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H. Lundbeck A/S

**Transcript : Q3 Financial Results 2015 :**

Operator

Ladies and gentlemen, thank you for standing by. Good afternoon, welcome to the H. Lundbeck third quarter results 2015 conference call. Throughout the call, all participants will be in a listen only mode and afterwards there will be a question and answer session. Today I am pleased to present Kåre Schultz, President and CEO, Anders Götzsche, EVP and CFO, and Anders Gersel Pedersen, EVP Research & Development. I will now hand the call over to Kåre Schultz. Please begin your meeting, sir.

0.00.29.9

Kåre Schultz

Thank you very much and thank you all for your interest in Lundbeck. Welcome to Lundbeck's third quarter teleconference for 2015. 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 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 repeat what I said last quarter that while I am pleased with the sales growth of our new products and also the progress we are seeing from R&D, I am not satisfied with our profitability though it will improve following our ongoing restructuring plan. Secondly, it is an interesting and very dynamic period Lundbeck is going through with strong growth of our new products and in the important US market. At the same time we see sharp deterioration of our European franchise following generic exposure and timing of market access, but now back to the results we 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 our overall operating activities had a satisfactory performance in the quarter, especially adjusted for the decline in Europe. I am obviously humble to the fact that we have been helped by currency appreciation, which has provided half the growth. 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. Let me provide you with a couple of examples. Brintellix continues to do

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very well in the US as well as in non-US markets where we have just made significant progress and where we are receiving a lot of positive feedback. The Brazilian approval with cognition in the label is important and so is the positive market access progress in South Korea and in the UK. And then I will try to accept that Germany seems less supportive. 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. I am aware that this is very early days for Rexulti but the volume uptake in the first three months or so has been encouraging.

Please turn to slide 4. In connection with the Q2 release, we also announced a major restructuring programme in order to reduce Lundbeck's cost base and regain profitability sooner. The programme covers all business functions in Lundbeck but primarily headquarters and commercial functions. The programme focuses on in-house R&D capabilities and organic profitable growth. We will focus our efforts on four areas in which we have proven expertise and are most likely to be successful. Mood disorders, psychotic disorders, Parkinson's disease and Alzheimer's disease. So far we have carried out approximately 50 % of the planned headcount reductions of around 1,000 of which the majority has been in headquarter functions and in Europe. We have also closed our US research site. The total cost in 2015 from this restructuring programme is expected to reach around DKK 6.5 billion of which only a fifth is cash.

Please turn to slide 5. 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 previous quarters or the third quarter last year. Revenue from Brintellix reached DKK 180 million in the third 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, Chile, Mexico and South Africa. The global launches of Brintellix continue as planned and feedback from patients and prescribers is encouraging and non-US sales now represent close to 40 % of the sales. All in all, a very positive performance.

In international markets, on slide 6 – please turn to that, in international markets Brintellix reached DKK 35 million for the quarter. The product was launched in Canada as Trintellix towards the end of 2014. Even though it is early in the launch, the uptake is encouraging. Countries like Australia, South Africa, Chile and Mexico also show solid uptake. In October this year the Brazilian authorities approved Brintellix with cognition in the label. Brazil is a very important country for Brintellix. It is the world's fourth largest anti-depressant market with an estimated market size of around \$800 million per year. Furthermore, the product has been granted first-line reimbursement in broad depression and without any restrictions in South Korea. In Europe, Brintellix has been launched in some 16 markets so far. As expected, however, market access remains a key challenge. In October 2015, NICE in the UK has in its final draft guidance recommended Brintellix as third-line treatment for

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adults with major depressive disorder. A decision I am quite pleased with. Unfortunately, though, the German G-BA has concluded that Brintellix has not shown additional benefits in the treatment of major depressive episodes in adults on purely formal grounds. Obviously a disappointing decision although it is hardly surprising as we have seen many new drugs struggling to get market access in Germany.

Please turn to slide 8. Here we have an illustration of the performance of Brintellix since launch. As you can see, it is performing very well and both New scripts and Total scripts as well as volume share continue to show steady positive momentum. Additionally, Brintellix has been outperforming the two most recent branded anti-depressant launches, Viibryd and Fetzima, in gross sales in the US by 33 % and 107 %, respectively. In general I believe it can be relevant to assess performance by using moving averages and for instance look at current four weeks versus previous four weeks. The branded market TRx and NRx increase by 1.8 % and 2.5 %, respectively whereas Brintellix TRx and NRx increased a bigger percentage, namely by 3.8 % and 4.2 %, respectively, during the same period. So we continue to be very encouraged by the steady growth momentum of Brintellix.

