

H. Lundbeck A/S

Transcript: Investor Presentation, Annual report 2017

7 February 2018 at 13.00

Operator

Ladies and gentlemen, welcome to the H. Lundbeck Annual Report for 2017. Today, I am pleased to present Anders Götzsche, the interim CEO and EVP and CFO, and Anders Gersel Pedersen, the EVP of Research and Development. For the first part of this call, all participants will be in listen-only mode and afterwards there will be a question and answer session. Speakers, please begin.

0.00.29

Anders Götzsche

Thank you very much, operator, and thank you all for your interest in Lundbeck and welcome to this Lundbeck teleconference covering our financial report for 2017. Together with me, I have our Head of R&D, Anders Gersel Pedersen. To help the two of us with the Q&A session, I have also invited Peter Anastasiou, Executive Vice President, North America, and Jacob Tolstrup, Executive Vice President, Commercial Operations.

On slide 2, you can see the company disclaimer which I presume you have seen many times before and I will refrain from reading it out loud so we will go directly to slide 3. I will elaborate on the key performance measures in a minute but please allow me to summarise on the strong financial performance we have had in 2017. In 2017, Lundbeck achieved its best results ever and we have seen a continued significant improvement in our profitability as well as shown solid growth in revenue. We are therefore very satisfied with the progress of our operational performance. Revenue grew 10% in 2017 and the revenue reached DKK 17.2 billion in total. Our key products continued their strong growth and sales of these products have grown 36%. In parallel with the sales growth, we have managed to bring down our cost and reported EBIT increased by 92%, reaching 4.4 billion and an EBIT margin of 24.6%. When adjusting for the divestment of the properties during the year, we have reached an EBIT margin of 24.2% for 2017. Therefore, we are well on track to achieve our long-term targets of a sustainable EBIT margin of at least 25%.

As our tracks rate is declining we see very strong growth also in earnings per share of share of 117%. We have also during the year substantially improved our cash position and since last year we have increased our net cash position by more than DKK 3 billion. For the AGM in March, we have proposed a trebling of the dividend to DKK 8 per share, which is in line with our dividend policy of pay-out ratio of 60-80%. Anders Gersel Pedersen 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 approval of Brintellix in China and Abilify Maintena for the bipolar, for treatment of bipolar disorders in Australia.

Please turn to slide 4. I think it is very important to continue to point out that we have a portfolio of mature products and also very stable products and we have a portfolio of key products which generates substantial growth. We continue to execute on our strategic growth platforms and we have seen a continued, significant sales increase in our key products. In 2017, our key products realised revenue growth of 36%, which is very satisfactory, considering that we are beginning to see some negative impact from depreciation of currencies. Sabril and Xenazine are down 12% combined following generic competition. Here, 2½ years after the first generic version of Xenazine was introduced, Lundbeck still has approximately 20% of the market in volume. Regarding Sabril, the generic version has taken approximately 25% of the volume and so far, it looks relatively stable. I will get back to our regional performance in a minute but it is our North American region that delivers the most of our growth performance in 2017, but we have also seen growth in the internal market and underlying performance in Europe is also showing growth.

Please turn to slide 5. Revenue from Brintellix, Trintellix reached DKK 1.7 billion in 2017 of which 59% was generated in North America. However, countries such as Brazil, Canada, Finland, France, Italy, South Korea, Spain as well as South Africa also made valuable and increasing contributions to the total Brintellix revenue. In the three large European markets – France, Italy and Spain – we see value market share exceeding 4%. We also see a solid performance in countries such as Canada and South Korea with value market shares between 3 and 4% and still increasing. In the US, Trintellix has a value market share of close to 17%. Trintellix is continuing to grow significantly four years post approval, reflecting strong appreciation of the value that the product provides in helping to address unmet needs for patients with depression. In 2017, Trintellix grew at approximately the same rate as the year before reflecting that the clinical demand amongst decision and primary care physicians is continuing. The expanding clinical experience further strengthens prescriber appreciation of Trintellix in acute MDD and on long-term maintenance. Across all segments, increased prescriber preference for Trintellix is further supported by patients successfully remaining on therapy longer and it is complemented by sustained growth from new patients. More than 75% of all anti-depressants prescriptions volume flow through commercial and Medicare Part D Class. Trintellix coverage continues to strengthen and is supported by the strong growth in patient and prescriber demand. Trintellix covered without prior authorisation for around 80% of commercially insured patients and over 97% of Medicare Part D patients nationally.

