and obviously that makes it a little difficult for me to give more clarity than what we have been able to before. The only thing that is clear from what we have seen at this stage is that they continue to accept the cognitive dysfunction as an appropriate and relevant target in depression which is new. They also accept the SST as a relevant measure of cognitive effects in these patients, which is also important and in terms of why specifically they have not adjusted anything in the label we need to get that clarity in the discussion

with them. At this stage without particular reference to our situation, I would say that normally when you have a complete response letter from the FDA you would expect we would have to go out and do another clinical trial before you can change that position. So that is my expectation that we will have to be extremely lucky to change that position also in this situation so I would look into a multi-year activity prior to having a label adjustment within the United States but I cannot guarantee anything on that until later on in the year.

0.24.32

Kåre Schultz

And then with regard to the third question on Rexulti demand, I can say that we have a very steady progress in TR_x NR_x and in volume share in the US and therefore what you see in the first quarter is based on solid underlying demand increase so that is just very positive and as we also state we are at around 6 % share of the branded segment and we have seen that increasing steadily over the 9 months that the product has been in the marketplace so very optimistic about the outlook for Rexulti in the US. Thank you.

0.25.09

Sarah Potter

Okay, thanks very much

Operator

Thank you. Our next question comes from the line of James Gordon of J.P. Morgan. Please go ahead. Your line is now open.

0.25.20

James Gordon

Hello, thanks for taking my questions – a couple of questions please. One on pricing or US pricing – since my question was just a political commentary and US pricing is quite more hostile and at the same time it does look like Lundbeck has become a bit more aggressive in taking US price rises. So on that, one question would be just in terms of what have you assumed in the business plan where you have given this medium-term guidance on my/the ??? 0.25.41 margins right there. Do you assume that you are going to continue to have some further price rises and would it be fair for us to assume that the recent subpoenas for Northera and Xenazine do those relate to pricing behaviour? And the second question is on Cipralex. Can you quantify how much stocking there was in Japan and is that something you expect to avert in subsequent

quarters or do you think that now there is a steady state there and any comments about why you will get back in Cipralex could it be sustained that we have a slower decline in Cipralex and then just finally on the margin in cost saving targets 3 billion is the plan for what you take out. How much have you now taken out at the end of Q1? Thanks.

0.26.19

Kåre Schultz

Thank you so I think I will try and answer question 1 and 2 and then Anders Götzsche can answer question 3. So in terms of the pricing you are absolutely right that it is part of the political debate in the US. It has been for many years, actually, but it is certainly also part of the debate right now. We do not see any dramatic change or expect any dramatic change in our pricing behaviour in the coming years compared to what we have done in recent years. We see a situation where we do take list price increases but we do also increase the rebating to Medicaid, Medicare and Managed Care and we expect that that will be continuing. With regard to the two subpoenas then there is no reason to believe that that is specifically linked to pricing. It is not something that we are aware of, at least. We have very limited information we have just had a request for information on sales and marketing activities on Xenazine and Northera and that is really all we know. On Cipralex, I think what you should look at is the big picture so not so much the small deviations from quarter to quarter and the big picture is that the substantial patent expiry in the US and Europe, Canada, a few other countries that is over, washed out. Now we have a situation where there are still some pockets left of Cipralex in certain countries that is dropping at a slow speed and then we still have sales growth in China and in Japan due to the fact that Cipralex got to these markets very late so it is still protected in those markets. And that is why instead of this very steep drop we are now getting more to a plateau. We still expect the product to marginally drop in turnover this year, but nothing compared to the dramatic drops we have seen the last four years. And then on the last question, would you Anders.

0.28.13

Anders Götzsche

What in the margin improvement and the link to the cost of the restructuring programme what we said was that we had an ambition of improving the cost base with 3 billion and that we would improve the cost base with 1.5 billion in 2016 and 1.5 billion in 2017. What we have now communicated is that it is going slightly better and we are doing better with the restructuring so you should expect that we will gain savings of 1.5 to 2 billion this year and then of course the savings will be a little less in 2017 because what we are aiming for is the totality of the cost saving.

