

## H. Lundbeck A/S

### Transcript : Second Quarter 2015:

Ladies and gentlemen. Welcome to the H. Lundbeck second quarter results 2015. Today I am pleased to present Kåre Schultz, President and CEO, as our first speaker. Also Anders Götzsche, EVP and CFO, and Anders Gersel Pedersen 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. Kåre Schultz, please begin.

0.00.34.5

Kåre Schultz

Thank you very much and thank you all for your interest in Lundbeck. Welcome to Lundbeck second quarter telephone conference for 2015. With me I have our CFO, Anders Götzsche, and our head of R&D, Anders Gersel Pedersen. This is my first IR meeting since I joined Lundbeck on 20 May as President and CEO and I look very much forward to meeting you all in person at some point in time. On slide 2 you can see the Company Disclaimer which has to be there but which I also presume you have seen many times in the past and so I will refrain from reading it out loud so therefore we will go directly to slide 3.

Firstly, I would say that while I am pleased with the sales growth of our new products and also the progress we have seen from R&D I am not satisfied with our profitability. Therefore, together with my management team I have initiated a restructuring programme, which we also announce today. It is our opinion that this is necessary and that it will make Lundbeck drive sustainable value creation for all our stakeholders going forward. But now back to the results we have presented today so please turn to slide 3. Anders and Anders will expand on some of these items in a minute but please allow me to summarise the quarter. I think it is fair to say that we had a satisfactory performance in the quarter also in the light of the decline in Europe. We have of course also been significantly helped by increasing exchange rates, primarily the strong US dollar. I believe we have executed on our strategic growth platforms. We have seen a significant sales increase in our key products, which we are very happy about. A couple of examples: Brintellix has done very well in the US as well as in non-US markets where we have just made a significant number of launches and where we are receiving a lot of positive feedback. We see continued solid uptake of Abilify Maintena in both the US and in Europe. We launched Northera towards the end of last year. We have seen good uptake and especially Onfi has done very well on the US market and the strong development that we have seen over the last years in several emerging markets continues.

We have also seen several successes in our R&D efforts foremost with the approval of Rexulti in two indications in the United States. Rexulti is now being launched there. We

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have also started the regulatory process in order to update the US label on Brintellix with cognition.

Please turn to slide 4. We have today announced a restructuring programme in order to reduce Lundbeck's cost base and regain profitability sooner than in the current outlook. The planned programme covers all business functions in Lundbeck but primarily headquarters and commercial functions here in Europe and includes a proposal to reduce head count by around 1,000. It is important for me to stress that our strategic direction is as such unchanged. And we still see significant potential in our key products Abilify Maintena, Brintellix, Northera, Onfi and Rexulti.

They are in my opinion the best products on the market within their respective fields and we wish to place the bulk of our investment in these products in the markets where we can expect the best return. We will now further focus our investments to realize this potential. With the risk and uncertainties this industry operates under it is imperative for me that we are profitable, so that we can continue to invest in projects that can lead to better treatments for patients, secure, competitive return for our investors and maintain Lundbeck as an attractive place to work. This means that it is necessary to pursue cost savings. Through this programme, the cost base in 2016 is expected to be reduced by some DKK 1.5 billion and DKK 3 billion in 2017 thereby securing a positive reported operating profit in 2016 and with further improvement in 2017.

In the quest to provide better treatments for patients we have in recent years expanded our research and development into new areas such as stroke and pain. We will now return to a R&D focus on the four areas in which we have proven expertise and are most likely to be successful. Depression, schizophrenia, Parkinson's Disease and Alzheimer's Disease. We are therefore closing our US research site and some selected early-stage research projects. The total cost in 2015 from this restructuring programme is expected to reach DKK 6.6 billion of which only a fifth is cash.

Please turn to slide 5. As I said before, Lundbeck remains fully committed to our long-term CNS focused innovation driven strategy. We also stay fully committed to our key products, which we believe all are best in class. Over the years, we have taken major steps to improve profitability and returns on investment recognizing that this demands concerted company-wide action. Today's initiative should be seen in this strategic context as we continue to reshape our business to improve profitability, productivity and focused innovation and with it our long-term ability to generate attractive products for our customers and attractive returns for our shareholders. Our current focus will remain execution of our numerous product launches but with an even sharper focus on profitability in order to position us better for delivering profitable growth.

