

H.Lundbeck A/S**Teleconference Q4 2015****10 February 2016**

Operator

Welcome to the Lundbeck annual report 2015. Today I am pleased to present CEO and President, Kåre Schultz. For the first part of this conference, participants will be in a listen only mode and afterwards there will be a question and answer session. I will now hand the call over to Kåre Schultz.

0.00.16.3

Kåre Schultz

Thank you very much and thank you all for your interest in Lundbeck. Welcome to Lundbeck's full-year and fourth quarter 2015 teleconference. 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 therefore we will go to directly to slide 3. Anders and Anders will elaborate on some of these items in a minute but please allow me to summarise a very eventful year. Firstly, I would say that our restructuring programme, which we announced back in August, is well on track. It might even be a little ahead of plan. As you probably remember the programme intends to address what I together with the management group believe has been a major issue for the Company, viz. the low profitability. And I am very comfortable with the improvements we have already been seeing and which we expect will continue. Additionally, we see continued very fast growth in our US operations, also adjusted for the tail wind the currencies are providing for us. Lundbeck's key products are continuing to deliver on expectations, which I will get back to in a minute.

Please turn to slide 4. Anders Götzsche will elaborate on the financial guidance for 2016 so the only thing I will say is that the guidance provides the first signs of our improved profitability which will be more pronounced in the following years. In the past months, we have been working on our corporate strategy and refining the strategy for Lundbeck's path forward which I will elaborate on in a minute, but it is a strategy that comprises a much sharper therapeutic focus, larger emphasis on internal capabilities beyond our current partnerships and finally a stringent focus on profitability and cash generation. In order to measure our success we have defined financial long-term targets covering the next 3-5 years to describe

what we strive for on the journey to realise our strategy and to govern the Company's path towards increased profitability and enhanced cash flow generation. Again, Anders will revert to these targets in his presentation.

Please turn to slide 5. The strategy consists of a simple framework with three elements. Our vision describes what we strive for, our principles guide our actions and our strategic objectives define the strategic focus for decisions and execution of the strategy in the years to come. Lundbeck's management has defined 5 strategic objectives which describe the focus for decisions and execution of the strategy in the years to come. I will not elaborate on all five here but in the coming years we have – which I also communicated at the last conference call – decided to focus our efforts on four disease areas where we believe Lundbeck can lead innovation of improved treatments: Depression, schizophrenia, Parkinson's disease and Alzheimer's disease. All four disease areas are characterised as areas with huge unmet medical needs and where Lundbeck has expertise and competitive advantage throughout the value chain. By focusing our efforts on areas where we have the most expertise, we believe that we will be able to create significant value for patients, society and shareholders. For other psychiatric and neurological disorders, Lundbeck will have an opportunistic approach if compounds developed to treat the four focus diseases also can help patients with related psychiatric or neurological disorders. Regarding business development, Lundbeck will not expand the existing commercial portfolio through external opportunities and will focus our efforts on early-stage opportunity in the future. We will expand and optimise our global organisation. Today, we have our own organisations in 57 countries and have made our pharmaceutical treatments available in more than 100 countries. With a global presence, we are able to increase the value of the pharmaceuticals we commercialise. We will grow our business with a strong focus on profitability. The ability to create a growing business and deliver profitable results is what Lundbeck able to improve treatments for patients, offer an attractive return to our shareholders and contribute to the societies we operate in.

Please turn to slide 6. In August last year, Lundbeck initiated a restructuring programme in order to significantly improve profitability and the Company's value creation. Lundbeck needs to restore an improved profitability to be able to invest in initiatives with growth and profit potential which could lead to better treatments for patients, secure a competitive return on investment and create shareholder value. We expect to be able to reduce our cost base by DKK 3 billion by 2017 compared to the 2015 cost level expected when I joined the Company. Approximately half of this will be delivered already this year.