0.28.47

James Gordon

Thank you and how far through this year are you already on the 1.5 to 2?

0.29.04

Anders Götzsche

How far?

0.29.06

James Gordon

Yes as in ?

0.29.07

Anders Götzsche

Yes, I would say how far. We expect that by mid-2016 we have more or less executed on all the plans you know that of course we don't need to make the restructuring it is in different geographies but we expect that we have finalised everything and then there will be tail and that is of course the reason that we will have a spill-over effect into 2017.

0.29.33

James Gordon

Thank you.

0.29.37

Operator

Thank you. Our next question comes from the line of Eleanor Fung of Goldman Sachs. Please go ahead, your line is now open.

0.29.45

Eleanor Fung

Hi, thank you for taking my questions, three if I may. Firstly on guidance – just looking at the numbers it implies an uplift to the EBIT margins. How much of this comes from a shift in product mix driving higher gross margins versus faster pull through from the cost savings programme that you anticipated? Secondly and thinking about gross margin evolution over the next 12-24 months, how should we think about that as your product mix shifts towards the new products and you move the lower margin Xenazine and Azilect products? And finally just one on Brintellix cognition recognising that you still have to have your meeting with the FDA but as I notice there are a number of trials and clinical trials that get ongoing for cognition. Wondering what your thought process is in using these for a potential re-filing versus commencing on a new trial. Thanks very much.

0.30.43

Kåre Schultz

Thank you very much I will try and answer the two first ones and then Anders Gersel will take the last one. In terms of the guidance and the fact that of course the increase in the EBIT is over proportionate to the increase in sales and therefore the margin is indicated to be increasing you could say that there is some – there is a couple of effects but the most important effect is really that compared to our regional expectation we are seeing a slightly improved cost profile due to the faster realisation of the restructuring and then also some better sales on our key products which are carrying a higher margin so that is the short explanation for the improved implicit EBIT margin in the guidance. In terms of how the gross margin will develop the next 12-24 months it is of course hard to say precisely because you have a lot of moving parts, products growing and other products declining but in general you will see a situation where the gross margin will be improving and this is actually something that will follow us for the next coming years. Some of the older products where we pay high royalties are fading out and some of the new products that we have developed ourselves are kicking in so improved gross margins also over the next 24 months. And then, Anders, on Brintellix.

0.32.11

Anders Gersel

Yes you are correct we have a couple of smaller studies ongoing as we speak and they have not been designed size-wise with an aim to actually support a claim as such. But if in any way they can contribute to any information following our discussions with the FDA in terms of when we learn what they really are looking for we will obviously take advantage of whatever we can with those studies but I have no assumption at this stage they will be the key driver of the discussions with the FDA.

0.32.50

Eleanor Fung

Thank you.

0.32.52

Operator

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

0.33.03

Michael Novod

Yeah, hello it is Michael from Nordea. Three questions also. First of all, to Brintellix the plan is to – or Trintellix – start a DTC campaign here during the summer nationwide in the USA. Are those plans still intact given the name change but also that will be no cognition claim. So are you running full speed with that or how do you see that? And the second thing also relating or follow-up to pricing. Could you please try to back out pricing of gross – most other companies can give us that information. So I would be appreciative to get that. You grow 32 % in the US. Maybe you could cover on what the gross is in volume and in pricing. And then lastly on a follow-up to the cost reductions. Can you try to split out, of the 3 billion how much is actual say operating cost reduction and how much is coming from say the royalties that you don't have to pay losing Xenazine and Azilect.

0.34.04

Kåre Schultz

Thank you. I think I will try and handle all the three questions and if we take the first one on Trintellix then it is correct that we have been doing some pilot DTC in a regional fashion to see, you know, decide on which format would work the best for us. And there we have concluded that it is looking good and that we will have it of course using the name Trintellix because we are changing to that name so it looks good and we are starting soon and we have high hopes that this will further increase the nice penetration we are seeing of Trintellix where basically on a constant monthly basis we see new all-time high market shares for Trintellix in the US. In terms of the second question on pricing I cannot give you the specific split between volume and price for the first quarter but I can tell you that the key driver of the growth is the volume as you can easily imagine from newly launched products that are doing well such as Rexulti, Trintellix and so on. There the volume increase is a key driver but of course pricing also plays a positive part of this so it is a combination.