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Please turn to the next slide (slide 6). Innovation is a key contributor to achieving our long-term goals as well as improved profitability. We believe our key products are innovative and differentiated and I expect to see continued solid growth of these products. Our product and geographical mix will change in the coming years and together with the results from the restructuring programme I am certain we can deliver significantly increased profitability already from 2016 and in the years to come. However, just to pre-empt questions then I am not ready here to commit to specific, absolute financial targets. That has to wait until early 2016.

Please turn to slide 7. We will now look at some of our key products and let us start with Brintellix. As you can see there is a very dramatic increase in Brintellix sales compared to last quarter or the second quarter last year. We see solid growth in the US as well as outside and non-US sales now represent more than 30 % of sales. I will come back to that. All in all a very positive performance.

Please turn to slide 8. If we look at what we have seen in some new markets starting with Canada, Brintellix or as it is called in Canada Trintellix has done very well. We have had very positive feedback both from physicians and from patients. In reality you could say that in international markets the uptake has been comparable in what we have seen with previously launched antidepressants. In Europe sales are meeting expectations. But it is very early days in Europe and we have not launched in the major markets yet so there are a lot of important things happening over the next few months. And what we are noticing all over is that when we are able to talk about cognition, it has a major impact. And as you probably know we do not have that opportunity yet in the United States. And this is of course the reason why we are seeing that Brintellix is a little bit inferior to historic launches. But still superior to more recent introductions in the United States.

Please turn to slide 9. Here we have an illustration of the performance of Brintellix since launch. As you can see, it is performing very well and both TRx and NRx and share continue to show positive momentum. Brintellix has been outperforming the two most recent branded antidepressant launches, Viibryd and Fetzima. In gross sales in the US by 29 % and 99 %, respectively. Around 200,000 patients have already used Brintellix so we continue to be very encouraged by the positive feedback that we have got from psychiatrists, from GPs as well as from patients. But it would make some difference for us if we get the opportunity to talk about cognition. In spring, together with our partner, Takeda, we started a DTC TV pilot programme in 12 US test geographies. It is still too premature to evaluate any impact hereof but we expect to have solid data towards the end of the year.

Please turn to slide 10. If we turn to Abilify Maintena, our long-acting anti-psychotic that has done extremely well both in the United States and in Europe, and you can see the increase compared to last year. We have seen strong initial launches in a number of

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European countries and we have recently launched in some major markets like France, Spain and Australia. We are also developing Abilify Maintena in terms of additional data and the ongoing phase 3 study in bipolar disorder is expected to be finished approximately a year from now. And we have also recently received approval by the FDA of the deltoid injection site and earlier in the year the pre-filled syringe, which we think will add to our competitive edge in the US.

Please turn to slide 11. If we go back to the US, our neurology products are up 73 % in the second quarter, obviously helped by the US dollar appreciation. We see an incredibly strong performance on all our products. Of Onfi, of Xenazine, Sabril and Northera, which was launched less than a year ago. We have seen a lot of interest from physicians and the feedback that we have had from the patients so far is also very positive. But we should remember it is early days with Northera, but so far I feel comfortable that we will reach our expectations but all in all very, very strong neurology franchise in the United States, which is of course also the basis for us being able to launch our psychiatry products in the US market. I will now hand over the presentation to Anders Götzsche to go through the financial performance.

0.11.23.3

Anders Götzsche

Thank you very much, Kåre, and please turn to slide 12 with the financial performance and as you can see from the revenue line it is pretty much in line with last year and there is of course a mix of factors impacting revenue, a strong FX impact has helped us but also what Kåre just alluded to a very good improvement in the new products and then of course a decline in the older more mature products. Core EBIT decline and that is due to the fact that we have been investing heavily in the new product launches and therefore the SG&A percentage is also at an all-time high this year. Reported EBIT will for the quarter or what we are showing in the release is that it is of course dramatically low and that is due to the fact that the reclassification of R&D costs the milestone payments earlier paid to Otsuka is now expensed under the R&D line and therefore we have reported a -4.8 in reported EBIT. Operating cash flow has been impacted by the payment to Otsuka in the spring of \$ 200 million and we have a net debt of 1.4 billion by the end of the quarter. What you should expect is that by the end of 2015 we will have a net debt position around 3 billion because we also have in August payment to Otsuka of the additional 200 million for the indications and the approval of Rexulti in the US.