Please turn to slide 7. All over the world, psychiatric and neurological disorders are a growing burden, not only for individuals but for families and societies as well. Seen as diseases in general, but definitely also our four core therapeutic segments are characterised by substantial unmet medical needs, many patients and patients and doctors on constant search for the optimal treatment for the individual and therefore a great need for differentiated and novel choices. The segments are vast representing some \$ 50 billion in sales

and when that is put in relation to Lundbeck's revenue base of \$ 2.2 billion then I believe there will be room for significant growth opportunities.

Please turn to slide 8. I believe it is important with category leadership. In order to operate a successful company you have to build on what you are good at. Historically, Lundbeck has had the biggest successes in the four therapeutic categories both scientifically and commercially. It is also in these areas we are closest to our customers and looking at what we have it is also in these areas we have the best opportunities for continuing successfully to develop and commercialise new innovative and differentiated products.

Please turn to slide 9. I believe we continue to execute on our strategic growth platforms. We have seen significant sales increases in our key products, which we are very happy about. For the quarter these key products generate a revenue of DKK 1.2 billion corresponding to 32 % of total revenue. We are expecting continued high growth for these products.

Please turn to slide 10. We will now look at some of our key products. And let us start with Rexulti. As you can see there is a significant uptake and as we are now some 6 months into the launch I believe the momentum begins to look solid and sustainable. The week over week growth continues to outpace the branded market and the competition and the uptake relative to prior analogue antipsychotic launches is strong. Rexulti has so far achieved more than 4.2 % branded TRx share and close to 6 % branded NRx market share. In terms of revenue, Rexulti achieved DKK 59 million in sales in the fourth quarter compared to DKK 58 million in sales in the third quarter. This seeming lack of growth can be attributed to some pipeline filling patients for programmes being recognised as negative revenue among others. I am very confident in Rexulti as a growth driver for Lundbeck.

Please turn to slide 11. Revenue from Brintellix reached DKK 211 million in the fourth 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 reached revenues of DKK 125 million for the fourth quarter of 2015. Brintellix volume share of branded total prescriptions was 18.5 % and this year our branded NRx volume was 21.1 %. In value, Brintellix has a similar strong position in the branded market with an NRx share of more than 23.5 %. Anders Gersel will get back to the positive recommendations from last week's AdCom but it goes without saying that I am very pleased with the outcome. We are getting ready to launch Brintellix in Brazil and in general we see substantial opportunities for the product in Latin America. Brintellix has now been launched in four markets in South East Asia, Singapore, the Philippines, Malaysia and Thailand, a region that represents a combined market value opportunity of DKK 1.8 billion. For all four countries, cognition data is mentioned in the label. In Europe, market access remains a constant key challenge and most European markets are still minor, but in countries like Denmark and Slovakia we see a very positive market share development with more than 7 % value share.

Please turn to slide 12. If we turn to Abilify Maintena our long-acting antipsychotic that has done well both in the United States and in Europe. Sales grew 155 % or 138 % in local currencies and reached DKK 211 million in the fourth quarter. For this product, the US and Europe are almost of equal size and both regions see substantial growth. In Europe, Spain, France and the UK are the largest markets.

Please turn to slide 13. Our speciality neurology products in the US continue their solid growth, obviously helped by the US dollar appreciation but also a continued strong demand for all the products. Onfi continues to impress and has almost doubled its size in 2015. Northera was launched some 1.5 years ago. We have seen a lot of interest from physicians and the feedback that we have from the patients is positive.

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

0.10.47.1

Anders Gersel Pedersen

Thank you, Kåre. Please turn to slide 14. I will first address Brintellix where last week we announced that the FDA's PDAC voted 8 to 2 supporting that we – together with Takeda – have presented substantial evidence to demonstrate that the effectiveness of Brintellix for treating certain aspects of cognitive dysfunction in adults with depression. Importantly, in connection with the meeting the Committee also discussed that cognitive dysfunction in depression represents an appropriate independent drug target for development. We are obviously very pleased with the advisory committee's recommendation and we look forward to working with the agency as they complete their review for the PDUFA on 28 March 2016.