Now please turn to slide 8. If we turn to Abilify Maintena, our long-acting anti-psychotic that has done extremely well both in the United States and in Europe. Sales grew 209 % or 182 % in local currencies and reached DKK 181 million in the third quarter. And you can see the increase compared to last year. In Europe, sales uptake of Abilify Maintena is encouraging with sales in the third quarter reaching DKK 77 million. Spain, France and the UK are the largest markets followed by Germany and Italy. In the US, Abilify Maintena grew 86 % and sales reached DKK 86 million, which represents Lundbeck's 20 % share of total net sales of the product for the quarter. In international markets, Abilify Maintena has recently been launched in Australia and Canada and reached revenue of DKK 18 million in the quarter. We are also developing Abilify Maintena in terms of additional data and the ongoing phase III study in bipolar disorder is expected to be finished some time during the second half of 2016.

Please turn to slide 9. If we go back to the US, our neurology products continue their solid growth. Obviously helped by the US dollar appreciation but also a continued strong demand for all the products. Xenazine is starting to see the negative effect from generic competition but we see an incredibly strong performance on Onfi. Northera was launched a year ago. We have seen a lot of interest from physicians and the feedback that we have from the patients is very positive but we should remember it is early days with Northera but I feel comfortable that we will reach our expectations. But all in all a 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 and in the longer perspective also being able to execute a launch of our Alzheimer's product, idalopirdine, a few years from now assuming data supports an approval.

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I will now hand over the presentation to Anders Götzsche to go through the financial performance.

0.10.06.9

Anders Götzsche

Thank you very much, Kåre. Firstly, I want to mention that the difference between reported revenue and core revenue arises from the divestiture of shares in a small US biotech company called Naurex which provided us with a gain of DKK 113 million, which is booked in the third quarter. In the third quarter core revenue increased by 12 % and reached DKK 3.6 billion in local currencies. The growth was 5 %. The main reasons for the growth realised in the quarter are very strong growth in general for all our US products, growth of our key products across all regions, and then of course the US dollar appreciation. These growth factors are partly offset by of course the declining mature product portfolio in Europe and international markets. Core EBIT actually was growing in the quarter. The increase is driven by strong sales, especially in the US, and of course more than offsetting the loss in revenue due to the patent expiry for Cipralext. Reported EBIT is significantly negative and that is due to the impact from the ongoing restructuring programme. And then you can also see that we have a negative free cash flow of around 3.3 billion and of these 3.3 billion that relates actually to \$400 million in payments to Otsuka for milestones of which \$200 million is paid in the third quarter.

Please turn to the next slide – slide 11 – Lundbeck had total assets of DKK 22.2 billion at the end of the period and that is compared to DKK 25.6 billion at the end of 2014 and the significant decline in the total assets is mainly due to the reclassification of certain product rights, mainly related to Abilify Maintena and Rexulti as we communicated in August and furthermore the balance sheet is impacted by the financial consequences of the ongoing restructuring. Our equity amounts to DKK 9 billion corresponding to a solvency ratio of 41 % compared to 53 % by the end of 2014 and by the end of the quarter we have an interest bearing debt of around DKK 4.3 billion and a cash position of 1.3 which corresponds to a net debt around DKK 2.9 billion. We still expect that the net debt position by year-end will be around DKK 3 billion.

Please flip to the next slide – slide 12. As you have seen from the stock release and also from this slide, the financial guidance for 2015 has been slightly lifted. We still expect revenue to be around DKK 14 billion, which is unchanged and it is important to say that the outlook is based on unchanged exchange rate and expectations for continuous robust performance of the portfolio of key products and that will of course be offset by the generic erosion of mature products but following slightly lower cost Lundbeck now expects core EBIT, assuming unchanged exchange rates, to be around DKK 0.7 billion compared to the previous guidance around DKK 0.5 billion for 2015.