Please flip to the next slide (13). So on the balance sheet, normally we do not talk a lot about that but I think it is important to have a little more detailed walk through of the different reclassification and restructuring items so what you will see is that the 4.8 billion will have an impact of course on the product rights that will be reduced and on the contrary it will also impact equity and we will see a reduction in our assets and liabilities. What you will also see from the P&L is that we have booked the tax benefits of that

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reclassification and that is included as income – a little less than 1 billion in the quarter and what you should expect in the third quarter is that we will include impairment of Selincro and some buildings and that will be approximately 600 million. Then there will be some provisions for the severance payments and restructuring charges around 1 billion and then we will have a tax benefit which will be income in the P&L in the third quarter so all in all you will see that the equity ratio will of course decline, not dramatically, but you will see a decline and then we have to go through this period we have assigned additional 2 billion bank revolving credit facility which will help us during the next 12 months.

Please flip to the next slide (14) and as you have seen from the release we have revised our financial guidance and that is due to the fact that the US products are doing extremely well and that we have also seen a good development in the US dollar and therefore we have raised the previous guidance for core revenue to be around 14 billion and core EBIT has been revised 0.5 billion and then due to the restructuring we will have a deficit of 7 billion. It is very important to emphasize that most of these restructuring costs are non-cash items. We expect of the total restructuring programme that between 1 to 1.5 billion will have a cash impact and the pay-back time will be less than a year for these costs. You should also of course expect that going forward we will have a dramatic adjustment in our cost ratios and as we have said for this year you should expect that the R&D ratio will be around 20 % and the SG&A ratio – excluding the restructuring – will be around 50 % and you will also see an increase in our Cox ratio due to the fact that the change in product mix and amortisations so that is in line with what we have said previously and then you should see an expectation for the financials that will have an expense of around 150-200 million and you will of course see income in the P&L from these tax assets and you should expect income around 20 % of the profit before tax. With that I will hand over to Anders Gersel to take you through some of our pipeline news.

0.17.10.1

Anders Gersel Pedersen

Thank you, Anders. If you turn to slide 15. In July Rexulti passed the major milestone. FDA approved the product both as adjunct therapy for the treatment of adults with depression as well as for treatment of adults with schizophrenia. Furthermore, in July the FDA accepted a supplementary new drug application for review to add clinical data regarding the effect of Brintellix on cognitive dysfunction in adults with depression to the current product label on Brintellix. The FDA is expected to take action on this filing by March 28 in 2016. In connection with the restructuring plan, in R&D we will see a reduction and consolidation of the research and development footprint globally and we will focus our efforts towards selected projects. This will enable us to take full control over Lu AF35700 and develop the molecule ourselves in the treatment of treatment resistant schizophrenia.

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Please turn to the next slide (16). Rexulti has been studied in more than 4,300 patients in phase 2 and 3 trials and the approval was supported by four completed placebo control clinical phase 3 studies in the now approved indications. Two studies as adjunct therapy to antidepressant in depression and two studies in schizophrenia. We have, together with our partner Otsuka, started the launch on 3 August and Rexulti has a price point in line with other available antipsychotics in the US. We expect to file Rexulti in the first international markets within the next 6 to 12 months.

Please turn to the next slide (17). Rexulti is launched in the US with indications of schizophrenia and depression. It is our view that the product addresses the fact that many patients, care givers and psychiatrists are concerned about getting good effect without having too many side effects impeding a predictable experience that is patients may experience side effects with many antipsychotics that sometimes overshadow the perception of the treatment effect. Rexulti significantly reduces symptoms while also having a low level of side effects. We are now looking forward to seeing the feedback from the market on this product.

Please turn to slide 18. As you probably are aware when we have studied the elements of cognitive dysfunction in depression extensively, the recognition of cognition as a separate target for medication in the treatment of depressed patients is new. Therefore, I am very pleased with the decision by the FDA to accept the sNDA for review to add clinical data on specific aspects of cognitive function in adults with depression to the current product label of Brintellix, a first for a depression product. According to a 3-year perspective study of people treated for depression cognitive symptoms defined in that particular study has diminished the ability to think or concentrate and/or indecisiveness were reported in 94 % of the patients at the time of major depressive episodes but also interestingly in 44 % of patients at the time between major depressive episodes. With this as a reminder of the major issues we are still facing in depression disease I will hand over to Kåre for concluding remarks.

