H. Lundbeck A/S

Transcript: Investor Conference Call Q3 2017

8 November 2017 at 13:00

Operator

Ladies and gentlemen. Welcome to H. Lundbeck's results call for the first nine months of 2017. Today I am pleased to present Anders Götzsche, interim CEO and Executive Vice President and CFO and Anders Gersel Pedersen, Executive Vice President of Research and Development. For the first part of this call, all participants will be in a listen-only mode and afterwards there will be a question and answer session. I will now be handing over to Anders Götzsche, please begin your meeting.

0.00.33

Anders Götzsche

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 nine months of 2017. Together with me I have our head of R&D Anders Gersel Pedersen. To help me with the Q&A session I have also invited Peter Anastasiou, Executive Vice President in North America, and Jacob Tolstrup, Executive Vice President, Commercial Operations.

On page 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 the period. Revenue in the first 9 months of the year was the highest in the history of the company. We have narrowed our financial guidance range and based on the strong performance we are raising our financial guidance range for EBIT for the full year 2017 and we are well under way to achieve Lundbeck's best financial result ever. We have continued previous quarters' significant improvement in our profitability as well as shown solid growth in revenue. We are very satisfied with the progress of our operational performance. Revenue grew 12% in the period thereby reaching DKK 12.8 billion. Our key products continued their strong growth and sales of these products have grown 39% and now constitute more than half of our revenue so the past year's journey to replace lost revenue from generic competition is well on track and expected to continue going forward. In parallel with the sales growth, we have managed to bring down our costs and we have reached an EBIT margin of 27.1% in the period. I think it is fair to mention that we have recognised DKK 242 million in non-recurring gains from divestiture of properties. If we adjust for this, the EBIT margin reaches 25.2%. Therefore, we are well on track to achieve our long-term target of a sustainable EBIT margin of at least 25%.

As our tax rate is declining, we see very strong growth in earnings per share of 182%. We have also substantially improved our cash position and since last year we have increased our net cash position by close to DKK 3 billion. Anders Gersel will revert with a pipeline update but let me just say that we are satisfied with the progress in our development and registration work and most recently leading to the approval of Abilify Maintena for treatment of bipolar disorder in Canada.

Please turn to slide 4. I think it is important to continue to point out that we have a portfolio of mature and relatively stable products and we have a portfolio of key products which generate substantial growth. During the first 9 months of the year, we realised revenue growth of 12% despite the continued generic erosion of products such as Xenazine in US. To pre-empt questions, we saw the first generic version of Sabril in early September. By the end of October, generic Sabril was 23% of total Sabril volume and 32% of the market for sachets. I will get back to our regional performance in a minute, but it is our North American region that delivers most to our growth performance but we also see growth in international markets and underlying improvements in Europe. Finally we have listed our largest markets. I think it might be underappreciated that especially China but also Japan is already quite important markets for Lundbeck. An importance which is expected to increase in the years to come.

Please turn to slide 5. We continue to execute on our strategic growth platforms and we have seen continued significant sales increase in our key products. In the first 9 months of 2017, our key products generated revenue of DKK 6.5 billion corresponding to 51% of total revenue.

Abilify Maintena grew 24% to DKK 995 million in the period, primarily driven by non-US markets such as Australia, Canada, Spain, Italy and France. Abilify Maintena now has between 15 to 25% volume share in most markets. The penetration of long-acting atypical anti-psychotics varies a lot from 5.4% in the US versus around 10% in Denmark. Northera grew 54% to DKK 1.2 billion in the first 9 months of the year whereas Onfi grew 25% to DKK 2.2 billion. We expect continued high growth for these products, also Onfi might phase generic pressure a year from now.

Please turn to slide 6. Revenue from Brintellix, Trintellix reached DKK 1.2 billion for the period of which 58% was generated in North America. However, countries like Brazil, Canada, Italy, Spain as well as France continue to make valuable and increasing contributions to the total Brintellix revenue.

In France, Italy and Spain, we see value market share exceeding 4-5%. We also see a solid performance in countries such as Canada and South Korea with value shares between 2 and 4% and still growing. In the US, Trintellix has a value share of 13%, Trintellix is continuing to grow significantly 4 years post approval reflecting a strong appreciation of the value that Trintellix provides in helping address unmet needs for major depressive disorder. Already the leading branded anti-depressant, Trintellix continues to benefit a rapidly growing number of patients with more than 600,000 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 and we expect the number of patients experiencing the benefit from Trintellix to continue to grow in the future.