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Following the announced restructuring initiative Lundbeck is also providing guidance for the reported EBIT which is now expected to be improved with the same amount as core EBIT so now we expect a minus of DKK 6.8 billion compared to previously DKK 7.0 billion negative. Looking at the expected cost ratios for the year, the Cox percentage for 2015 will be sensitive to product mix but it will – if we exclude the restructuring cost - be slightly higher than in 2014 and that will also be driven by additional Northera amortisation. The SG&A ratio should be expected to be around 50 % excluding restructuring as we continue to roll out the launch of new products and have heavy investments. The R&D ratio will likely stay just below 20 % adjusted for the reclassification effect. Net financials you should expect a net loss of around DKK 150 million and that concludes the financial presentation and with that I will hand over to Anders Gersel Pedersen for a walk-through of the latest development in our pipeline.

0.15.08.0

Anders Gersel Pedersen

Thank you Anders. Please go to slide 13. Regarding Rexulti we have closed the study in PTSD. We still see a potential for Rexulti in this indication. However, the trial design was sub-optimal leading to a mismatch between the number of patients screened and the number of patients enrolled to an extent that led us to close the study. And we will now consider how to progress in this indication. Regarding Brintellix, the regulatory process with the FDA continues and we now anticipate an ADCOM in the beginning of 2016. Remember that the sNDA that is under review is to add clinical data regarding the effect of Brintellix on cognition, on cognitive dysfunction in the adults with depression to the current label within depression. The FDA is expected to take action on this filing by 28 March next year.

In connection with the restructuring plan, we will in R&D see a reduction and consolidation of the research and development footprint globally and we will focus our effort towards selective projects within the chosen four disease areas.

Please turn to the next slide. Abilify Maintena for the maintenance treatment of bipolar disorder – back in August 2012 Lundbeck and Otsuka Pharmaceuticals initiated a programme trial to assess the time to recurrence of any mood episode in individuals with bipolar 1 disorder who maintain stability on Abilify Maintena for at least 8 weeks. This programme is getting close to finalisation, which is why I find it worth mentioning here. The study is expected to recruit approximately 700 patients in the US, Canada, the EU and Asia and it is expected to be finalised by the mid of 2016.

Please turn to slide 15. In October 2013 Lundbeck and Otsuka initiated a phase III programme in Idalopirdine in order to explore the effect of the compound in mild to

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moderate Alzheimer's disease as adjunct therapy to acetylcholine-esterase inhibitors. The key end points are ADAS-Cog and activities of daily living and the clinical global impression of change scales. The programme will enrol approximately 2,500 patients worldwide and recruitment is on track in order to finalise the programme in the first quarter of 2017.

Please turn to slide 16. The clinical phase III programme on Lu AF35700 is planned to start during the first quarter of 2016 with the study in patients with treatment resistant schizophrenia. The first study is expected to enrol approximately 950 patients to meet the target and randomisation of 675 patients. Several phase I studies have been completed including a multi-dose study in patients with schizophrenia. 35700 has a novel and unique pharmacological profile with a high D1 and 5-HT6 receptor affinity in combination with a low D2 receptor affinity. The compound therefore represents a potential new option for patients not adequately responding to anti-psychotics with a high D2 receptor occupancy and may be able to address a broad part of symptomatology of schizophrenia. In completed safety trials, 35700 was generally safe and well tolerated with efficacy in spite of low D2 occupancy the compound could improve treatment adherence due to its potential to cause less drug induced dysphoria and fewer other mood changes often seen with antipsychotic treatments.

0.19.18.9

Kåre Schultz

Thank you very much Anders. Before I hand over the floor to the Q&A-session I would say that Lundbeck stands in front of exciting times and with the announced restructuring programme I am convinced it will also be profitable times. With that I will say thank you ever so much to all of you for your interest and hand over the floor to Q&As

0.19.40.8

Operator

Thank you. Ladies and gentlemen. If you do wish to ask a question please press the 0 followed by the 1 on your telephone keypad. If you wish to withdraw this request you may do so by pressing the 0 followed by the 2 to cancel. The first question comes from Tim Race from Deutsche Bank, please go ahead. Your line is now open.

0.19.59.3

Tim Race

Thank you and thank you for taking my questions. A few if I may. First just on the financials. Rexulti you have not disclosed the exact sales number unless I missed it. Of the

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US other sales since we increase 88 million in the quarter, Q/Q, Y/Y that is, how much of that can we assume is to be Rexulti?