Already for leading branded anti-depressants in the US, Trintellix continues to benefit a rapidly growing number of patients with more than 680,000 patients having received

Trintellix since launch. Trintellix is now being used in more than 60% of all new patients starting a branded anti-depressant for the first time.

Please turn to slide 6. As you can see from the graph at the right side, the significant uptake continues and the momentum looks solid. In terms of revenue, Rexulti achieved DKK 1.2 billion in sales in 2017, which represents growth of 51%. But the fourth quarter is to some extent impacted by the USD depreciation as well as quarterly fluctuations not visible in the volume growth. We continue to have high expectations for this 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 uptake is strong related to prior competitive anti-psychotic product launches. The value market share now exceeds 10%. In 2017, we also initiated the first launches outside the US with Canada and Australia.

Please turn to slide 7. Abilify Maintena grew 19% to DKK 1.3 billion in 2017, primarily driven by Europe. Abilify Maintena has between 15 and 25% volume share in all markets and is continuing to gain market share. In the US, we have seen a positive effect from the approval of bipolar disorder. Based on the net sales, it seems that the LAI market has picked up somewhat as the year-over-year growth has increased to 14%.

Please turn to slide 8. We are very pleased with the performance of these two products. Northera grew 51% to DKK 1.6 billion in 2017 whereas Onfi grew 25% to DKK 3 billion. We expect continued high growth for these products although Onfi might face generic pressure towards the end of 2018.

Please turn to slide 9. It is our North American region delivering most of our growth performance driven by our key products which constitute around 70% of sales in the region. North America is up 17% for the year and constitutes 63% of Lundbeck total sales. For most of the year, we have not really seen any impact from the USD depreciation but in the fourth quarter we see some headwind from currencies with growth being reduced from 17% in local currency to 9% reported. In 2018, North America is expected to continue growing in local currency even with the effect from loss of exclusivity on Onfi.

Please turn to slide 10. International markets including our emerging market and countries such as Japan, Korea and Australia grew 2% in 2017 and constitute 20% of our total revenue for Lundbeck. This region is still early in the launch of our key products which constitutes 12% of the total revenue in the region. We expect to see significant growth going forward of these products in the region. We are also looking forward to following the launches of Azilect and Brintellix in 2018 in China.

Please turn to slide 11. Europe is still showing a decline in revenue as sales dropped 3%. However, underlying we have seen a very significant improvement in our European business, both in terms of revenue but definitely also in terms of profitability. If we adjust for Azilect which Lundbeck no longer sells and [which was] handed over to Teva, Europe is up 1%. In 2018, we expect Europe to be growing both reported and underlying.

Please turn to slide 12. Now I will turn to our performance on some of the financial business. Cost of sale declined from around DKK 4.1 billion to DKK 3.9 billion or 5% while at the same time growing the top line by 10%. Our gross margin has therefore improved following improved product mix with reduced royalties and reached 77.5% in this period compared to 73.9% last year. The gross margin is expected to improve significantly in the coming years. SG&A cost increased slightly from DKK 63 billion to DKK 65 billion, which is an increase of 3% and far less than the growth in revenue. The SG&A ratio for the year was 37.6% compared to 40% the year before. The EBIT margin has significantly improved from last year. The margin improved from 14.7% to 25.6%. This means that the positive development we have seen in the last few quarters continues.

Next slide please. Following the improvement in our cost ratios, our EBIT reached DKK 4.4 billion in 2017 and has therefore almost doubled. In the fourth quarter, EBIT grew from DKK 751 million in 2016 to DKK 932 million or 24% growth. The effective tax rate continues to decline and as a result we see very strong growth in our net profit and subsequently in our earnings which have grown by 117%.

Next slide please. Lundbeck continues to generate a very strong cash flow. Cash flow from Operations has increased 29% to DKK 4 billion.

Please turn to the next slide. We ended the year with a positive net cash position of DKK 3.7 billion. The strong improvement in our net cash of more than DKK 3 billion is obviously a reflection of our improved cash flow, mainly driven by our improved profit. We expect net cash to be between DKK 5.5 and 6 billion by the end of 2018.