Please turn to slide 15. Our new antipsychotic 35700 is going into clinical phase III programme and is planned to start in the next few months with patients with treatment resistant schizophrenia. The first study is expected to enrol approximately 1,000 patients and will likely take 2-3 years. 35700 has a novel and unique pharmacological profile with a high D1 and 5HT6 receptor affinity in combination with a low D2 receptor affinity. The compound represents a potential new option for patients who are currently not adequately responding to available antipsychotics which are all targeting the D2 receptor in various ways. So we believe we may be able to address a broad part of the symptomatology of schizophrenia patients not being treated today.

Please turn to slide 16. Lundbeck's strategy includes a stronger emphasis on in-house development. At the same time we will continue to search for external innovation and early stage inter collaboration with for instance early stage companies and academia. The reason why I believe we can be successful doing that is

firstly that Lundbeck has a broad and interesting early stage pipeline even though we are not very much communicative about that part. We have both projects as well as technologies which we hopefully can turn into late stage projects as we learn more about these. Secondly, Lundbeck has a long history in the four chosen therapeutic categories and that we have a solid disease biology understanding which together with our experience in running clinical trials in these areas makes us better able to translate data into clinical relevance. With the recent discussions at the AdCom we showed that we are able to find new ways of addressing patient needs and move the field in our areas of expertise.

Next slide please. I have now gone through the most important news from R&D. Additionally, European CHMP has issued a positive opinion for label update of Abilify Maintena to describe new clinical data for the treatment of acute relapsed adults with schizophrenia. The update of the SmPC includes new Abilify Maintena data related to its effect and safety on acutely relapsed adults with schizophrenia. These data and the updated product label established the utility of Abilify Maintena in these acutely relapsed adult patients and for the maintenance treatment of patients with schizophrenia. This week we announced that FDA has accepted for review a supplementary NDA for the proposed labelling of date of Rexulti for the maintenance treatment of adults with schizophrenia allowing us if approved to discuss long-term data on Rexulti in the market. After this overview, I will now return the presentation to Anders Götzsche to go through the financial performance.

0.14.57.7

Anders Götzsche

Thank you very much Anders. Please go to slide 18. In the fourth quarter revenue increased by 15 % and reached DKK 3.7 billion. In local currency the gross was around 7 % and the main reasons for the growth realised in the quarter were very strong growth in general for our US products. It is growth in the key products across the regions and then of course the US dollar appreciation. The growth is, however, partly offset by the declining mature product portfolio in Europe and especially also in Canada. EBIT is still impacted by the ongoing restructuring programme but we have seen an underlying continual improvement during the second half of the year and we have seen a positive result on profitability. The free cash flow has again turned positive and has almost doubled compared to the first quarter in 2014 and for the year as a whole the cash flow has been impacted by the major milestones to Otsuka earlier in the year.

Please flip to page 19 for the financial guidance. In 2016, the financial guidance and the performance will be impacted by the loss of Azilect as we are having back the right in Europe to Teva and also of course a generic erosion on Xenazine. However, with expected continued growth for our key products the outlook for 2016 indicates a revenue in a range of DKK 13.8-14.2 billion and we also expect to see a significant improvement in our reported EBIT where this year we are around 0 we will have an improvement to between DKK 1 to 1.2 billion corresponding to a margin around 7-8 %. The changes in product mix will have a significant positive impact on cost of sales which is expected to be around 25 % for the year or the cost of

sales will be around 25 %. The CNA ratio for the full year is expected to be at a level around 45 % for 2016 and the R&D ratio is expected to be around 20 % in 2016. You should expect that net financials will be loss around DKK 100 million and we, of course, based outlook on changed exchange rates from where we are now.