There is still a considerable unmet need for this patient population due to the heterogeneity of depression and the varied patient response to different anti-depressant medications.

Please turn to slide 7. It is our North American region delivering most to our growth performance driven by our key products which constitute around 69% of sales in North America. The region is up 20% for the period and constitutes 62% of Lundbeck total sales. In the first 9 months we have not really seen any impact from the US dollar depreciation but in the third quarter we are starting to see a little headwind from currency with growth being reduced from 19% in local currency to 16% reported.

Please turn to slide 8. As you can see, the significant uptake continues and the momentum looks solid. 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 the uptake is strong related to prior competitive anti-psychotic product launches. Rexulti has so far achieved more than 15% branded total script market share and some 16% branded new script market share. The value share is expected to reach 10% quite soon. In terms of revenue, Rexulti achieved DKK 911 million in sales for the period, which represents growth of 64%. We are starting to see the first launches outside the US starting with Canada where Rexulti was launched in the private market in April and most recently in Australia. Additionally, we have filed a product for depression in Canada and for schizophrenia in Europe. More countries are expected in the upcoming quarters.

Please turn to slide 9. International markets which besides from our emerging market business also consist of countries such as Japan, Korea and Australia, grew 6% in the first 9 months of the year and constitutes 21% of our revenue. This region is still early in the launch of our key products which constitute close to 12% of the total revenue in the region. We expect to see significant growth going forward of these products in the region. It is my opinion that this region will become increasingly important, especially following the recent introduction of Azilect in China and the expected approval of Brintellix in China

around year-end. And this is combined with strong underlying growth for the remaining products in China.

Please turn to slide 10. China represents a significant growth potential for Lundbeck. The treatment of CNS diseases is still emerging here and we also see an increased focus on treating these conditions. The four disease areas Lundbeck is focusing on have shown an average market growth rate of 21% over the last 6 years and are now valued around 12 million Chinese Renminbi which is approximately the same in Danish kroner. The growth rate will probably not stay at that level in the years to come, but we still expect to see – the growth is still expected to stay at double-digit numbers. Lundbeck entered China in the early 90s through a partnership with China, Medical Systems, regarding Deanxit and in the late 90s Lundbeck partnered with Xian-Janssen on Cipramil and Lexapro. In 2006, Lundbeck established our own presence to support the launch of Ebixa. Lundbeck has since then grown significantly and today China is our second largest market.

Please turn to slide 11. Europe declined 3% in the first 9 months of the year. It constituted 17% of revenue. This region is also quite early in the launch of our key products which constitute close to 36% of total revenue in the region. We expect to see significant growth going forward of these products in this region. Europe is mainly impacted by Azilect and adjusted for this product we see growth of 2% in the period. Additionally, we see significant improvement in Europe's profitability so overall a very nice development in Europe.

Please turn to slide 12. Cost of sales declined from around DKK 3 billion to DKK 2.9 billion while at the same time growing the top line by 12%. Our gross margins have therefore improved considerably following improved product mix with reduced royalties and reached 77% in this period compared to 73.4% last year.

The SD&A cost increased by DKK 200 million to DKK 4.8 billion driven by a 3% increase in sales and distribution costs which is far less than the growth in revenue. The SD&A-ratio for the period was 37.1% compared to 40.4% in the same period the year before. The EBIT margin has significantly improved from last year. The margin improved from 13.4 to 27.1%. This means that the positive development we have seen the last few quarters is continuing.

Please go to the next slide (13). Following the improvement in our cost ratios, our EBIT reached DKK 3.5 billion for the first 9 months and has therefore more than doubled. In the third quarter, EBIT grew from DKK 589 million last year to DKK 1.4 billion this year.

The effective tax continues to decline and as a result of this we see very strong growth in our net profit and subsequently our earnings per share which have grown by 180%. Please let me also repeat what I 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 39% in 2017 and then decline in the following years and by 2021 probably end up around 25%. Beyond 2021, the long-term reported tax rate is expected to decline to a level between 23 and 25%.

It is important to note that there is a difference between reported and cash tax and the cash tax is expected to be somewhat lower, around 30% in 2017 and hereafter the rate is actually expected to decrease to a level between 23 and 25%. So in your financial models from 2018, you should expect the cash tax rate to be at a level around 23-25%.