Please turn to the next slide. We expect continued growth from our key products and also growth in all three regions in local currencies for the year. However, this will partly be offset by the current trend of weakening in the main currencies. Additionally, we assume that 2018 will be impacted by the introduction of generic versions of Onfi and Sabril and Xenazine will continue the generic erosion. Therefore, the outlook for 2018 indicates revenue in the range DKK 17.2 to 18 billion. We expect to see continued improvement in our profitability in 2018 and EBIT is expected to reach between DKK 4.8 and 5.2 billion for the year, which indicates a margin of at least 26.7%. For the financial items, you should expect a net amount plus/minus DKK 50 million, depending on currency development. The

reported tax rate is expected to be around 26-28% in 2018, which will also be the range going forward but it is of course important to emphasise that the cash tax rate is somewhat lower at around 30% in 2017 and we expect it to be around 20% in 2018.

I will now hand over to Anders Gersel Pedersen to go through the latest development in our R&D pipeline.

0.16.01

Anders Gersel Pedersen

Thank you very much, Anders. Let me first ask you to turn to slide 17 and then I will address Brexpiprazole or Rexulti where we – after discussions with the FDA – will continue to build on the programmes that we concluded last year. We will initiate a third study together with Otsuka and expect to do that some time during the second quarter of 2018 with around 300 patients in it. It will include patients also at different dose ranges and a slightly adjusted population based on the experiences that we have had from the previous programmes. I am also pleased that we now feel comfortable and expect that we can start the first human testing for at least two and possibly three projects in schizophrenia and Parkinson's disease in 2018. We will in the work so far be looking at early product accesses and technologies and acquiring those and will continue to do those also in the year to come.

If we look at the next slide, you will see that we normally don't discuss a lot of details about early projects but I will introduce the alpha-zynuclein project to you because it is a bit complicated and it is a very new area, not only for you probably but also for Lundbeck. It has been a desire for us for a long time to develop antibodies against the alpha-zynuclein which is a key disease hallmark of several degenerative diseases, including Parkinson's disease. And therefore, we would like to discuss it a bit before we get into the first human testing. The monoclonal antibody that we have developed together with Genmab is one that recognises all major antinuclear forms, including both the aggregated and misfolded forms that are involved in the pathogenesis of the Parkinson's disease. Alpha-zynuclein is found extensively in neurons and is a major component of pathological inclusions that characterise several neuro-degenerative disorders, including Parkinson's disease, dementia with Lewy bodies and multiple system atrophy which collectively are termed synucleinopathies. In synucleinopathies, the alpha-zynuclein protein can misfold and aggregate to form soluble aggregates and insoluble fibrins that contribute to the pathology of the disease. There is genetic evidence for a causal role of alpha-zynuclein in Parkinson's disease. There is also increasing evidence that the disease causing alpha-zynuclein can be propagated and transmitted from neuron to neuron resulting in an infection-like spread of neuronal death. Recent studies in several animal models suggest that the spread of alpha-zynuclein associated neurodegeneration can be disrupted by targeting aberrant forms of alpha-zynuclein.

The first study is a single-ascending dose study to evaluate the safety and tolerability of our alpha-synuclein antibody AF82422 and it will take place in healthy volunteers and in Parkinson's patients. The intervention is aimed to delay in disease progression in Parkinson's Disease or other synucleinopathies.

And now I will hand back to Anders for concluding remarks.

0.19.58

Anders Götzsche

Thank you, Anders. With that I would like to thank all of you for your interest in Lundbeck and we will open for the Q&A session. Operator, please.

0.20.11

Operator

Thank you very much. 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 we have a question from the line of Trung Huynh of Credit Suisse. Please go ahead, your line is now open. Trung Huynh of Credit Suisse, please go ahead and ask your question.

0.20.43

Trung Huynh

Sorry, I was on the.. Hi. Thanks for taking my questions. You are basically at your long-term guidance. When do you expect to give the market an update on this? For EBIT consensus, it is set to reach 30% by 2022. Is this a realistic target? Secondly, you put up a slide to outline your plans and priorities for capital allocation for the year. Can you expand your thoughts on the use of cash with regard to investment in the pipeline, M&A or potential buybacks, given your significant cash generation? And then finally, can you comment on if there were any notable rebate adjustments, true-ups or one-offs in terms of the product sales in Q4? In particular, Northera seems to be quite strong, can you comment on the strength of this? Thanks very much.