0.21.23.1

Kåre Schultz

Thank you Anders, let us have the last slide. Before we hand over the floor to the Q&A session, I will say that Lundbeck stands in front of exciting times and with the announced restructuring programme I am convinced it will also be a profitable time. With that I will say thank you ever so much to all of you for your interest and hand over the floor to Q&A. Please operator.

0.21.45.9

Operator

Thank you very much. Ladies and gentlemen, if you have a question for the speakers please press 01 on your telephone keypad. And a first question comes from the line of Tim Race of Deutsche Bank. Please go ahead. Your line is now open.

0.22.04.3

Tim Race

Hi again, yes this is Tim Race here from Deutsche Bank. Thanks for taking my questions. First on the savings how painful are these savings going to be. Can you just talk us through how much is low hanging fruit and how much is actually savings where you actually could damage your top line so what should we expect in terms of any impact to the top line due to this restructuring? The second question is just on the savings in terms of the headline figure of DKK 3 billion, clearly there are some amortization charges that won't happen going forward because of the R&D capitalization but can you talk us through how much you expect to actually flow to the bottom line in terms of what you actually forecast previously versus what you have now to give us a sense of how much is real savings versus reinvestment. And then maybe on the R&D with 35700 could Anders perhaps just fill us in a little bit more about what is interesting about that product. Thank you.

0.22.59.0

Kåre Schultz

Thank you very much Tim. I think I will try to handle the painful part you asked about in the beginning and then turn over Anders and Anders for the two subsequent questions. The way we have done our analysis in preparation for the restructuring has been very thorough and we have looked at individual products in individual markets and of course the whole purpose of the exercise is to improve earnings and therefore one of the key conditions is that we do not hurt in any way the progress and the marketing of the new products. We have a high number of new products that are doing extremely well in both the US and in international markets and in a few European countries. So we will continue to focus on those. As we speak we are expanding the sales force in the United States in connection with the launch of Rexulti so the new products will get full attention and full backing. However, we also have a situation where sales in Europe the first six months dropped 35 % and where we are not getting reimbursement on our new products in all markets so there will of course be markets where due to reduced business and due to lack of progress on reimbursement we will see reductions in sales and promotion costs and in sales force so it is a very specific way we have done this analysis and we think we can do it without causing any pain for the launch and the progress of the new products but that was the first question. Now over to you Anders on the composition of the savings.

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Anders Götzsche

Yes, we will out of the 3 billion you will have a saving that is of course, as you also say, approximately 4-500 million in saving on amortization and depreciation and the remaining part will be improved cost of sales, it is a better mix, it is efficiency in our production facilities, it will be reduction of cost, a combination of number of heads and sales in motion and also a focus on what we are actually doing and securing the right resources behind the product launches. One example as we have told you before is that we would evaluate mid this year what is the potential for Selincro and what we can see is that it flies very well in a few countries but in most other markets we are struggling with access and reimbursement and therefore we are also pulling the plug for investing so heavily and that is one of the issues also for the restructuring in Europe. Then you will see that we have on a constant basis been around 20 % for R&D and of course a combination of less people and fewer projects will lead to us being a benchmark for the industry for R&D from 2017 and also due to the fact that we have most of the heavy lifting in some of the new products behind us and therefore we will focus as Anders will come back to on 35700 and Idalopirdine. For administration, we will also go after savings that will be around 2-400 million that will lead to us being in top-tier class with our admin ratio and that is how we come to the figure of around 3 billion.

0.26.36.2

Kåre Schultz

Thank you, Anders. Now would you Anders for 35700?