Then on the cost reductions you can say that there is one part you could call the gross margin improvement and the other part is what then is between the gross margin and the operating margin and my expectation is that once we get to the end of this then you will roughly see a fifty/fifty between the two so a significant part of the improvement is the fact that we are changing the portfolio from being in licensed products where sometimes both cost of goods or royalty or amortisation, whatever element it is, places a higher burden on the gross margin to own developed products developed either with partners or alone which typically carries a better gross margin and then at the same time the cost reductions throughout the operational part of the organisation you could say well manufacturing is also operational but throughout the sales, marketing and idea organisation so in both areas there will be significant price reductions.

0.36.33

Michael Novod

Thank you very much

0.36.37

Operator

Thank you. Our next question comes from the line of Olivia Capra of Barclays. Please go ahead, your line is now open.

0.36.44

Olivia Capra

Yes hi, thank you very much. I think a few might have been answered. If I can just have two more, please. For Rexulti, if I am correct most of the scripts right now are actually being written for MDD rather than schizophrenia. Is this a normal breakdown versus what we see for other oral antipsychotics at this stage of the launch or is the MDD component unusually high for Rexulti and could we see the schizophrenia segment expand now that you will have the maintenance treatment out of your label. And then just lastly for Rexulti in terms of launch into ex-US markets. Any update on your thoughts here? I think it is a reminder of what are the obvious markets where you think the return to Lundbeck stacks up and then just lastly on Abilify Maintena – How can we sort of a little bit in the last few months at the high dose option be the biggest driver for taking shares for Abilify Maintena and I know it is too early to see this in IMS because of sampling but what is the feedback you are getting from the sales reps? Are there any signals of a slowdown in new prescriptions and what do you think it would take to see use of injectables overall pick up?

0.37.51

Kåre Schultz

Thank you very much. I will try and comment on both questions and Anders Gersel can also comment on Abilify Maintena, how we see that with the news we have just had on clinical trials we have done in bipolar but if we take Rexulti first in the US then it is correct that about 80 % of scripts are assessed, estimated to be from MDD and it is really not I think that different from other antipsychotics but it is a very, very good profile for MDD and if you look at the patient populations then of course the size of the MDD segment in terms of numbers of patients is significantly higher than the size of the schizophrenia segment and that alone given that it is a very good therapy sort of lends itself to the fact that you will see higher absolute numbers on MDD than schizophrenia. But it is also penetrating very well in schizophrenia and we don't expect to see any sort of dramatic step changes due to the maintenance approval from the FDA but we think that it is overall looking very positive. In terms of outside the US, then we are waiting for some clinical data in several of the markets before we will see launches but we have sort of started the regulatory process in different markets including Canada so over the coming years we will see launches. In terms of value creation we probably have to be realistic and say that the biggest value creation will be in the international markets and in the United States whereas in Europe we will probably be facing reimbursement challenges that will limit the total value of the product in Europe. With regard to your second question on Abilify Maintena I will just say in general on LAI products that are injected once a month or every third month, it is quite clear that this market segment is growing in all geographies and due to the benefits of the stable therapy you obtain with this type of therapy as opposed to daily oral therapy I have expectations that the volume share of the market being on long-acting injectables will be increasing over the next 5-10 years so we will hopefully see Abilify Maintena grow in sales, both as a consequence of the market increasing in terms of volume but also as a consequence of us taking market share and in that connection maybe Anders you could comment on the latest clinical data?