0.21.33

Anders Götzsche

I can start with the rebates, you know, we have a really strong underlying demand in the fourth quarter and Northera is actually, it did really well, there are no true-ups of rebates. We saw some fluctuation in the wholesaler buying patterns but we actually, for most of the products, saw better performance in Q4 than Q3. The only two products which actually saw lower growth were Rexulti and Abilify and if you look at the underlying demand, the demand curves for Abilify Maintena are actually, you can see a trend shift in the fourth quarter so we are very happy with the development and for Rexulti there were also some fluctuations in the buying pattern, so we don't see any weakness at all in Q4. Capital allocation, we will continue to pay out dividend with a pay-out ratio in the range of 60-80%, we started this year, we moved up the ratio from 30% last year, so we have definitely taken one step further to reallocate some of the cash to the shareholders and then we have also said that we want a strategic reserve of DKK 4-6 billion and we will have that by the end of 2018 and at the same time we will also see the first result of 35700, at that point in time we will decide what to do with the remaining cash. What we will continue is to look into opportunities to strengthen our pipeline, especially in the early phases, because that is where we can see we get the most value upside and we have also received a lot of questions around what if 2019 will be a slight decline in revenue, would you be concerned about that? Do you want to bridge that gap? And I can promise you, we will not do any deals that are not value-creating. We will focus on the long run, we will focus on creating growth and value for the shareholders and Lundbeck. And regarding the long-term financial targets, we will not come with any targets, definitely not before we have a new CEO and I expect it to be during 2018 but it hasn't been finally concluded. We can say that without the one-offs from sale of properties, we delivered 24.2%, it is definitely the aim with the numbers we have laid out as expectation for 2018 that we will reach all the three financial targets and then we believe that Lundbeck as a pharma company will be a well-performing pharma company and we will of course build on top of that, continuing to streamline this company but also to find if there are any areas where we can see more growth in the different commercial areas.

0.24.37

Trung Hyunh

Thank you.

0.24.40

Operator

Thank you. Our next question comes from the line of Shruti Kapila of JP Morgan. Please go ahead, your line is now open.

0.24.49

Shruti Kapila

Hi, I have two questions if possible. So firstly, where do you see the cash tax rate going? Previously you suggested it could be 25%, could this fall to 20% maybe? And secondly, what is your expectation for amortisation this year?

0.25.07

Anders Götzsche

The amortisation, I just need to double-check before I am answering that, amortisation/depreciation will be around 1.1 billion but the amortisation in itself will be around 800 million. The tax rate, as you know, we have four products in the US that are taxed in the US, Sabril, Xenazine, Northera and Onfi and the US tax reform will have a positive benefit on that so that is also why we expect around 20% for the upcoming years in cash tax. What the impact of the US tax reform will be in the long run, we need to see how the administration in the US is implementing all these Base Erosion Anti-abuse tax or BEAT and all the other side implementation to this tax reform. But of course, it is positive, at least in the short run. Okay?

0.26.11

Shruti Kapila

Okay, thank you.

0.26.15

Operator

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

0.26.23

Michael Novod

Yes, hello, it is Michael from Nordea. Just two small questions. If we look at your Q4, you maintained a very solid gross margin but you still saw your operating costs go up a lot, that differed a bit from what we have seen at least last year where the cost development was more stable, so can you explain what actually, how this took place, were there any special marketing activities going on in Q4 or anything, say, extraordinary? And then on 2019, I know that you are not guiding, of course, on 2019. But maybe you could explain to us both for 2018 and 2019 the hedging mechanics in terms of FX and how we should try to grasp the potential negative effect we see in 2019 where you don't get the same hedging benefit just so we are more aligned in terms of modelling? Thanks a lot.

0.27.20

Anders Götzsche

Yes, I will try to address that and what you should expect is that you will see a continued improvement in our COGS ratio, just to take all the ratios, you know, the gross margin you have seen an improvement this year. It will continue. For the next 5-6 years, you will see a continued improvement, a significant improvement in our gross margin, that will definitely help. And from a cost perspective, we have had additional marketing activities but the underlying cost development is actually totally under control, it is not, there will be fluctuations between the quarters, what we focus on is that, you know, if you go 3-4 years back, you could also realise that we would have a zero in earnings in Q4 and what we have, the numbers we have now is it is close to 1 billion so the weak quarter for Lundbeck this year was around 1 billion in EBIT, so we are pretty confident with both the sales and the cost development and from the FX perspective, you should expect that the improvement in profitability next year in the EBIT margin, that half of that is underlying improvement and half of that would be due to the FX development and that is of course due to the fact that we are hedging our EBIT but you will see that there will be a decline in revenue and that combination will actually have an impact on our profitability and improve the profitability. The profitability improvement from hedging will be, you will see the biggest impact in the first half and then it will slightly decline so when you come to Q4, it is of course natural we, on a kind of a monthly basis, make new hedging contracts and therefore you would see that in the end of the year that we more or less will have been, the hedging effect will be washed out. A general rule of thumb is that if the dollar declines 5%, then it will have a revenue impact of around DKK 500 million revenue-wise. Sorry. I hope it answered your question.