Anders Gersel Pedersen

Yes, 35700 is an anti-psychotic with a profile that is somewhat different than most drugs available. The one that has some resemblance on some of the parameters is actually the older anti-psychotic clozapine because of its strong engagement also with the D1 receptor and also with the 5HT6 receptor. What we see is that many of the drugs that are available on the market today are predominantly driving effects through D2 and we have in a product with a similar profile seen data already previously that shows that if you switch onto products like 35700 then you can actually get some very nice effects and we see that that is predominantly or we expect that that is predominantly driving to the switch to the D1 and 5HT6 receptors. Based on also what we have seen with the historic use of clozapine in treatment resistant schizophrenia. The major downside, as many of you may be aware, on Clozapine is that it has blood dyscrasia or imbalance as part of its side effect profile but also very significant weight gain and metabolic disturbances which we have not found in the frontrunner before lu AF35700 so we think in this particular population which has a great need for new therapies today there is an opportunity for us to take 35700 forward.

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0.28.13.9

Kåre Schultz

Thank you very much, Anders, back to the operator.

0.28.21

Operator

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

0.28.27

Martin Parkhøi, Danske Bank

Hello, just three questions where some are quite basic because you are quoted, at least from Danish media, that you expect to in 2017 to be close to industrial standard on operating margins. Just to be sure what kind of peer group you use, what is your definition industry standard? Then second question just to be absolutely sure with respect to the reduction of DKK 3 billion in cost at least including amortisation what is the absolute baseline for cost where you reduce from? And then a final question on Rexulti, given the substantial restructuring you are doing in Europe, could you potentially decide not to launch Rexulti in Europe at all?

0.29.26

Kåre Schultz

Thank you, Martin. I think I will try and answer the questions first and then my colleague can chip in. So if we take the first question about what is standard for you could say operating margin we are discussing, then first I need to clarify one thing and there is a fine difference between whether you are close to or you are getting closer to and if I translate what I said in Danish then what I said was, we will be approaching not that we are close to, so we will be unfortunately from the wrong end, from the bottom, we will get up and get closer to but not close to necessarily the margin that we will see as industry benchmark. We are talking about the European pharma industry and I don't have this precise number but I would guess they have on average around 25 % in operating margin. So we will not be at that level in 2017 but we will be getting closer as we progress over the next two years.

With regard to the DKK 3 billion cost that we are planning to take out it is everything else being equal the baseline we are starting from. So it is not like we have a definitive number

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but it is what we had planned to do this year we are taking it down by 3 billion. Then we have other things that might be happening where we will do small adjustments. We are increasing the sales force in the US for instance so you cannot sort of expect us to come up with a specific, absolute number.

And then the last very good question, Rexulti in the EU, we have not yet taken a firm decision about when and how to launch Rexulti in the EU, that is too early, we are evaluating that together with our partner Otsuka and when the time comes to take a launch decision, whether we do it in all or few or none of the European markets, then we will of course inform you when we get to that point in time. But I don't know, Anders, if you have any further comments.

0.31.37

Anders Götzsche

You could say in principle we use the cost run-rate as it is today so it is basically a 2015 run-rate that we evaluate against.

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Kåre Schultz

Thank you. Next question please.

0.31.53

Operator

Thank you. Our next question comes from the line of Mr. Terence McManus of Credit Suisse. Please go ahead, your line is now open.

0.32.00

Terence McManus

Hi. Thank you for taking my questions. Just starting on Abilify Maintena with another strong quarter and an impressive launch there I was just wondering if you could give us some colour on how big this product could be or perhaps should we view Abilify Maintena as a larger opportunity than Rexulti? And then in terms of Brintellix and the filing for cognition with the FDA, we haven't really heard from management since the filing was accepted and I just wondered how much more confidence you have in an FDA approval

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label change now that the filing has been accepted? And then also on the early reimbursement discussions you have had on Rexulti in the US. Thank you.

0.32.46

Kåre Schultz

Thank you very much. I think I will try and cover question 1 and 3 and then I will ask Anders to comment on Brintellix in the US and the filing with the FDA. If we take Abilify Maintena then we are of course very, very happy about the progress of Abilify Maintena in many, many markets and we see it as a great opportunity, we are not really interested going forward in commenting on specific peak sales or specific sales numbers into the future. We expect to see continued positive momentum on Abilify Maintena and we are happy about the approvals we have had in the US as we mentioned of the new device we are using and on the deltoid injection side. If you compare to Rexulti then I would say long term I would expect Rexulti to become a bigger product than Abilify Maintena and that is of course because we believe it has a really good clinical profile and that it has a very strong long-term potential. In terms of reimbursement and those negotiations for Rexulti we are quite optimistic that we will have comparative access of Rexulti to other newly launched products in those categories we don't see it being in general blocked from managed care so we are quite optimistic about that, we expect to have a rebating situation which is similar to other similar products, we don't see any dramatic reasons to assume that it should be significantly worse or better. Now Anders over to you on Brintellix and the sNDA.