0.40.28

Anders Gersel

Yes, first and foremost I think when you look not only on the Abilify Maintena bipolar scenario where we have gotten positive data but also in the question on Rexulti relative to other antipsychotics you have to remember that there are only very few antipsychotics that actually have claims outside of the schizophrenia area and particularly both in the anti-depressive and bipolar area so you cannot look to all products and see what they are behaving like. For bipolar we had some very positive data and I think the type of study that we have been running here is one which clearly indicates the value of intervening both with bipolar and depression in general because it is sort of a relaxed prevention type design which clearly shows the benefit of staying on therapy for a long time and there obviously long-acting injectables have a particular role to help patients both on the compliance but also from an efficacy-in-general perspective. So we see this as a strong addition to the current position with Abilify Maintena to have that sort of data now becoming available.

0.41.50

Olivia Capra

Okay, great thank you

0.41.54

Operator

Thank you. Our next question comes from the line of Martin Parkhøi of Danske Bank. Please go ahead. Your line is now open.

0.42.02

Martin Parkhøi

Thank you very much. Martin Parkhøi, Danske Bank. Also three questions. I think firstly on Sabril, just to see your experience now with Xenazine this year where the generic erosion has been lower than you expected what do you then think about Sabril for I know you don't give any guidance but just in broader terms since this could face general competition also later this year or next year and this has a much tougher REMS so .. and also lower sales so have you changed your mind on how big erosion you would expect on that product? And then a second question, I have to come back to the cost side, Kåre, because it is not the first time since you started as CEO that you are saying that the costs savings are going faster than expected. It is really difficult for me to understand because I guess you should have been able to have pretty good control on the cost so in relatives is it just the buffer coming through and is there also since you don't really – you are surprised by it, so is there.. where is the chance that you would actually also come up higher than the 3 billion and then a final question just to Anders Götzsche on the tax rate. Of course it will be very high for 2016. Could you give some broader comments on 2017 and later on given that I think that of course the impact from Northera will be lower and lower as the overall earnings become higher.

0.43.34

Kåre Schultz

Thank you very much Martin. I will try to answer the two first ones and then Anders can handle the tax at the end. With regard to the generic erosion that we will expect to see on Sabril it is very difficult to say and I think that your analysis might be as good as our analysis on it because it is very complex. It hinges on a lot of detail factors. One factor here is, what is going to happen with the REMS. Another factor is how many generics will actually be launching and at what time will they be launching which we have seen now with Xenazine, it is pretty hard for us to predict actually when the first will launch but also will the next one then launch immediately after or will there actually as there has been with Xenazine be quite a long time gap before the next generic launches so this is not a very precise answer, I know, but it is simply because we do not exactly know when we will have generic competition on Sabril and how it will play out. I think it is fair

to say that long-term you need to expect to lose most of the turnover you have on a product that goes generic in the US but recent experience shows that the short-term planning you know of the first couple of years can be difficult and therefore it is also going to be hard for us to say exactly how it develops. Then on the cost, it is correct that we have seen a couple of times that the execution by the organisation is a little bit faster than we were expecting and it is not because we are not trying to plan this carefully it is more you could say the effect of the management and employees doing an excellent job in following the strategy in the reorganisation and then if you have, you know, a hundred departments which all do a great job and they do slightly better than you are expecting then before you know it, it turns out to be real money so it is really the way we see it that we have the same plan overall . We don't see that it is going to end up in more than 3 billion in total cost reductions throughout the whole P&L but we do see it being realised slightly faster than what we were planning for and then the last one on the tax rate – over to you, Anders.

0.45.54

Anders Götzsche

Yes, you should expect that when Northera has – is coming off exclusivity in 2021 then our structural tax rate will be between 22 and 24 %. It will of course depend on how the revenue mix is but then we will be very close to the Danish tax rate and then there will be these transfer pricing rules which will lead to a 1-2 % addition to the Danish tax rate and from 2016 until 2021 it will of course decline, the tax rate. Next year you will see a reduction to maybe around 40 %. It is difficult to predict fully. And then it will of course decline very fast until 2021 so that is what you should expect. And now I am talking reported tax.