Please go to the next slide (14). Lundbeck continues to generate a very strong cash flow and a solid increase in our cash reserves. We ended the quarter with a positive net cash position of DKK 2.2 billion. The strong improvement in our net cash of close to DKK 3 billion is obviously a reflection of our improved cash flow, mainly driven by our improved profits. We expect the net cash to be between DKK 3 and 3.5 billion by the end of 2017.

Next slide please (15). We assume that the remaining part of 2017 will be somewhat impacted by the introduction of generic versions of Sabril and continued generic erosion of Xenazine. We expect continued growth for our key products and higher sales for the year. However, this is partly offset by the current trend of weakening of main currencies. Lundbeck has revised the financial guidance. We have narrowed the revenue range and now expect revenue to reach between 16.9 and DKK 17.4 billion and the EBIT range has been raised to between DKK 4.3 and 4.6 billion for 2017. For the financial items, you should expect a net loss of around DKK 50-100 million for the year, which is unchanged from our previous guidance.

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

0.17.12

Anders Gersel Pedersen

Thank you, Anders. Please go to slide 16. For the quarter, I am satisfied with the progress of our development in the registration work, most recently leading to the approval of Abilify Maintena for the treatment of bipolar 1 disorder in Canada and in the United States.

Regarding the FDA process around the supplementary NDA for Trintellix, I do not have additional information. Takeda and Lundbeck are in continued discussions with the FDA and it will be premature to comment on next steps until we have concluded these discussions. In parallel the alliance continues to explore multiple potential clinical development targets for Trintellix that extend beyond MDD. Regarding Rexulti and Alzheimer's agitation, last week we and Otsuka announced that following discussions with the FDA regarding the two completed Phase III clinical trials for the agitation indication, one study in the pivotal programme was considered positive and one study was considered supportive at this meeting. Therefore, Lundbeck and Otsuka have decided to initiate a third clinical Phase III study for Brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type. The third study is expected to commence during the first half of 2018 but I would not comment on any details about the potential design of that study before we have concluded our discussions with the FDA.

Please go to slide 17. We normally do not comment on our early development pipeline, but as there has been quite a lot of focus on Alzheimer's projects in general and most recently also from the presentations on aducanumab, I think it is important to just list the AF2513 in clinical trials has changed direction – no not direction, but the timing and let me finalise with some remarks on that project.

0.19.20

AF2513 is an active anti-beta (Aβ) vaccine against Alzheimer's disease. It is designed toward an optimal immunogenic response in the elderly based on the hypothesis that cognitive function will be preserved through the early inhibition of amyloid beta depositions in the brain. The on-going first-in-human study or phase I study commenced in March 2015 and was actually planned to conclude around this time point. We have, however, decided to follow the patients because of positive titer developments and see how long they stay and how they progress over time and we therefore have changed the timing of the study on clinicaltrials.gov we do not expect it to finalise until the turn of the next year. In December 2013, Lundbeck and Otsuka announced that we expanded the collaboration to include the development of AF2513. The agreement covers the development of this molecule through clinical phase I. Following completion of this trial, the parties have an option to enter into a co-commercialisation agreement and co-development agreement on terms to be agreed upon. Just so that you are aware of this part related to this product. And now, I will hand it back to Anders for concluding remarks.

0.20.51

Anders Götzsche

Thank you very much Anders. With that I would like to thank you all for your interest and open for the Q&A session. Please, operator.

0.21.01

Operator

Thank you. Ladies and gentlemen. If you have a question for the speakers, please press 01 on your telephone keypad. Our first question comes from the line of James Gordon from J.P. Morgan. Please go ahead. Your line is open.

0.21.17

James Gordon

Hello, thanks for taking the questions. A couple of questions please. One was about R&D, so I know you are going to go back and start another study for Rexulti for Alzheimer's agitation and maybe you will set out the details of Rexulti studies so is there going to be output pressure on R&D because you are starting further studies or could we see further reductions in R&D spend and a similar question on SG&A – for SG&A you mentioned that you had grown more slowly in revenues and SG&A was below the market expectation today. Could we extrapolate on SG&A cost control today forward to 2018 or other investments you might require and cost savings start to being close to being exhausted. And then just a final question on 2018 pricing and gross to net. Are you seeing similar trends to previous years in terms of or anticipating to be able to hold on to a similar amount of price rises or is it harder to do that looking to 2018? Thanks.