0.29.47

Michael Novod

Thanks a lot.

0.29.49

Operator

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

0.30.00

Emma Newey

Hi, thank you for taking my questions, I have got a couple, please, and firstly, your guidance has seen a significant margin improvement in gap EBIT and you have obviously talked through some of this. Can you talk about what your assumptions are for core EBIT and how much of the EBIT improvement will flow through to that? And also, what are the variables in the gap, in the EBIT margin that could get you to the top and the bottom of that range? Secondly, I was wondering if you could give us an update on the timing of the CEO search from what you said at Q3? Thank you very much.

0.30.38

Anders Götzsche

I think it is easy to answer the question about the CEO search. I don't know what the status is, it is only the board that knows that, so it is a pretty easy one. When we have a CEO, we will announce it immediately, so for the time being the team here will do as we have done also in 2017, we will deliver financial excellent results with a focus on driving the pipeline forward and I am really happy that our folks in R&D will move 2-3 compounds into man during 2018 and then of course we will focus on strengthening our pipeline as we have done in 2017 with external opportunities and from a core EBIT perspective, you should add the 1.1 billion, no, you should add the 800 million in amortisation that is the difference between core and non-core. Did you have more questions?

0.31.38

Emma Newey

And I was just wondering about, with your guidance range for the EBIT margin, what would get you to the bottom of the range and what would get you to the top of that? What are the key variables for us to look for?

0.31.49

Anders Götzsche

I think it is pretty straightforward. The key component in 2018 is, of course, the genericization of the mature portfolio in the US and then of course how good we are at executing on the key products. I think we have done excellent in 2017 and the pace we see for the underlying demand in Q4, I think, was excellent. So, you know, let's see how it turns out, and of course then it is not embedded in the guidance, we have included the FX rate US dollar to DKK is 6.7, that is what we have baked into our guidance and we hope that there is an upside but you can also see the risk that it has a downside but not from an EBIT perspective because we have hedged 12 months.

0.32.45

Emma Newey

Thank you.

0.32.47

Operator

Thank you. Our next question comes from the line of Wimal Kapadia of Bernstein. Please go ahead, your line is now open.

0.32.54

Wimal Kapadia

Hi guys, it is Wimal Kapadia from Bernstein. A couple of questions, please. First on 35700, I guess just to get your thoughts on whether a positive study from the ongoing phase III would be enough for a filing and approval in the US, and then my second question is on Rexulti, actually specifically in Europe. So, I guess, how do you think about the launch of this product in Europe? I mean, what sort of impact do you think, not including an MDD adjunct onto the label we will have on penetration in this market? Thanks very much.

0.33.35

Anders Götzsche

The 35700, the question about 35700, Anders Gersel will answer that.

0.33.41

Anders Gersel Pedersen

Yeah, hi. We do not believe that we will be able to file on a single positive study, even if it may be strongly positive, and there are two reasons for that: One is that it would be highly unusual to do that on just a single study, even with a very significant p-value and secondly there is also a matter of amount of exposure that you have in the clinical programme. I think, for those two reasons it would be, we do not expect to have a launch or filing based on just one study. It will obviously be important for us to look at that study and see what are our opportunities, given the number of other studies that we have initiated and also which other studies following that we will initiate. You have to remember that the current programme is focusing very much on the US, we have done work that allows us to potentially expand that also to the other geographies like China and Japan and that is obviously something we also need to take into consideration as these markets become increasingly important going forward also.

0.34.56

Jacob Tolstrup

And this is Jacob responding to your question around Rexulti in Europe. So, we are carefully evaluating on a market-by-market basis the opportunities for Rexulti and one of the important factors that we are looking at, of course, is also pricing and that is why we have gone for the strategy that we have right now. So, we expect an approval of Rexulti in 2018, at this point in time we only expect to launch in one country in Europe in 2018 and then there will be multiple launches taking place in 2019 and then also remember that we have filed Rexulti for approval outside, so 9 markets outside of Europe where we expect to see up to 3 launches taking place in 2018 and that will be markets like Mexico and Saudi Arabia. So, market-by-market evaluation and then we go from there.