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Anders Gersel Pedersen

Yeah. I think the important thing to us about the acceptance of the file on Brintellix is a shift that may not have been as obvious to many which is that it has been considered in the acceptance of the filing that cognition is an appropriate target to develop drugs for within depression. That is not something that was possible to do in the eyes of the FDA several years ago and therefore that is a shift in the mindset of the FDA which opens this opportunity. And we believe that through some of the discussions that have happened both in the academic communities and scientific conferences, that the FDA has both seen and heard some of the data that we as well as others have delivered indicating that there is a distinct element of cognitive impairment that is not in itself embedded in what we measure with MADRS scores and therefore it is very important that we now can take a product forward with this something we can add on to the label and potentially be able to have our sales people speak freely about. As you know with these procedures with the FDA you don't know where you are until you are at the very last state. I can say that we are certainly more optimistic about getting there given that they have accepted it as an appropriate thing to do but in terms of the actual technical assessment of it we will have to wait until we have the mid March or so. Thank you.

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Kåre Schultz

Then on to the next question.

0.36.23

Operator

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

0.36.30

James Gordon, JP Morgan

Hello, thanks for taking my questions. Three questions please. One was on the long term aspiration that has previously been given and one of them was at the Capital Markets Day in December 2013, there was the aspiration to fully replace Cipralex with Brintellix by 2018. So the first question was whether the aspiration and the other aspirations given then still stand or whether we should think that they have been superseded. A second question would be the Brintellix launch has gone a bit slower than the market had expected. Should we anticipate as well as cost savings that there could be a change or any sort of change in how Lundbeck goes about promoting products? Could there be any shift there? A third question was you mentioned impairments. I saw a reference to impairing Selincro. Can you say what the new peak sales estimate is at Selincro, the extent to which you have impaired it? And actually just one final clarification which was I think if I heard correctly that the DKK 3 billion of savings include depreciation and amortisation. Can you say what the core saving would be, or what the saving would be on a core basis?

0.37.40

Kåre Schultz

Thank you James. I think I will try and answer the first three questions and then Anders will take the last one. If we look at the long-term aspirations that have been communicated earlier on then of course I wasn't there when they were communicated so I don't really know exactly what was said. But I can say that it is my firm belief that it doesn't add a lot of clarity or value to analysts, investors or stakeholders that we come out with specific expectations for turnover levels for newly launched products. What is important is that we see a good take-up in the market place, that we see good, steady market share development and that we have you could say our whole value story, our whole pricing in good shape. So in that sense you can say that the previous long-term

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specific targets have been superseded by a new communication strategy where we will not give peak sales in absolute numbers but rather indicate what segment we are going for and what the strength we see we have of the different products.

In terms of how we launch products, in terms of the launch of Brintellix and now Rexulti you should not expect to see any change as a consequence of the restructuring. We are doing it to the best of industry standard with a very high scientific profile with a very strong pre-launch process for all products and with a classical activity which is both based on medical scientific information from medical affairs, traditional sales efforts by the sales organisation and traditional promotion efforts and there is no initiative in the current restructuring to reduce the sales and promotion efforts behind our key products. So that will not be the case.

Then there was a question with regard to the impairments and I will hand that over to Anders.

0.39.57

Anders Götzsche

What we have done with the impairment of product rights, it is a small amount, less than DKK 200 million for the impairment of Selincro, and that is due to the fact that we definitely see a lower peak sales potential. What I also said was that it is, you know we basically see it having good traction in two markets and the major traction is in France and therefore it is meaningful to continue that when you see it from a marginal basis using our sales reps and having the product in second line but if you make a fully loaded business case it doesn't hang together and therefore we take the impairment, that is the way the accounting principle needs to be evaluated. And then the savings you could say roughly DKK 4-500 million is amortisation and is hitting EBIT and the DKK 2.5 billion is impacting core EBIT. Was that answers to your questions?