0.22.12

Anders Götzsche

Thank you very much, James, for your questions. We anticipate in the long run that we will use around 16-17% of our revenue to invest in R&D but there will be swings between the years so one year could be 15 or 16 and one year could be 18 but of course we do not expect huge increases in our nominal spend for R&D going forward so we also expect to be able to include this Alzheimer's agitation study in the normal trend for our spending in R&D.

And with regard to SGNA, you should of course expect that we do not see material changes in going forward to our SGNA line. Of course, by the end of next year or during 2018, we will ramp up with some more sales reps in China due to the expected approval of Brintellix in China together with the approval of Azilect but it will be by the end of the year and it will not be material additional costs. And from the restructuring programme, of course, 95% of that is actually already included in our – we have seen reduction in our cost base, we will see some minor reduction going forward due to the fact that some of the last initiatives are fully embedded in the business mid-next year. But it is minor size. We

can just see in general that the restructuring programme aim was DKK 3 billion and we have definitely achieved that and that people in general are very cost-conscious and they are also focusing a lot on – and we are focusing a lot on securing that we use the resources in the market where we can create growth so that is kind of the profitable growth concept that we have been using for a couple of years.

Then you had a third question, that was regarding?

Gross/net

0.24.19

James Gordon

Exactly, is it gross/net whether it is tougher to hold onto the same amount of price rises looking into 2018 versus what we saw this year and the year before?

0.24.27

Anders Götzsche

No, we don't anticipate that it will be more tough in 2018 so we expect it to stay at the same level.

0.24.37

James Gordon

Thank you.

0.24.38

Operator

Our next question comes from the line of Trung Huynh from Credit Suisse. Please go ahead.

0.24.44

Trung Huynh

Hi, thanks for taking my questions. I have three if I may. Firstly, could you give us an update on your CEO search and any broad timelines you have in place? The chairman mentioned an aim to have an external candidate. Can you perhaps discuss what skills and experience Lundbeck wants from an external candidate? Secondly, in the unlikely event that Trump's tax reform gets through, what would be the implications to Lundbeck? And finally a product related question on Northera. That was particularly strong this quarter. Is this simply a seasonality effect or is there uplift in the underlying growth? Thanks very much.

0.25.24

Anders Götzsche

Okay, the CEO search, there is not a lot more to say on top of what our chairman has said already one week ago. So you know they are looking for an external candidate and we hope within six months to be able to announce a new CEO and I can tell you I am not part of the process to define the skills and the capabilities for this CEO so that is a board matter so I cannot give you any more comments to that. And then the tax reform, there are two parts of the tax reform. One is first of all it needs to go through in the US so we have seen multiple proposals but the tax reform that is in front of us, it will be a lowering on the general tax rate, it will of course have a huge positive impact on us but then as I also understand it, there is an inter-company part, a border taxation on inter-company transactions and when we talk with tax advisors it is a bit confusing about what will that actually impact but in the short to medium term we believe that we will be able to actually handle that because we have a lot of partnerships so we can handle that. Of course, in the long run it could have a negative impact but I think it is definitely too early to say and speculate about. And then Northera. So what we have said, we have definitely seen a very good trend for Northera, you know, we have seen more patients, we have seen an upward-going trend on the numbers for Northera so we are very pleased with the development. You just need to remember that when we are coming into the more cold months of the year then there is also a tendency that we see a bit of decline in the revenue numbers because the patients are not so much out and therefore we could be in a position where we see a slight decline. So we cannot in general follow this trend that has been very favourable but of course we hope that the good trend will continue also when you look into 2018 but you might see some dips.

0.27.42

Trung Hyunh

Thank you.

0.27.45

Operator

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

0.27.51

Michael Novod

Yes hello it is Michael from Nordea. Two questions, starting with Abilify Maintena and Onfi, while you have seen sequential growth for the other drugs then Onfi is flat and Abilify Maintena is down. I know there is an FX headwind of course to be taken into account but have you seen anything regarding additional discounting in the US and what kind of trends are you seeing outside of the US where you also see Abilify Maintena decreasing? Is it something around competition in the US as well or what are you seeing at those two drugs? And then following up on the pricing question, we talked about gross/net but what about the actual list price hikes which have been a growth driver. How do you see that going forward? Other companies are talking more moderately around this. Is that also your view or can you continue in the same trend as you have seen the last couple of years? Thank you.