Then just a question on timing in terms of the cost saving programmes. Obviously you have made fast work in terms of the headcount reductions. Could you just talk about the timing between 2016 and 2017 in terms of one or more elements that are benefits in terms of the savings we should see and also given that you are sort of increasing your R&D spend on a few new phase III studies could you just talk about how that will evolve in 2016? And then if I may – sorry for so many questions – but in terms of the R&D side of things. The Rexulti in Alzheimer's agitation could you just talk to me about how Rexulti differs from what we have seen in perhaps the agitation in Alzheimer's or at least dementia versus anti psychotics previously and obviously there were some safety issues with that in the previous decade so I would just be interested to know your thoughts on that element. Thank you.

0.21.12.9

Kåre Schultz

Okay, that was a lot of questions. I think we will try to do them in the order that you asked them and I think the last one I will ask Anders Gersel Pedersen to answer. The first three ones I will give them a go and then Anders Götzsche can complement my answer. So you correctly state that we do not give out exact Rexulti sales for the quarter. That is due to the fact that the product is just recently launched and that means that the actual sales are a result of pipeline filling and as such with lack of insight into exactly how the product will develop it will be sort of premature to comment too much on that. What we can comment on is that the TRx and NRx development on a weekly basis that I am sure you also follow is very encouraging and we are looking at that as an indication that the product is off to a very good start in the US market and we are optimistic about the future for Rexulti.

On the cost savings and the timing then you can say there is nothing significant new there. We have seen slightly lower cost here in Q3 than we were anticipating as a consequence of slightly faster realisation of some of the savings. That does not change our total saving programme so the overall programme is still aiming at a reduction of 3 billion in 2017. The reason why we have this prolonged timing is linked to your question here and that is because when we ask people to leave the company then there is a lot of rules and processes around the world including many European countries where there is a quite lengthy process of negotiation and then there are quite lengthy times before you actually leave your position and therefore you don't see the full effect of the roughly 1,000 FTEs that we are reducing the total workforce – you don't see that full effect until 2017 because it is not all the people that are leaving Lundbeck until during 2016. The same thing goes with the R&D cost. We do expect to see a reduction in the total R&D cost but that is also happening gradually over 2016 and 2017. Part of the reason is of course commitments you have to ongoing activities that it does not make sense to stop and it is manning that is needed to carry through different activities that you have already started so again the

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same argument goes there. But before we move on to the last question, I don't know, Anders, if you have any further comments to it?

0.23.55.10

Anders Götzsche

I can just add, Tim, that we have said when we made the restructuring that we would expect approximately 50 % of the savings to come through in 2016 and then the full effects as Kåre also alluded to the 3 billion will have effect in 2017.

And then the last question on Rexulti to you, Anders

0.24.12.9

Anders Gersel Pedersen

Yes, I think the answer will be in two parts. The first is on the efficacy side. We think with the profile of Rexulti it is well positioned to address agitation without making individuals with Alzheimer more drowsy as you would with some of the other antipsychotics that you could even think of using in these patients. Concerning the safety element that you are alluding to which is adhering to many antipsychotics in use with Alzheimer patients it is mainly related to the cardio-vascular problems not least driven by some of the metabolic profile distortions and as you know from our development programme we have a very strong position with Rexulti in that respect with very little impact on the metabolic profile and therefore presumably also less side effects related to the cardio-vascular problems so we see the molecule as being a good molecule in that scenario. I don't expect that we will – even if we apply for this indication in Alzheimer patients – will be exempted from the black box warning – so that the physician will still be alerted to the concern but we see the molecule with its pharmacological activity and with the safety profile to be the better suited product in this position.

0.25.53.7

Tim Race

Okay, perfect. Thank you.

0.25.56.7

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The next question comes from Jo Walton from Credit Suisse. Please go ahead. Your line is now open.

0.26.02.6

Jo Walton

Thank you. Just a couple of questions, please. I wonder if you could tell us about how the commercial marketplace is evolving now that Alchemist is entering with another long-acting product. Do you see that expanding the market or do you expect that to take some share gains and is there anything you can tell us about rebate pressures and how that might be developing? Could you also tell us a little bit more about what you plans would be in Germany for Brintellix assuming that the now that you have got the decision showing that the Germans don't think that there is an additional benefit would you actually remove the drug from the market if you cannot get a decent price? And can you tell us a little bit about the timing that you are expecting for decisions in other European markets? You told us about Germany and the UK, but is there anything else that we should be looking for in France, Italy, Spain, something like that? And, I will leave it to that. Thank you.