Please go to slide 20. This is the slide which shows the long-term financial targets. In order to measure our success we have defined these long-term targets to govern the Company's path towards increased profitability and also enhance the cash flow generation. We foresee a significantly increased profitability in the coming years. Currently, Lundbeck targets an EBIT margin of 25 % which will bring us close to the level of many other European mid-sized pharma companies. By increasing the earnings and keeping the investments and the net working capital requirements low that will also lead to a substantial improvement in our return on invested capital and our aim is to be around 25 %. To secure that we also convert our earnings into cash we have defined a cash-to-earnings ratio and our aim is to generate more than 90 % cash-to-earnings to secure that we get a conversion of the operational performance into cash. Additionally, Lundbeck has a financial policy which aims to have a Net debt/EBITDA less than 2. We already have that by the end of the year. Lundbeck also has a policy for Dividend pay-out ratio which has been adjusted from a previous range from 25 to 35 % to a range between 30 to 40 %. And this is a revised range and that will bring the expected pay-out ratio more in line with similar-sized pharmaceutical companies in Europe.

Please turn to page 21. On this slide, we try to illustrate the EBIT margin target compared to our historic performance and you can see that we have had a decline for the last couple of years and that is of course in 2015 impacted by the restructuring and 2016 will be the first step on the way to reach our target of 25 % and we hope to further improve both our margin and our earnings in nominal value in 2016-2017 substantially and be on our way within 3-5 years to reach the 25 % EBIT margin. With that I will hand back to Kåre for the concluding remarks.

0.20.20.1

Kåre Schultz

Thank you, Anders. Before I hand over to the operator for the Q&A session I would like to say that Lundbeck stands in front of exciting times. Where 2015 has been a year where we have implemented significant change to our business we believe that 2016 will be a year where we will begin to see the 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. Operator.

0.20.47.7

Operator

Ladies and gentlemen, if you have a question for the speakers please press 01 on your telephone keypad. We have a question from Michael Novod from Nordea, please go ahead sir.

0.20.59.9

Michael Novod

Yes, hello it is Michael Novod from Nordea in Copenhagen. Just a few questions. Could you just try to describe Brintellix and say the upcoming potential label update because it puzzles me a bit that we actually see a slowing between quarters from Q2 to Q3 and Q3 to Q4 despite actually a higher dollar in Q4 than in Q3. So do you expect since you also guide as you do on the top-line that you will already in 2016 be able to significantly boost the uptake of Brintellix in the US or what is driving it? And then secondly on Rexulti, going into 2016 I would imagine that you foresee a massive ramp in sales in 2016 in order to guide as you do. Do you also expect more of your say patient support programmes to go away and thereby also increase the sales numbers? And then the last one, just a clarification. Anders Götzsche said something about reported EBIT going from 0 to 1.2 billion. I really cannot recall the reported EBIT of 0 but maybe you can just clarify.

0.22.15.9

Kåre Schultz

Yes, thank you very much Michael for those three questions. I think I will take the two first ones and then at the end Anders can answer the last one. With regard to Brintellix, in our estimations and the basis for our guidance for 2016 we have not included any change to the progress of Brintellix scripts and sales in the US based on any changes to the labelling. However, should we be so fortunate to get an updated label from the FDA which includes some elements of altering cognitive impairment then I don't think it will have a major impact in 2016 simply for the reason that we will get this in a couple of months' time. Then we have to work on how to actually bring it to the market, how to give medical education, how to do the marketing material. We need to get those approved by the FDA. Once they are approved we can start using them but that means that there will be relatively little left of the year so it will be a marginal impact. The big impact of an improved label will be something that we see in 2017 so the short answer: It is not included in our guidance to get an improved label. With regard to Rexulti, we are expecting to see a continuation of the very nice increase in TRx and NRx on a week over week basis. We don't expect any dramatic change in the current trend line. We don't expect any dramatic change in the gross to net including all the different types of rebates that we have in the US so it is simply a continuation of the current very positive trend for Rexulti that is the basis for our guidance. And then, Anders, if you could answer the last question.