0.46.57

Martin Parkhøi

Yes. Thank you very much

0.46.57

Operator

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

0.47.09

Peter Welford

Hi, yes, thanks – just two left. Firstly on Brintellix – looking at what Takeda reported in US sales and trying to extrapolate from that maybe my math is wrong but it looks like you have booked more perhaps royalty than we would anticipate for the quarter I wonder if you could perhaps give us an insight into the factors that stacked up and how we should think about that going forward. And then just on the pipeline with regard to the Alzheimer's programme Idalopirdine but I think it is 28513 if my memory serves me right. I wonder if you could give us an update on how that is going and whether we can expect seeing any results from that this year and perhaps any comments you have seen on the safety profile so far. Whether there have been any stops due to safety analysis at all. Thank you.

0.47.57

Kåre Schultz

Thank you very much. I will answer the first question and Anders Gersel will answer the second question so with regard to Takeda I cannot really comment specifically on their numbers – there is currency conversion and there can be some timing issues and rebating and accruals and so on. But in general we see a very steady progress on Brintellix. We are now above 20 % volume share on scripts so we see steady growth quarter over quarter in the US and we are very optimistic about it, that this will continue and we have an excellent collaboration with Takeda. Everything is working extremely well with our collaboration in the US but the details on their reporting you have to basically clarify with them.

0.48.49

Anders Gersel

This is Anders – the sound was a little bad but I think you were asking about the AF20513 I believe in the pipeline and that is a vaccine programme for Alzheimer's and for these programmes the progress is very slow because you have to wait to see readouts of titers for different dose levels before you dose escalate so you should not expect to see any or hear any data from that programme this year. We don't know for sure, we are obviously dosing patients and we are also monitoring titers. We have in terms of adverse events we have not seen anything that has any cause for concern in any respect so it is a slow-going programme but that is the nature of these vaccines where you need to see a titer before you can escalate to next dose level.

0.49.49

Peter Welford

Thank you.

0.49.51

Operator

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

0.49.59

Trung Huynh

Hi guys. I have got three questions if I can? A couple on Brintellix and one for Anders. The first one is could you give us an update on Brintellix across the other European markets? If Lundbeck doesn't reach an agreement in Germany by the end of the year and it is removed what loss of sales would this be? And then, secondly, how long are people taking Brintellix for? And how long is this compared to other anti-depressants? And finally what is the cash costs for the restructuring this year and next year? Thanks very much.

0.50.35

Kåre Schultz

Thank you very much. So I will answer the first questions and then Anders will answer the last one about the restructuring. So in terms of Brintellix penetration in Europe then we have primarily launched in a couple of the smaller countries where we have been able to get reimbursement and in those countries we see very nice penetration curves with market shares that in volume significantly exceed that of.. what we have seen so far in the United States. In Germany we have this specific situation that, as you know, you are allowed to launch and then you have the whole mNOC ??? 0.51.12 discussion about the pricing and we have not been able to reach a conclusion on the pricing which means that until that is clarified we will from now on be booking quite limited sales in Germany. Maybe we can reach an agreement then of course we will continue to see strong penetration in Germany or we cannot reach an agreement in which case we will withdraw the product from Germany. The effect on our total Brintellix sales will be marginal but of course we would like the product to be available in all European markets in order to bring the benefit to all patients. In that context of course we are happy about the fact that basically as we speak we are launching in Spain and Italy and we hope of course to be able to negotiate solutions where we can launch in most European markets but the reimbursement discussions and negotiations have taken longer than we sort of were used to 5-10 years ago but that is simply the situation overall in the European pharmaceutical market right now that it takes longer to get market access than it used to do.

0.52.23

Anders Götzsche

And with the cash question around how the restructuring is impacting. Last year it was around 250 million. This year we expect approximately 600 million and then the remaining part will come in 2017.

0.52.45

Trung Huynh

Great. Thanks.

0.52.48

Operator

Thank you. Just to remind all participants. If you would like to ask a question please press 01 on your telephone keypad. And we have no further questions at this time. Please go ahead speakers.

0.53.09

Kåre Schultz

Thank you very much for listening in. It was a pleasure to answer all your questions. Have a nice day.