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James Gordon, JP Morgan

That is great, thanks.

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Kåre Schultz

Thank you very much, then we go to the next question.

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Operator

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

0.41.13

Michael Novod, Nordea

Yes hello it is Michael from Nordea. A few questions, first of all to Alzheimer's. You have previously been indicating that we would get data by around mid 2016 but now on clinical trials it is evident that some of the trials are ending in November this year and one is ending in January 2016 so maybe you could update us on those plans? And secondly also regarding Alzheimer's, how important is Alzheimer's to, say, long-term top-line growth in Lundbeck at the current stage? And then lastly on Xenazine, do you expect to see generics in the market this year? Previously you have been guiding that there would likely not be generics until 2016.

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Kåre Schultz

I think Anders you will take the first one on Idalopirdine and then I will cover the two next questions.

0.42.05

Anders Gersel Pedersen

It is correct that all the way back in 2013 we projected that we possibly could have the results mid 2016. The plans as they have been going forward in the initiations of the studies basically means that we will not have data until the turn of the year around 2016-2017 for us to be able to communicate, you should expect that to be on the safe side on the first quarter of 2017. The reason for that was that it has been slower to initiate the amount of studies that we actually needed to get to in terms of just capacity wise, both from an internal perspective, CRO perspective, but also at the sites there is a tremendous amount of efforts in many sites so it is not necessarily that we are competing for the patients but we are competing for the attention of the physicians to run the clinical trials. So that was the reason for the slower start of some of these studies. I could say that at this moment the run-rate of the study is as we have expected with a plan readout as stated here in the first quarter of 2017, perhaps we can get something late 2016.

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0.43.25

Kåre Schultz

Thank you Anders. With regard to the importance of Alzheimer's then we have said today that we have four core areas that we want to focus on, that is depression, schizophrenia, Parkinson's disease and Alzheimer's disease and as such it is of course important to us, it is very important to us and it is one of the areas where we really would like to make a difference and where we would like to treat more patients to give them higher quality of life and of course also generate turnover and profitability for the company.

With regard to Xenazine, I am not aware of exactly what has been said in the past but I am acutely aware that the orphan drug protection ran out 14 August which is only a couple of days ago, I would say it is more likely than not that there will be generic competition of course and that it can happen any day so I would expect that within the next months we will see generic competition, the speed with which it will actually happen since this is a speciality product remains to be seen but we should expect to see a major loss of turnover on this product within the coming year. Thank you for those questions; let's move on to the next.

0.44.41

Operator

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

0.44.47

Peter Welford, Jefferies

Hi, thanks, a few questions left please. Firstly on the projects in R&D that you mentioned have been discontinued. I wondered are those all early stage projects that we wouldn't be aware of or are there any projects you have highlighted in the past in R&D that have been discontinued that we should know? I guess particularly, I presume, 20513 is being continued. Secondly then on Northera I wonder if you could just outline is there anything particular in the second quarter sales number we should be bearing in mind not to use that as a run-rate or is the Q2 number a fair reflection of demand in the US? Thirdly, I guess Anders just on future Otsuka milestones that are related to sales. Are those now going to be expensed? And, if so, how or how should we think about those? Because I understand the R&D related ones but what about the future milestones related to the sales? And then finally, sorry about this, the Cipralext rest of world, is that now likely to be

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in terminal decline? Or are there any sort of things we should be bearing in mind for that business in the future? Thank you.

0.46.00

Kåre Schultz

Okay, thank you very much. I think the first one I will hand to Anders on the projects.

0.46.07

Anders Gersel Pedersen

Thank you Peter. It is early projects that will be discontinued and I think what we are looking at is trying to not just focus what we are doing as such but also there are projects that we knew over the next three years in the progression could potentially be very costly and will still be in high risk areas, projects that we have not disclosed at this stage. And some of those will be closed in the process of this prioritisation process. The remaining projects that are very early on, we will make sure that they are projects that are only in areas where we think that we know the most and when I say know the most it is not seen from a competitive perspective relative to the companies but relative to the science so to speak. We have to put our bets where we think we have the best ability to translate science into products through the various compositions of the value chain and that is why we have made these focused efforts into areas where we know how to translate insights into new products.