0.24.04.4

Anders Götzsche

Michael, if you have the core EBIT for the full year was 847 and if you look at the core EBIT for this then the difference between core EBIT and EBIT is around 1 billion and therefore we will improve core EBIT with around 1 to 1.5 billion and that is also according to what we have said due to the restructuring we will further improve our cost base with 1.5 billion next year and when I said reported EBIT around 0 it was adjusted for all the restructuring costs. It was not precise enough. I hope it clarified it.

0.24.43.3

Michael Novod

Sure, thank you.

0.24.46.3

Operator

We have a question from Eleanor Fung from Goldman Sachs, please go ahead madam.

0.24.50.9

Eleanor Fung

Hi, thank you for taking my questions, a few. Firstly, on your long-term target at 25 % EBIT margin just curious what are the pushes and pulls to this given that there is particularly a disproportionate stability from you at Brintellix. Is this a conservative number? Secondly, you mentioned your cost savings programme is moving ahead of expectations. On your target of DKK 3 billion cost savings is there a potential for this to further increase? And finally, just on your comment on M&A and early stage opportunities. Could you remind us what is on your wish list and if you could comment on whether you are looking to do straight in-licensing or is there a potential to partner similar to the Otsuka collaboration that you did previously? Thank you.

0.25.39.9

Kåre Schultz

Thank you very much Eleanor. So let me take the first question. So the 25 % EBIT margin is a long-term financial target and the elements that will be getting us in that direction from the very low level of 7-8 % EBIT margin that are expecting this year is a combination of structural cost savings as we have announced in connection with the restructuring, improvements of gross margins due to a change in the product

portfolio and growth in our core products – the five key products we have that are growing very, very strongly. So these are kind of the key levers and it is not specifically related to any of the products so it is not specifically hinging on something dramatic happening in a positive way to Brintellix. It is more a continuation of the current trends we are seeing. That is the basis for it. With regard to the 3 billion in cost savings, I think Anders you can comment on the timing and the total target.

0.26.46.2

Anders Götzsche

I think we will still aim for the 3 billion it is not that as a consequence of the fact that we are a little ahead that we then are aiming for 3.5 – we are aiming to go through the planned and secure that we take out the cost. We are just happy that we can see that we are a little ahead of the planned but it still means that when we have gone through 2016 all savings have been implemented and we will see the full impact in 2017.

0.27.15.0

Kåre Schultz

And the last question with regard to in-licensing and partnerships, then I think I will start by making it clear that the new strategy is based on us organising and steering the development of new products in an organic way so we do not aim at acquiring already approved products or late stage phase III products for different markets around the world. On the other hand, we do need early collaboration with lots of partners and we do need early in-licensing of technology and different patents but I think Anders Gersel, you can just comment a little bit on what we do in the early stages of our research activities.

0.27.54.6

Anders Gersel Pedersen

Yes Kåre, I think you are right. I mean the early-stage in-licensing will be both project and technologies but the key for each of this in-licensing will be that we will be the driver of the further development of these projects or to utilise these technologies in conjunctions with our projects so that we can develop them internally for a full product. I don't know if that answers your questions but we expect to have multiple collaborations with multiple technologies out there and if there are good very early projects that we can see maybe even better than some of those we have in-house we will obviously be willing to swap them if it is at an early enough stage that we can see that we can bring our innovation into these molecules.

0.28.44.1

Operator

Great. Thanks very much. We have a question from James Gordon from JP Morgan, please go ahead sir.