0.35.58

Anders Götzsche

Okay?

0.36.00

Wimal Kapadia

Great, thanks very much.

0.36.01

Anders Götzsche

Next question, please?

0.36.03

Operator

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

0.36.12

Tim Race

Hi, it's Tim. Okay, a few questions. First of all just on Rexulti and Brintellix, obviously very core products for you for the long term. When we look at the trajectories, they are somewhat towards the probably lower end of expectations when originally these products were sort of devised. Can you talk us through whether you think this trajectory would be consistent which we actually should expect or if there is any inflection points in the next couple of years that we should be seeing? Then just moving on to perhaps a comment from Anders Gersel in terms of the Brexpiprazole Alzheimer's study. Can you just talk me through what is changing and why? That would be very useful. And then maybe just a couple of other small questions, just on the US price increases, we saw a few at the start of January, could you just talk us through those and what should we expect to actually make it to the bottom line? And then lastly, you mentioned Onfi, you might see generics so just that what might.. Could you just talk us through the status of generics and where we are there and maybe also for Sabril and generics and what you are expecting there, thank you.

0.37.23

Anders Götzsche

Anders Gersel will start with the Brex question.

0.37.26

Anders Gersel Pedersen

Yeah, the study that we will initiate will be a study that will include other dosages than we had in the first study as one part. The second thing is that we can see both from the geographies included in the studies, I think I alluded to that in earlier communication that we will limit those compared to where we were at the first study to secure that we have a more consistent population in the current study and then we will also just to some of the segments of patients that we will be looking at within the population to make sure that we have less variability in them but basically still address the agitation group as such in the programme that we are going forward with.

0.38.15

Anders Götzsche

Yes. And Peter Anastasiou will give some insight into the US strategy about Brintellix and comment on Onfi.

0.38.24

Peter Anastasiou

Yeah, you asked the question about Trintellix and actually Rexulti in terms of progress. As you probably saw, for Trintellix it was a very strong fourth quarter and we expect continued growth despite the fact that it is entering its fourth year on the market. We have essentially now dominated the branded space in the market and we are turning a lot of our attention to it helping to differentiate Trintellix as an outstanding antidepressant versus the generic products, a lot of those older products have features that Trintellix differentiates from quite nicely so we are focused on that and you might have seen some of the impact of those efforts. We also have very good access for Trintellix and so we are focusing on pulling through that access that we have with the vast majority of patients having access without prior authorisations and most being able to get it with only one generic step. So those are areas of focus. Also, in terms of inflection points, we are continuing to look at potential life cycle management opportunities to find new uses and new populations who could benefit from Trintellix so that is certainly an opportunity and the same is true for Rexulti, obviously, you asked the question about agitation that Anders will answer in a second, but in terms of that opportunity as well as we have made it clear that we have invested in phase III studies for bipolar so those are potential inflection opportunities for Rexulti. When you ask the question about generics, it is public information that the regulatory exclusivity, orphan exclusivity for Onfi ends at the end of October. That we know for sure. What we don't know and why Anders probably used the word 'might' is when generics might be approved or launched. That is certainly out of our control but I think that is what Anders was referring to when he mentioned that and in terms of Sabril, to date we only have one generic and that is only for the sachet version and it is unclear to us when there will be other generics available so that is the status as it stands right now.

0.40.31

Anders Götzsche

Yeah, and I can add to that that we expect to see generic entrance and we also see, we expect that generic entrance will be fast but of course it is, we have been surprised with Xenazine and Sabril but they are also different products so therefore we expect faster genericization for Onfi. Okay?

0.40.55

Tim Race

Okay, thank you.

0.40.59

Operator

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

0.41.07

Peter Welford

Hi, yes, thanks. Just a couple there, just on the revenue outlook, just to try and understand here the pushes and the pulls, should we be considering the top end of the outlook is assuming continued very slow erosion of brands like Sabril and etc. and perhaps limited erosion of Onfi or are things like that potentially upside to your guidance range? I guess what I am asking is, is that the major difference for the broad revenue guidance that you have given? Secondly then, I wondered if you could possibly give us the royalty rate that you are eligible to receive on Treanda in the future? And a slight bizarre one, but Selincro, sales of that seems to be declining over the last few years, I am pretty sure it is clearly not a focus brand for you but are there any possible opportunities to potentially drive that product further in the future in Europe or should we just anticipate that product now to continue eroding? Thank you.