0.27.06.7

Kåre Schultz

Thank you very much, Jo. I think I will try to cover both questions. The first one on long-acting products for schizophrenia. Well, of course Alchemist is going to launch where we have Abilify Maintena together with Otsuka. The expectation we have there is that they are of course not yet in the market but once they get to the market we expect that as a fourth player in many markets. They will have a marginal impact both when it comes to the growth of the segment and when it comes to market share. However, in general we see that the long-acting segment is growing as a part of the total market for treatment of schizophrenia and that is the case not least in the United States, which is of course very positive for Abilify Maintena and I guess one more player with the same message will not make a huge difference since it is number four but will probably push towards the direction of continued market expansion. When it comes to Germany and Brintellix and Brintellix in Europe in general then if we take Germany first, it is correct that the German authorities, G-BA, have concluded that they do not see any additional benefit from Brintellix – as a side comment I can say that it is of course remarkable that EMA sort of the official European health authorities have approved the product with a unique label on improvements of cognitive functions. That does not seem to sway the German Authorities in any way and we do not expect, actually, that we will be able to reach a compromise on the price. I am expecting that they will offer a price close to 34-year old generics which in no way matches the value of Brintellix so there is a big likelihood that we can't reach agreement on the price. The German regulations are quite peculiar in the sense that if you do not reach agreement on the price you are being forced to remove the product from the market. You are not allowed to keep the product on the market without reimbursement

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or with some kind of partial reimbursement so in case that becomes the end result, which we don't know yet, but which is a theoretical possibility, then the product will actually be removed from the market and only be available from through what you call international pharmacies. In terms of other markets, you are correct that NICE has recommended it for third-line therapy. It is on the market in the UK, it is on the market in several other European countries. We are currently in negotiations in France, Italy and Spain. It is my hope that we can reach a conclusion in all the markets but there is no guarantee here. As you know, it is difficult to reach sensible reimbursement levels in Europe, but let us hope for at least two out of three, I would say, in the next year so that we can see a launch in some of these very important markets.

0.30.14.4

Jo Walton

Could I also ask – I apologise, just looking at the other pharmaceuticals. I know it is a collection of older, mature products but they were up very strongly in the third quarter, up 22 % in the quarter, only up 13 % year-to-date. Is that just the timing of tenders and where it was strong in the third quarter we should expect it to be weak in the fourth quarter?

Kåre Schultz

Anders could you give an answer to this?

Anders Götzsche

It is a combination of seasonality fluctuations and then, of course, Rexulti is also booked in that. So it is a mix of – you can see that in China and Japan, CipraleX, Lexapro and Ebixa will continue to grow. We also – in some of these mature products, they are of course not included in other pharmaceuticals but there are some of these products that will still grow and the main reason is seasonality on Rexulti.

0.31.14.5

Jo Walton

Thank you.

Operator

The next question comes from Peter Welford from Jefferies. Please go ahead.

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0.31.20.2

Peter Welford

Hi thanks for taking my questions. A couple – firstly on the 35700. I am just coming back to the data you have in-house. I appreciate obviously that we don't have access to this so we are sort of at an information disadvantage but just so I can understand what gives you the confidence to move so rapidly into what will be a relatively expensive phase-III programme from phase I given that only one dose range finding has been done in schizophrenia patients and I guess how have you got confidence on the best doses to take forward or should we assume that the phase III will include a multitude of doses perhaps more than is typically done with the Rexulti type trials. Secondly then, just going to Rexulti – I wondered if you could give us any sort of initial feedback you have had from payers – I appreciate it is still very early days but any sort of information you can give us either from Otsuka or your standpoint on how that product has been positioned by or could be positioned by payers in the US? And then thirdly just coming back to the costs – I know you made the point that you managed to take out costs faster than you thought so you are just sticking with the aim. There was this, I guess, what are the sort of pulls and pushes here with regard to that 3 billion cost aim in so far as what could be done to potentially exceed and what at this stage are the biggest challenges to miss that aim? Thank you.

0.32.57.0

Kåre Schultz

Okay, thank you very much, Peter. I think we will start with Anders Gersel answering the question around 35700.