0.28.51.3

James Gordon

Hello, thanks for taking my questions. One on guidance – you have given the long-term guidance targets on a reported basis but a lot of people are focused on reporting on a call basis to better understand the cash flow regeneration so you said 25 % reported. Would it not be fair to assume that the target is to get something like 30 % core EBIT margin long-term? One pipeline question which should be Idalopirdine for Alzheimer's – just the read-through from Pfixer's decision to drop their 5HT6 project. I think they were saying they did not know if they were going to hit the end point. Maybe they were not having a high enough dose and were not getting high enough receptor occupancy. And I know you have gone when you went from phase II to phase III for your compound you have gone for a lower dose. Can you remind us what you think your receptor occupancy is going to be? And what other characteristics might differentiate your products? So we don't need to worry that the same thing could happen and then just housekeeping, for Rexulti, can you – what do you think the number would have been without the stocking so that we can sort of extrapolate from a clean Q4 number for the rest of the year or for this year now for 2016?

0.29.53.0

Kåre Schultz

Thank you very much James, I think I will ask Anders Götzsche to comment on the core EBIT and how that would look in terms of margin. Then Anders Gersel will answer about Idalopirdine and I will clarify Rexulti.

0.30.08.3

Anders Götzsche

What you should expect for the next couple of years – 2016 and 2017 – is that the difference between core EBIT and EBIT is the amortisation of product rights and it will be around DKK 1 billion – it will be a little dependent on the exchange rate but in principle it is around DKK 1 billion and then going forward it will actually decline due to some of the products – the profile of the products – but you should expect if you use 1 billion in general then you are safe. And then if we go beyond 5 years then it will be much less because then some of the products like Northera which carries amortisation and so forth will – they will decline.

0.30.56.2

Anders Gersel Pedersen

And with respect to the Idalopirdine, first and foremost the molecules are somewhat different and I cannot comment specifically on why they have chosen to stop that development. First and foremost, they had a different patient population they were addressing with the molecule. Secondly, we believe it may have been at a lower binding level – and we are beyond 80 % binding in our target dosages so we are not uncomfortable with the dose reductions that we have made in the phase III programme compared to the phase II programme.

0.31.35.0

Kåre Schultz

With regard to Rexulti, I would say the best way if you want a model on it is to look at the TRx and then take into consideration the sort of list price in normal gross to net and then the fact that we in Lundbeck book 45 % of the revenue. That would be sort of the way to predict that going forward.

0.31.57.2

James Gordon

Thank you.

0.32.00.3

Operator

We have a question from Trung Huynh from Credit Suisse, please go ahead.

0.32.05.6

Hello, I have a few questions if I may. First, does your 2016 EBIT guidance include any one-off payments or potential disposal proceeds from products like Selincro? The second one is given your improved performance in the US, how is that going to impact your tax rate going forward? And then finally, do you expect to invest further in Brintellix's sales forces? The cognition benefit is added in the US. Thank you.

0.32.33.7

Kåre Schultz

Thank you very much. I think I will answer the first one and then Anders Götzsche can comment on the tax rate and then I will also answer the lost one on Brintellix. So the first one is very simple. 2016 does not include any assumptions about selling anything or having any extraordinary income from disposal of assets or anything like that.

0.32.57.4

Anders Götzsche

And the US tax rate – as you know then the products we acquired through the Ovation acquisition in 2009, it is some of the neurology products – they are taxed in the US with around 40 % and then most of the new products with IP rights that are linked back to Denmark will be taxed at 22 %. What you should expect for the next couple of years is that the reported tax rate will be little higher. It will be around 50 % but going forward you should expect that the cash tax rate will be between 22-24 % depending on.. there will be some deviations in the next 5 years but the cash tax will be in that range going forward.

0.33.42.9

Kåre Schultz

And then lastly on Brintellix, it is too early to say exactly what we will do. We will have to wait and see exactly the outcome from the FDA and what labelling we will get from the FDA. Based on that we will be assessing this together with our partner in the US, Takeda, and then we will take the decision as to if, when and how we might increase our promotional and sales efforts.

0.34.10.7

Trung Huynh

Excellent, thanks very much.

0.34.13.7

Operator

We have a question from Peter Welford from Jefferies, please go ahead sir.