0.42.03

Anders Götzsche

Okay, the range of the revenue is of course due to the fact that we have planned, we have made a lot of analyses of the trend we see for Sabril and Xenazine and it has been pretty steady so we believe that we can actually predict that but we might be surprised and then it might go faster, then you would definitely be in the lower end or if, you know, for some reason somebody entered at risk for Onfi or if it is going to be slower for these three products then we will maybe be in the high end. Those are actually the things that can impact but then of course we are having very nice growth on our key products and they might also have an impact on the revenue guidance so those are actually the major factors that can impact that. Sorry. The royalty for Treanda is not very mature so I don't think we should use a lot of time on that and then Selincro, we are not having a lot of resources behind in Europe but of course it will be interesting to see what Otsuka can do with Selincro in Japan. But it is not a product that we have high hopes for in Europe.

0.43.30

Peter Welford

That is great, thank you.

0.43.33

Operator

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

0.43.41

Jacob Lademann

Hi, thank you, thanks for taking the questions. Could you detail a bit regarding the product category other revenue and what to expect going into 2018? It seems like significant increase that you had here in Q4. Finally, could you also talk a little bit about Europe - your Trintellix market exclusivity? When does that expire in the US based on the currently approved label? Thank you.

0.44.09

Anders Götzsche

The other revenue, you should expect it to continue to decline, there is, of course, some of the more mature products so you should expect it to decline in 2018. And then what you should also expect.. the reason for seeing a steeper decline than you have seen in the past is of course that we have handed back Treanda, that is included in there, so you actually need to re-base the 2017 number. And then for the exclusivity on Brintellix?

0.44.55

Anders Gersel Pedersen

I don't quite follow your question. Basically, we know that we have exclusivity of Brintellix, that is publicly known there and that is basically what we rely on there, we don't have any particular other insights or ideas that should be different than what the market expects there.

0.45.15

Jacob Lademann

Okay, so my question was basically revolving around the potential label for improved cognition which would, as far as I understood, have given you further exclusivity. So I was just wondering where the exclusivity stands without that label update, is that 2022 or 2023 currently?

0.45.38

Anders Gersel Pedersen

We do not see any particular exclusivity of extension based on the cognition label. I don't think we have calculated that at any time in our discussions here.

0.45.54

Anders Götzsche

Jacob, I also wanted to just clarify, my comments were regarding other pharmaceuticals so I might have misunderstood your comment about other revenue because other revenue will, we expect that to continue to increase due to the fact that we have increased volume in our manufacturing external business in our manufacturing facilities.

0.46.18

Jacob Lademann

That's great, thanks.

Anders Götzsche

Okay, next question?

0.46.24

Operator

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

0.46.31

Carsten Lønborg

Yeah, thanks a lot. Just, first, an overall question when it comes to M&A in licensing etc. Could you try to describe a little bit how active are you, do you feel a sense of urgency in doing something? How do you see the market, do you see many assets out that could be suitable for you etc., just in order for us to understand what your ambition is here, for example within the next 12-24 months. And then on emerging markets, it is always relatively lumpy when we look... Trintellix or Brintellix launch in China, what do you think sort of the average growth rate will be for emerging markets say for a 3-4-5 year period or

something like that, so what is the underlying growth rate capacity of that franchise for you? Thanks.

0.47.28

Jacob Tolstrup

Thanks, Carsten, this is Jacob so perhaps I can provide you with some answers to that. So, if we start with the M&A and in-licensing, I can lay out for you what our BD strategy is and it has been for the last few years and I think also Anders alluded to it in the beginning. So, we are actively searching for innovation and that means that we have defined what we believe is interesting innovation within our four key areas and also innovation that could be of high benefit of patients and treating their biggest unmet needs and doing so we are going for external innovation at an early stage – an early stage for us means pre-clinical assets up to clinical phase II – and there we are actively searching within or for disease areas and if you look at the things that we have done over the last couple of years, we are actively always doing deals, it is just early deals and I think over the last couple of years we have done more than 10-15 early stage deals that have either provided us with technology or collaborations or specific assets that we have brought into our pre-clinical research. So that means that that work will continue and also in 2018 and going early, we can get our hands on the right innovation and we are going for innovation where we can get control of the assets so that we don't have to partner it down the line.