0.28.51

Anders Götzsche

We actually expect that we can take exactly the same or make the same price adjustments in 2018 as we have been doing in 2017 so we actually see, we don't expect any change in that sense. For Abilify Maintena we have seen between Q2 and Q3 some seasonality in the numbers but if you look at the underlying trends, if you look at the script numbers we are not concerned at all. So US is improving, all the other countries we can see steady growth. So it is seasonality. Peter, will you address the Onfi question?

0.29.35

Peter Anastasiou

Yes, with Onfi there is no material underlying events that are driving that. I think it is quarter to quarter fluctuation nine months on the year. We have seen a good growth rate for it being the sixth year on the market, 25% for the first nine months of the year so we are happy with the development for the year for Onfi.

0.29.59

Michael Novod

Okay. Thank you.

0.30.03

Operator

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

0.30.09

Carsten Lønborg Madsen

Yeah thank you very much, just one question here to start out with. It is actually a little bit of a follow-up on Michael's question but more broadly for example if you take a look at Europe and international markets Q2 and Q3 you saw Q2 Europe 4% local currency growth, Q3 -6%, international markets 17% local currency growth in Q2, 9% in Q3 and only US is holding up moderately. So in broader terms it seems like there has been a sort of volume shift in Q3 for you. Is that fair or is it not something we should worry about?

0.30.49

Jacob Tolstrup

Yeah, sure, this is Jacob, Carsten. I don't think you should read too much into that. Also, if you look at the quarters also going back in time then it is not unusual to have these quarterly swings and there is nothing in the quarter that we see for the Q3 that makes us worry about the development going forward. I think also if you look at the Q2 numbers that we reported then we were actually above many of the analyst expectations and now we are a little bit below. I don't think there is anything in there that changes our predictions for the products going forward. So it is they are tracking according to our plans.

0.31.33

Carsten Lønborg Madsen

Okay and then just quickly on 35700 in your models when do you have it as a base case that it will actually reach the market?

0.31.44

Anders Gersel Pedersen

We are currently expecting that we will conclude the ongoing study and have data in the first part of 2019 and that we will then from that move into another pivotal study from that which basically puts us into a time frame of around 2021 before we can submit something and that will generally give us for the US an approval probably around 2022.

0.32.18

Carsten Lønborg Madsen

Okay. Thanks.

0.32.22

Operator

Our next question comes from the line of Emma Newey from Bank of America Merrill Lynch. Please go ahead.

0.32.26

Emma Newey

Hi, thank you very much for taking my questions and a couple, please. Firstly on Rexulti and agitation associated with dementia. Does the FDA have any specific concerns with your data that led you to start the trial or was it just that you had any hitch with the primary end points in one of the T trials? Secondly, what are your expectations for Onfi generics in 2018? Are you aware of any current filers? Also what generic erosion can we expect? Could it be more like a Xenazine erosion curve? And just lastly looking into 2018, can you talk a bit about the precedent direction that we should take into account when forecasting on core operation margins? Thank you.

0.33.11

Anders Götzsche

Anders, you can start on Rexulti.

0.33.15

Anders Gersel Pedersen

I think the FDA had no particular concerns at all with the data that be submitted to them, I think that is also the reason why we are very clear on moving forward with a third study. I

think basically it was the totality of data that they didn't think would be convincing enough at this stage for us to be sure of a successful filing process and that is why we collectively with Otsuka have decided to initiate a third study to secure a stronger process with the FDA going forward.

0.33.51

Anders Götzsche

And for Onfi, it is correct that we have a lot of exclusivity in Q4 2018 and you know it is really, really difficult to predict what will be the, you know we have tried to use analogues so you can expect everything from a very fast generic entrance to a more slow generic entrance as we have seen with Xenazine so you know it is really difficult to predict. But we anticipate that we will see generic impact in 2018. And with regard to margins, we look very, very much forward to give financial guidance in February 2018 and then we can also elaborate more about what you should expect from a margin point of view.

0.34.42

Emma Newey

Okay, thank you.

0.34.46

Operator

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

0.34.52

Peter Welford

Hi, thanks for taking my questions, three I think, firstly just on Trintellix, apologies if it is my math that is wrong here but it looks as though Trintellix in Canada is trending down quite sharply Y/Y if I try and extrapolate from the data we have. Can you maybe give us some insight into what the Canadian trend there is or whether there was something that happened last year that we should be aware of? And then on tax, I think I am right to say you previously guided to 30% by 2021 on the P&L so is the tax on the P&L now anticipated to more closely approach or more rapidly rather approach this cash rate than previously we should have been assuming? And then finally just on R&D, AF2513, the Alzheimer's drug, I guess I am just curious here I mean the primary end point of that are studies of safety in tolerability and also I mean you are looking at antibody titers I mean presumably

those data are available. So is it now that there are end points that are looking at efficacy that you want to follow patients for longer or is there something else that we should be aware of when we consider why that trial has been extended? Thank you.