0.47.18

Kåre Schultz

Thank you very much Anders and I will take the next question on Northera and the question was whether there was something extraordinary on the Northera business in the second quarter. That is not the case, we see a classical gradual build-up of demand and of sales and we are very happy about the trend that we are seeing right now in the US on Northera. Then the next question I think that is one for you, Anders, that is about future Otsuka milestones related to turnover thresholds.

0.47.50

Anders Götzsche

Yeah, and I think it is, just to give it a little more broad perspective, it is important that the next milestones that might happen for Rexulti is if and when we launch in Europe then we need to pay milestone and that will be capitalised as we have also done with the US

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milestones. Then the sales milestones it is when you reach a line where you have created a Blockbuster in dollars and that is a minor milestone and then the next milestone of major impact is if we read a line where we have together with Otsuka a multi-billion dollar product and it will be capitalised and amortised, I don't think we have any choice there for actually expensing it. So the reclassifications we have done is to secure that the cost we pay by milestone for R&D cost is like for like if we have the cost on our own. I hope that answers your question.

0.48.58

Kåre Schultz

Thank you Anders. And then the last question on CipraleX, what to expect from the rest of world so to speak. You could say it is still in a way a bit of a mixed bag in the sense that we still have the patent run-off in Canada that will affect the numbers negatively but then we have a number of markets including for instance Japan where we are not having that situation and where we will see sales hopefully growing going forward. So all in all the speed of decline of CipraleX is slowly coming down but you should still expect it to continue declining in the coming years.

0.49.34

Anders Götzsche

And just to reemphasize, we have set a decline around 50 % for the year, you should still expect that for the totality.

0.49.44

Peter Welford, Jefferies

Sorry, just following up on the 200 million milestone you owe Otsuka this month on the US so just to clarify that is going to be capitalised still?

0.49.53

Kåre Schultz

Of course, that is a regulatory milestone and we have defined it and say when you pay for regulatory approvals then you also get a value out of the future so you attach that to the future value of the sales of the product so that will be amortised.

0.50.08

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Peter Welford, Jefferies

That is very clear. Thank you.

0.50.10

Kåre Schultz

Let's have the next question please

0.50.14

Operator

Our next question comes from the line of Mr. Carsten Madsen of Carnegie. Please go ahead, your line is now open.

0.50.21

Carsten Madsen, Carnegie

Thank you very much, this is Carsten from Carnegie. Just sort of two longer term modelling household questions for Anders I guess but feel free. Firstly on the longer term tax rate you previously commented a lot on tax rate in relation to the US operations etc. How will it change now with the less R&D being carried out in the US impact your future tax rate and also for future dividend rate what are we looking at here for Lundbeck in the period past 2018 say you achieve all that you want to achieve?

0.51.04

Anders Götzsche

What you should expect is that the cash tax rate will from 2017 and onwards be around 25 % and the reported tax rate will be a little above 30 %. So if you put it into evaluation models you should use around 25 % and it is not a mistake that I don't mention 2016 and that is due to the fact that the tax could be higher in 2016 due to more profit coming from the US and neurology portfolio where the intellectual property rights are taxed in the US. And I think the dividend policy you know from the past is that we have said that we pay 25-35 % of the net result in payout and I think so far there has been no change in our dividend policy and that will of course be linked to the results we are creating. You should not expect us to pay any dividend related to 2015 and when we announce the expectations for 2016 in February then you will of course get a flavour of what is the level of net result we expect to create in 2016.

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0.52.26

Carsten Madsen, Carnegie

OK and could I just have one more question. Have you heard any impact from the new French drug pricing initiatives on your European organisation?

0.52.39

Kåre Schultz

No, we have not but you could say the restructuring we are planning takes into consideration the reimbursement level and the pricing level that we see in the various European countries and it is of course quite clear that over the past five years the general climate for reimbursement and pricing in Europe has deteriorated significantly and as a consequence of this you could say we are also reducing our European organisation.

0.53.10

Carsten Madsen, Carnegie

OK. Thank you very much.

0.53.19

Kåre Schultz

So I believe this concludes this teleconference. Thank you very much for calling in, thank you very much for listening, we look forward to talking to you again in the future. Thank you.