0.33.05.3

Anders Gersel Pedersen

Thank you, Peter, for the question. 35700 is a compound that has been developed as a further development of a molecule we did have notified in the pipeline earlier on Ziconapine so from that we have a lot of learning that we can use in moving 35700 forward and that is because of the comparability of some of the receptor levels and some of the pharmacokinetics that we have been able to model from and get to an understanding of how to proceed with the molecule. So having been in the phase I scenario and actually seen both the safety data there and some of the efficacy data although very sparse, obviously, and combining it with the PK-data that gives us confidence to go into a phase III programme that is not having a whole range of arms. It does have multiple effect arms because you must have that in a phase III programme obviously but it is not something that goes beyond what you have seen for example for the Rexulti programme.

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0.34.16.5

Kåre Schultz

With regard to Rexulti, I will cover that, so in the US it is early days of course but the feedback we are getting for payers in general is positive. Of course we have had contract negotiations. They are headed by Otsuka but we do participate in the discussions and we are aiming to have you could say competitive access in the US marketplace, basically you know in the range of 70-80 % of the market being accessible for us and we are seeing right now discount levels or contracting levels that I would say are comparable to what you see in the industry. As a personal comment I will say that in this category and knowing how the big PBMs are sort of working with category management there is of course the situation that Abilify went generic in the second quarter and that means there is a huge cost element for many managed care organisations within schizophrenia and psychosis which is being reduced significantly right now as a consequence of Abilify going generic so from a budgeting point of view I think there is good room Rexulti in US pharma spending. The last question about the cost I think I will just repeat that we are following the plan. It is going slightly not dramatically but slightly faster than planned. We don't have any additional and new initiatives so we are shooting for the 3 billion. I must say we don't see any major hurdles in reaching it but we have also not identified any major upsides in exceeding it so I really think you should keep your expectation that we will hit these 3 billion in 2017 as a cost reduction.

0.36.11.1

Peter Welford

That is great, thank you.

Operator

The next question comes from Michael Novod from Nordea Markets. Please go ahead.

0.36.20.1

Michael Novod

Thank you very much. It is Michael from Nordea in Copenhagen. First regarding the Brintellix ADCOM. How certain are you on say ADCOM actually to take place and with regard to that how do you see the trajectory for Brintellix after this. Do you see it change dramatically or are you past more seeing a situation now where Rexulti could be say the long-term bigger product compared to Brintellix? Secondly, on US pricing you have had some significant price hikes on much of your neurology business the last couple of years –

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how do you see that going forward – do you see that continuing or have you seen a change in the environment, especially recently? Yeah, I will stop with that.

0.37.07.8

Kåre Schultz

Thank you very much Michael. I think on the ADCOM I will ask Anders Gersel to comment on it and then I will give a comment to the sales following the ADCOM. Anders, if you...

0.37.16.5

Anders Gersel Pedersen

Michael, the ADCOM we believe is quite certain that that will happen. It was signalled to us from the FDA at the onset of the filing and we don't have a written confirmation about the date but in terms of understanding how things are moving within the process with the FDA we would expect it to be in the midst of the first quarter something around that. I don't think we will get a written exact date until they have all their internal experts in line so that they know that they can have it on a particular date but that is what we are aiming for in terms of how we are progressing with our preparation for the ADCOM.

0.38.08.7

Kåre Schultz

And with regard to the outcome of the ADCOM then of course we do hope to have a positive outcome of the ADCOM and following that if it is to happen we don't expect you could say like a catch-up effect on the sales of Brintellix. What we hope for is that we can strengthen our promotional message in the US marketplace that both we and Takeda can go out with a stronger promotional message and with cognition so we see it as positive in terms of being able to maintain the very strong trend line we have both for TRx and for total sales in the US and hopefully we will then be able to maintain this trend line for a higher number of years going into the future. On pricing it is correct that in our neurology portfolio in the US we have seen price increases over the past couple of years. What we expect short-term is the situation to remain unchanged. The big media focus in the US has been on some very extraordinary price increases for some very old and not innovative products. We believe that our products are all delivering high value to patients, to society, and that it is justified the prices we see and you could also say that within the coming years we will see a couple of them actually leaving exclusivity and as such they will no longer be in the focus in terms of pricing. This goes for Xenazine, Sabril and Onfi.

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Michael Novod

Okay, super. Thank you.

Operator

The next question comes from Martin Parkhøi from Danske Bank. Please go ahead.