0.36.02

Anders Götzsche

Anders, you can start with the Rexulti question, please.

0.36.06

Anders Gersel Pedersen

The vaccinal question, I think the vaccinal is.. the extension is purely because we want to see the robustness in duration of the titers seen there. You should not expect to see any efficacy outcome data from that particular study. I think first and foremost we have been looking at whether at all, which was not a given, that a subcutaneous vaccination would actually yield something meaningful in terms of an antibody titer, we have obviously seen that and we are in the process of characterising that titer in terms of quality but also strength and durability so that we can better design the next stage programmes and obviously we have also been looking at safety and we have, as you can imagine, seen no safety concerns since we are also extending the programme here. So from what we have and I think obviously you should be taking it with great carefulness, it is very early, is that we have seen some titers, we are looking to see the duration and quality of these titers so that we can better design next stage and we have with a limited number of patients no reason for any safety concerns.

0.37.30

Anders Götzsche

And regarding the question for Canada and Trintellix, when I look into our numbers, I can't see the decline in revenue that you are referring to so Peter we might take that offline because I can't see it in our numbers. We don't see any decline whatsoever; we actually see an increase compared to Q2. For the tax, so what I just said is what we expect so we expect from 2020 that the cash tax and the P&L tax or the reported tax rate will be more or less the same and already from 2018 you will see a decline in the tax rate and we expect, you know there will be swings between the years, but at average it will be 23-25%.

0.38.25

Peter Welford

That is great. Thank you.

0.38.26

Operator

I would like to remind you that if you want to ask a question, you will have to press 01 on your telephone keypad. Our next question comes from the line of Marietta Miemitz from Primavenue. Please go ahead.

0.38.41

Marietta Miemitz

Yes, good afternoon, a couple of questions please. The first is on leadership. So it looks like a new CEO will not be on board in time for the budget discussion for next year so how should we think about your future communication about financial targets and shareholder distributions? Should we look for a fairly wide guidance range for 2018 as you are looking to give the new CEO some flexibility? And is it fair to assume that we won't get any new long-term guidance or any buyback announcements until a new CEO has settled in? And then I just wanted to follow up on the sequential development of Abilify Maintena and also Brintellix Ex- US. So on Abilify Maintena in Europe I mean both the sales development and your commentary in the press release suggested to me that it might be nearing a plateau but now you are saying that it is still growing Ex- US as well so my question is if that is also true for Europe and what is the reason for any seasonality within Abilify Maintena? Is there a situation where people just don't get their long-acting depot while they are on summer vacation or is this just sort of a fluke thing? And then on Brintellix in Europe that also looks quite stagnant. So do you see that reaching a plateau in Italy and Spain and can you give us a sense for the momentum we should be expecting in markets where access was just recently granted? And then also on Brintellix and international. You said it was still growing in some countries like South Korea but again I mean in the numbers it looked a little bit like it had reached a plateau or maybe some of the sequential or lack of sequential growth was really just due to some quirks with foreign currency. So any comment there would be much appreciated. Thank you.

0.40.37

Anders Götzsche

Jacob, maybe you can start on Abilify and Brintellix?

0.40.41

Jacob Tolstrup

I can perhaps try to give you some answers there, Marietta. So I think also what I answered before is that there will always be some of these quarterly swings, especially for products that are still relatively new into their launch. But if we went into it then I could give you explanations on stocking in some countries that happen earlier in the year that didn't go through in the third quarter which is very common for products that are still growing. And then of course you are right that if we look at Europe then it is not uncommon that you have a little bit of a softening in the script rates in the third quarter as you are in the summer months so that is not an uncommon feature. But when I look ahead also for the fourth quarter, and also going beyond, we still see continued growth for Abilify Maintena and for Brintellix and also going into 2018 we expect that the key products there so those two products will deliver quite substantial growth that will offset the mature portfolio decline at the same time. So I don't think I will get into further details, the differences that we are looking at here are relatively small and that means that there will be quarters that could be impacted by some stocking swings or the like. In general, I think the main message from my side is that we continue to see growth for both products in both parts of the world.