0.34.16.6

Peter Welford

Hi, yes thanks for taking my question and firstly just if I look at the revenue guidance and then look at the drop due to EBIT it seems to suggest that you are receiving about a 50 % for the incremental margin on the sales guidance. Should we infer anything from that as regards the product mix and perhaps the products that you think have the biggest potential to be the delta during the year for your target forecast? And secondly, just on Xenazine and the amazing performance in the fourth quarter given generics. I guess if we look at the IMS prescription trend it shows a somewhat significant loss of share and can you perhaps give us some sort of insight into what drove the Xenazine fourth quarter number and how we should think about numbers in the future? And then, a bit also, I guess, related to that Sabril – have you any additional disability on Sabril generics in the US? I know the FDA likes REMS programmes to be shared. Have you yet started discussions of any potential generic companies to share your REMS for Sabril and have any companies approached you to do that? Finally, if I could. Just a point of clarification. The cost of goods sold that Anders Götzsche set at 25 % I assume that includes the billion amortisation charge. Thank you.

0.35.43.3

Kåre Schultz

Thank you very much, so I think I will cover the first two – then on the REMS I will ask Anders Gersel to comment on that and on the cost of goods sold I will ask Anders Götzsche to comment on that. So in terms of the revenue and the product mix and the gross margin it is correct that some of the products that are leaving us due to loss of exclusivity have had relatively low gross margins because they have been products that have been more or less finalised in their development before we took them on and as a consequence of that the combined royalty and cost of goods sold and so on we have been paying has been very high whereas some of the products going forward that we have either developed 100 % on our own or that we have developed in partnership with others, they have a more normal pharma gross margin and that is of course helping our gross margin and our total margin in the years to come. Then on Xenazine, it is correct that we have generic competition on Xenazine since August. It is also correct that we have a relatively lower loss of turnover in scripts than we had anticipated and most likely this is due to the competitive dynamics that there is one generic competitor right now, Sun, and we will most likely lose more once second generic competitors get into the marketplace. When that happens we do not know – it can happen tomorrow, it can happen any day. We do not know anything about that and that of course led you into asking about Sabril and exclusivity on Sabril and REMS and I will refer that to Anders Gersel.

0.37.28.5

Anders Gersel Pedersen

I think I will take that – it is normal with all products in the US that when you have exclusivity and have an orphan drug that you will at some point in time have a discussion with the FDA around REMS programmes but so far we are not willing to discuss what kind of – we expect to have exclusivity on that still and at some

point in time there will be some discussions with the FDA about REMS. With respect to the 25 % target – I think it was the EBIT target you asked about? – and it does not matter if it is EBIT or return on invested capital. It is of course including – you know deduction the amortisation – it is not core EBIT, it is reported EBIT that we are guiding on as the target.

0.38.14.2

Kåre Schultz

So Peter, I hope that that clarified your questions.

0.38.18.0

Peter Welford

Yes, sorry, could I just follow up. Do you still owe royalties now that the exclusivity has expired on Xenazine sales or do you now – is Xenazine now a higher margin product for you at this point in time? Thank you.

0.38.32.6

Kåre Schultz

It is unchanged, Peter, so there is no difference. The setup we have with regard to what we are paying for the product and how we share it with our partners is unchanged as a consequence of the generic competition.

0.38.48.1

Peter Welford

Thank you very much.

0.38.50.9

Operator

We have a question from Carsten Lønborg Madsen from SEB, please go ahead sir.

0.38.56.0

Carsten Lønborg Madsen

Thank you very much. Just two questions here. First the fall in CipraleX in the rest of the world. Could you try to put a little bit of colour on your expectations here. Obviously, patents are also lost but dynamics seems to look different going forward and for Onfi somewhat of a similar question actually. I guess it is pretty basic how long can this impressive trend continue for Onfi – have you taken any particular measures during 2015 in order to secure this great result for Onfi, thanks.