0.39.59.4

Martin Parkhøi

Yes, it is Martin Parkhøi from Danske Bank. Just – of course, Kåre, I totally respect that you are not commenting on details on any products, I know that, but could you comment on Brintellix on how you look at things now with respect to the split let us say 5 years from now between the regions that you are reporting on. How much do you think will be driven by the US and Europe and international relations and then a second question, that is a little bit more of a soft question because in the US you are very successful with your neurology products but the plan that you sort of set 2½ months ago on the R&D focus is not really focusing on these kind of products so how has the acceptance in the organisation been that you are actually not putting the R&D focus on these products which are the most successful for this US organisation right now?

0.40.55.0

Kåre Schultz

Thank you very much, Martin. I think I will try and cover the first one and half questions and then I think Anders can comment on the R&D focus at the end so you could say with regard to Brintellix it depends a little bit on how you look at it because, of course, in the US we are only having sort of a third of the sales since we have a partner, Takeda, and in many other markets we do not have a partner so that in a way skews the normal picture so it depends on how you look at it. If you look at it purely from a Lundbeck point of view and not from the point of view of what is being sold in the marketplace then if we start from sort of the not so bright end then we do not have very, very high hopes of getting into all European markets. We just discussed it, the challenges in Germany and the challenges in some other markets. I believe that we can get a good market access in more than half the European markets and I am sure that in the markets where we do get access we will see strong market shares developing over time so EU sales could maybe be around a third or maybe slightly less. In the US, I think we will continue the very strong track we are on but of course we are only booking a third of the sales so you could say even though it would normally be half of the sale of any product there would be in the US again my rough thinking if you'd ask five years out is that probably around a third of the sales would end up being in the US and then to make the math go up how much is international markets – that is also going to be a third I was going to say but in international markets

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there is timing element and that is as you know regulatory approvals in countries such as Brazil is an example where we just had approval, countries such as China where you need specific data, Japan and so on typically comes later. The benefit of it is that the product also typically survives for a longer time both on exclusivity and also after exclusivity. So quite a balanced picture and if you ask me do I see any sort of changes lately in that expectation – not really. Maybe slightly less in Europe than I might have thought if you had asked me a couple of years ago when I wasn't here anyway. So that gets a bit theoretical. But we are very encouraged by the script development in the US and we are very encouraged about the reception in the European markets where we have got reimbursement. Then you asked a question about the US neurology business and of course you are absolutely right that right now we have a portfolio of specialty products in neurology and that the R&D focus we have going forward you could say is slightly differently focused – we do of course focus a lot on both Alzheimer's and Parkinson's and it is depending on how you characterise those diseases. You can say that we will hopefully still have a strong position in the neurology but I think I will leave it for Anders Gersel to comment on how our organisation sees it in the R&D space in the commercial space I think the US organisation is very excited about their future. They are also marketing Northera where we have exclusivity for a long period going forward so with the growth we have in the US everybody is busy and there is enough to do for everybody. But Anders, what about R&D?

0.44.26.8

Anders Gersel Pedersen

I think basically in the R&D space you need to look at it over time periods and if you look over the next 5-7 years it is clear that we will have most products focused on the psychiatry area save the Idalopirdine which is going into the – what we normally would consider the neurology – it depends a bit on which country and which market you actually are operating in. But if you go further into the pipeline then we certainly have a strong both Parkinson's and Alzheimer's pipeline moving forward and I think that the major difference is that we are not addressing these for specialty pharma type – orphan position products and one of the reasons for that is that from an internal development perspective the strategies for developing orphan products from scratch are quite costly and actually not necessarily much less costly than doing it for slightly broader molecules. We do see opportunities in all of these indications for choosing to develop molecules not perhaps for every patient with a broad indication but for segments of patients within these indications that are somewhat broader than being what you would call specialty product or orphan products but still some that are not necessarily just for a GP segment with an all commerce label. I hope that clarifies it a bit.

0.46.08.4

Martin Parkhøi

Yes fine, fine.

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0.46.14.2

Operator

The next question comes from Eleanor Fung from Goldman Sachs. Please go ahead.

0.46.18.4

Eleanor Fung

Hi, two questions remaining please. Firstly, just on the cost base I was wondering if you could comment on the pushes and pulls to the current SG&A underlying run rate as we think about the fourth quarter and first half, particularly around cost associated with your new launches. Secondly, just on US Rexulti I was wondering if we could also hear about any feedback you have had from physicians around the product and if you could remind us of the key marketing messages that you are able to push in the context of differentiating it against generic Abilify. Thank you.