0.42.07

Anders Götzsche

And with regard to leadership, you know the chairman has said that the ambition is to be able to announce a new CEO within six months but you know it can take three months, it can take nine months, nobody actually knows before you have a new CEO in place and with regards to financial targets and guidance, our first priority is to deliver the best financial year ever in 2017 and we are going to do so and then of course when we have delivered – when and if we deliver the 25% for 2017 then we will take a discussion with our board and then we will probably during 2018 update our financial targets. But of course that will be a discussion with the board and we don't have agreed with them when we are ready to announce new targets.

0.43.15

Operator

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

0.43.21

Jacob Lademann

Thank you, just two questions please, the first one on Xenazine sales. If you look at the script rate it looks to me like the number of scripts is actually declining while you maintain the same revenue in Q3 as in Q2. So that would mean the actual value per script is

increasing. Could you talk a bit about that dynamic? And potentially also could you talk a bit about how you see the impact of generic Sabril competition for the remainder of the year? I think you alluded to the fact that it has some material impact on sort of the range of your guidance but given that we have seven weeks left of the year and you have a fairly wide EBIT margin guidance and perhaps you narrowed the sales guidance today but could you talk a little bit about what it takes to realise the upper and lower end of your sales guidance and EBIT margin guidance as well? Thank you.

0.44.14

Anders Götzsche

Peter you can comment on the specifics for these two drugs but in general it is natural you have seen over the last couple of years that we have actually not been very good in predicting the trend for Sabril and Xenazine and that has been due to the fact that we thought it would have a faster erosion but we have also been positively surprised by the brand loyalty by the patients in the US and therefore we have been able to upgrade our guidance several times. So you know there is a big range of outcomes also for the last seven weeks of how fast will the generics come into play and that is of course the reason for having a relatively big span in our guidance, also due to the fact that Sabril and Xenazine with the resources we are using are very profitable.

0.45.13

Peter Anastasiou

I would only add that when you are looking at IMS data on your question related to Xenazine, of course it is distributed through specialty pharmacies the branded Xenazine is in the US so there always is going to be some inconsistency and not the exactly full visibility from an IMS perspective but otherwise I don't think there is any materiality to some of the fluctuations that you are seeing.

0.45.36

Jacob Lademann

Okay, maybe just one follow-up to that. I understand that you are excluded from ESI contracts with Xenazine next year, is it possible that you in any way sort of could quantify the impact of that in broad terms?

0.45.51

Peter Anastasiou

You are correct that there are some plans that have been public in saying that branded Xenazine will either not be covered or only covered after failure on generics but we are not in a position to predict the impact of that at this time.

0.46.10

Jacob Lademann

Okay, understood, thanks.

0.46.14

Operator

Our next question comes from the line of Tim Race from Deutsche Bank. Please go ahead.

0.46.20

Tim Race

Hi there again, two questions please, first just following up from Peter's question on tax, could I just be absolutely clear, maybe it is me not understanding, but in terms of what you actually report in the P&L, what tax rate should we be expecting in 2018 onwards? And topping up cash tax is not really what we have seen at P&L so I would rather understand about what we should see in the P&L as such just so that we are not talking cross purposes here. And then the second question is just on Trintellix. I saw that you were excluded from the United contract – just wondering any of contracts on Rexulti where you have had exclusions and any idea of what sort of market share that you had on those contracts previously? So that would very helpful, thank you.

0.47.08

Anders Götzsche

Peter?

Peter Anastasiou

Yeah with regards to your question on Trintellix, you are correct about United but we see very little impact coming from that. First of all, the patients who are already on Trintellix will be grandfathered so they will be able to continue to stay on Trintellix and United doesn't account for very much of our volume and also we have good national coverage in

the rest of the plans and drugs widely accessible as well as we are having growing regional coverage. So we expect very little impact from that decision.

0.47.42

Anders Götzsche

You are fully right, Tim, I didn't say anything about the reported tax rate in 2018 but we expect it to be around 35% but please bear in mind that it is depending on product mix and where the earnings are coming from in the world so that will be up for.. it can change but around 35% reported.

0.48.07

Tim Race

Understood, thank you, that makes it clear.

0.48.11

Operator

There are no further questions registered so I return the conference back to the speakers for any closing comments.

0.48.18

Anders Götzsche

So thank you very, very much for listening in and thank you for all the great questions and we look forward to talking to you soon and have a great day.