0.39.33.0

Kåre Schultz

Thank you, Carsten, I think I will cover those two so first in terms of CipraleX we have seen, of course, dramatic decline of CipraleX due to generic competition and that has affected, of course, the US. It has affected Europe. In 2015 specifically, it has affected also Canada where we have lost a lot of turnover. Sales in Canada are down 50 % in 2015. We are reaching a point now where we are getting closer to a balance between the markets where CipraleX is still growing for historical timing reasons so we still have exclusivity in Japan where we have partners selling CipraleX. We have a brand preference in China where we are selling CipraleX and we have some other markets where we also have a stable development of CipraleX so what you should expect is a further generic erosion in some European markets in 2016 but counteracted somewhat by some of the other markets so we expect to see a modest decrease of CipraleX in 2016. In terms of Onfi, we are of course working with all the different support programmes and all the services that we are providing in the US to secure a continued successful uptake of Onfi and we are very optimistic that we can continue a positive trend for Onfi in the US marketplace.

0.41.01.9

Carsten Lønborg Madsen

Can I follow up on CipraleX? Is there anywhere where you have negotiated with some of those that are selling CipraleX where you can renegotiate when the patent has expired?

0.41.11.5

Kåre Schultz

No, that is not the case.

0.41.14.9

Carsten Lønborg Madsen

Okay. Thanks.

0.41.20.2

Operator

I remind you that if you want to ask a question you will have to press 01 on your telephone keypad. We have a question from Martin Parkhøi from Danske Bank, please go ahead sir.

0.41.31.3

Martin Parkhøi

It is Martin Parkhøi from Danske Bank. Just a follow-up on Carsten's question on Cipralelex – with the modest decrease you expect in 2016 would it also mean that if we look at your long-term forecast period of 3-5 years that we actually should expect it to be at the level of 2 billion or just above? Then a second question. Anders Götzsche was so kind to give some ratios – the cost ratios for 2016 – but can you also provide the ratios that you have based your 25 % EBIT margin on? And then a third question, back on Xenazine and also a caller has already discussed it that there could come any day further competition but it has not happened yet but what have you included of a decline in your 2016 guidance and of course also taking into account that we are already through mid-February? And I will wait with another question then.

0.42.38.5

Kåre Schultz

Thank you Martin Parkhøi, first of all on Cipralelex, of course we are getting closer to a steady state probably for the coming years so probably now as we are approaching 2 billion we will see it flatten off somewhere around 2 billion, maybe a little bit more – that is the kind of level that we are expecting it to flatten out at. And that is the combination of still various marginal erosion in some markets and growth in other markets including China and Japan. Then in terms of the ratios, I can promise you that they will be improved because otherwise we will not get to 25 so the different ratios you saw from the different elements we will be working on the entire profit and loss of course and that means that all the elements we will be working on and we will hope to see improvements in all the different elements that go into the cost picture, of course resulting in reaching the long-term financial target of an EBIT margin of 25 % and then on Xenazine we have in our guidance included a significant decline in Xenazine compared to last year, of course for the reason that it is now having generic competition and we do expect intensified generic competition throughout the year so we are expecting that we will lose more on the Xenazine sales than we saw in Q4. Significantly more. I hope that clarifies your questions.

0.44.15.8

Martin Parkhøi

Ah, not exactly you know – you are hitting more than 2 billion in 2015 on Xenazine so – and the decline, you can say, was not bad substantially in Q4, at least in value terms, so are we looking at a cut of 50 %, of 75 % or what are we looking at in 2016?

0.44.36.8

Kåre Schultz

Compared to what you saw in Q4 of 2015, which was a quarter where we did have generic competition from one generic manufacturer, we are expecting to see generic competition from more manufacturers during 2016 and we are consequently expecting to see a significant reduction in our sales meaning more than a 50 % reduction.

0.45.02.5

Martin Parkhøi

Okay, thank you

0.45.07.6

Operator

There are no further questions at this time. Please go ahead speakers.

0.45.12.7

Kåre Schultz

Thank you very much for listening in. This ends our teleconference. Thank you.