Then I think you also had a question – sorry, what was the second question? That was emerging markets. Yeah, so, looking at emerging markets, we have a very good position in the emerging markets so we have full established infrastructure in Latin America, in Middle East and North Africa and underlying volumes are very high for many of our products and in excess of 10%. That then is the different numbers when you look into reported currencies, there could be currency fluctuations and there could be specific markets where health care budgets are under pressure but generally we see high volume growth in the emerging markets also for our products.

0.50.05

Carsten Lønborg

Is this an area where you sort of plan for, on average, 5% organic revenue growth or 10 %? What level are we talking about?

0.50.15

Jacob Tolstrup

Well, it depends a little bit from market to market but I would say it is not uncommon that our products are growing in volume with 10% but I will not here sit and talk about averages also going out in the future.

0.50.32

Carsten Lønborg

Okay. Thanks.

0.50.36

Operator

Thank you. Our next question comes from the line of Marietta Miemietz of Primavenue. Please go ahead, your line is now open.

0.50.45

Marietta Miemietz

Thank you, first question following up on Trintellix specifically in China, can you give us a feel for the reimbursement timeline and also the importance of reimbursement milestones for the sales trajectory or do you actually think that this is a product that patients in China are willing and able to pay for out of pocket? Should we generally maybe think about a fairly gradual uptake over time and all in all do you still foresee growth in the teens in China for the foreseeable future which I think was your sort latest estimate? And then on Alzheimer's agitation data, I think we are going to be seeing quite a bit of that in the coming month so I was just wondering if you could run by us what the main venues you think will be and also if we are going to be seeing pool data or mainly just data from the larger successful trial and finally, I just wanted to quickly come back to the margin improvement that you are expecting because just a few months back, I mean my sense was that actually you were sounding more cautious on the margins and basically saying, whenever dogmatic on margins if for whatever reason in 2019-2020 the pressure on the top line is such that we actually have a down-year in terms of margins and we will just accept that whereas now you sounded quite confident that the only way is up for the foreseeable future driven by all of the individual margin ratios. So should we now look at the margin that is sort of implied in your 2018 guidance as a sort of floor margin or could 2019-2020 be below that before it goes up again? Thank you.

0.52.22

Anders Götzsche

I think that we are really ambitious for.. not ambitious but we are realistic about the margin improvement in 2018 and what I said was that the gross margin will improve significantly also in 2019 and 2020 but I haven't made any comments if we will make any kind of margin improvement in 2019 and of course it also comes with the dollar. The dollar has an impact on our earnings so that will also impact. So, going back to the agitation, Anders.

0.52.57

Anders Gersel Pedersen

The data on agitation will be presented at the geriatric association meeting in March, ATP, and there you will be able to see the data in full from the agitation studies.

0.53.16

Jacob Tolstrup

And to answer your question on China, we have high expectations for China going forward so if we look at the two products that we are actively promoting in rolling out launching right now, Brintellix and Azilect, those products will be growing over the years to come. That being said, it is a matter of getting into hospitals, getting into different listings and for some time, and that time can be 2-3 years, we should expect that these products will be paid for by individuals on a private basis before we obtain reimbursement in general. So it is a combination of both things, private payments and then at one point we will also get them the reimbursement list where you can see a steeper uptake in our launches. That being said, we have a broad portfolio in China and we have high expectations for the years to come in China.

0.54.22

Anders Götzsche

Okay, next question?

0.54.24

Operator

Thank you, our next question comes from the line of Peter Sehested of Handelsbanken. Please go ahead, your line is open.

0.54.32

Peter Sehested

Yeah hi, it is Peter from Handelsbanken, thank you for taking my question, there is not much left. I just wondered, Anders, could you just remind us about the US dollar exposures within each of your three cost lines? Thank you very much.

0.54.47

Anders Götzsche

No, I cannot. What I can say is that what I have said is that the margin improvement next year, half of that will come from the dollar decline and that if the dollar is declining 5%, our starting point embedded in the guidance for 2018 is DKK 6 per dollar and if it declines 5% going forward then it will have an impact of DKK 500 million. That is what I can disclose.

0.55.16

Peter Sehested

Okay. Just one follow-up just to understand where you are on the share buyback, I think.. the last communication from you is that you won't make any communication until after data with 35700. Is that still the case?

0.55.30

Anders Götzsche

Exactly. It was a yes.

0.55.37

Peter Sehested

Okay, thank you.

0.55.39

Anders Götzsche

Thank you for listening in, and for all the excellent questions and thank you for taking an interest in Lundbeck and see you soon. Have a great day.