0.46.53.0

Kåre Schultz

Thank you very much Eleanor. I believe I will take Anders Götzsche on the first question about the cost base and then I and Anders Gersel will cover the US Rexulti but first to you Anders on SG&A costs

0.47.06.1

Anders Gersel Pedersen

We never give specific guidance on the quarterly expectations but as I also said in the presentation we expect SG&A excluding restructuring to be around 50 % for the year, maybe a little less depending on how fast we do with our restructuring programme so that will more or less be in line with the SG&A margin we had last year.

0.47.38.9

Kåre Schultz

And then on US and Rexulti and feedback from physicians and experts. Well we have anecdotal evidence of course and it is very positive so we have statements from

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psychiatrists and doctors who have had very good experiences so far with Rexulti so that is very encouraging. The main thing to understand about Rexulti as an anti-psychotic is that you typically have two challenges with anti-psychotics – either they are too sedating in the sense that they sort of make you too drowsy or passive or because they are handling those symptoms or you get agitation because they are stimulating you too much and it is a balance between those two systems you could say which is the challenge for products like this and what we believe in layman's terms since I am not a scientist in layman's terms we think we have found the sweet spot between getting the right efficacy and avoiding the side effects of sedation and agitation. But I am sure Anders Gersel can give you a much more receptor-oriented explanation.

0.48.50.7

Anders Gersel Pedersen

Yeah, I am not sure I will get into too much receptor discussions here but mainly refer to the fact that first and foremost we are not particularly positioning it against Abilify as such. We are positioning the product in its own right which is that it has got a good efficacy profile combined with a very, very attractive safety and tolerability profile which is not something that anyone else has being Abilify, Selcro or any of the other molecules out there. And we can also see that both from the clinical trial part but also from the feedback we have had from physicians that they can actually see that they can give this to patients and reliably see the effect of the drug playing out without being intertwined with a lot of side effects that often the patients come back and complain about. And that is one of the reasons why we actually see physicians that have both been Abilify users but also users of other molecules they are actually very pleased with what they see using Rexulti because they can actually purely look upon the drug's efficacy side without having to worry too much about the side effect profile.

0.50.07.3

Eleanor Fung

Thank you.

Operator

As another reminder to register for a question please press 0 followed by the 1 on your telephone keypad. The next question comes from James Gordon from J.P. Morgan. Please go ahead. Your line is now open.

0.50.21.1

James Gordon

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Hello thanks for taking my question. Just a clarification on the restructuring. I understand the 3 billion target is unchanged for 2017 but if you are taking cost a bit more quickly could the roughly 1.5 billion for 2016 –could that prove conservative if you are going a bit ahead of plan already? And the other thing was can you give us runway of where we are for how much cost you have actually already taken out this quarter. I have seen the comment that you have taken 50 % of the headcount out already. Well I don't know if that is just at the very end of the quarter or earlier in the quarter will that really translate into the same amount of cost saving that will be available to collect there?

0.50.54.7

Kåre Schultz

Thank you very much, James. I will give you an overall answer then Anders can supplement. Overall, the plan we have is to take out the 3 billion. It is based on a detailed analysis of a lot of cost elements and a lot of elements of what is needed to drive the business on the new products. Keep the momentum there on all those new key products and making sure that our R&D pipeline can progress. We have not identified any new levers so our total plan is still for those 3 billion and with regard to the timing my assessment is that there is no change despite the fact that we are slightly ahead right now but the expert on that is of course Anders Götzsche.

0.51.42.5

Anders Götzsche

I think what is important to understand is that we announced the restructuring programme of taking out net position around 1,000 people. We did that mid-August. We executed by the end of August but not all of the 1,000 of course as Kåre also explained before you know – in totality we will be ending the process in all countries – it will be mid-next year so basically you have seen very limited impact from the restructuring so far because we basically executed by the end of August and the impact is in October and some of the positions or FTEs they are still working in the company and will be leaving by year-end so to see the full effect that will start by the end of 2015 and continue into 2016. So of course we will see an acceleration of the effect and some of the better cost improvement or the improvement we have seen in restructuring is of course that we have less positions, we are not hiring people at the same pace and all that kind of stuff that has kind of the effect securing that the cost programme is actually going a little better than planned.

0.53.00.8

Kåre Schultz

Thank you Anders

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So it seems that there are no more questions so I would like to thank you all very much for your interest in Lundbeck and thank you very much for all the good questions.