H. Lundbeck A/S

Teleconference Q3 2016

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Kåre Schultz, CEO
Anders Götzsche
Anders Gersel Pedersen

Operator
Ladies and Gentlemen, welcome to the H. Lundbeck Q3 report 2016. Today, I am pleased to present the president and CEO Kåre Schultz. For the first part of this call all participants will be in listen only mode and afterwards there will be a question and answer session. Speakers please begin.

Kåre Schultz
Thank you very much operator and thank you all for your interest in Lundbeck. Welcome to this Lundbeck teleconference covering our financial report for the third quarter of 2016 released this morning. With me I have our CFO Anders Götzsche and our head of R&D Anders Gersel Pedersen. On slide 2, you can see the company's disclaimer which I, as always, presume you have seen many times before and I will refrain from reading it out aloud so we will go directly to slide 3. We will elaborate on some of these items in a minute. But please allow me to summarise on the solid financial performance we have had through this quarter. Revenue grew 8 % in the third quarter hereby reaching close to DKK 4 billion and we are very satisfied with the development in the quarter. Now, 9 months into the year we have achieved a significant improvement in our profitability as well as growth in revenue. Our business is in such good shape that we again can increase our financial guidance for the year. We are raising our revenue guidance by DKK 700 million and our EBIT by DKK 600 million. Our key products have continued their strong growth and sales of these products have almost doubled in the 9-month period compared to the same period last year.

In general, all key products are performing nicely, but especially Northera and Rexulti are growing fast and are now among the largest selling products. In parallel with the sales growth we have managed to bring down our cost and have reached an EBIT margin of 14.9 %. This means that we are on the path to achieve our long-term target of an EBIT margin of 25 %.

Anders Gersel will revert with a pipeline update so let me just say that while I am obviously disappointed about the outcome of the first phase III study on Idalopirdine it is important for me to stress that our strategic planning has never been based on this programme being successful and our financial outlook remains the same for the years to come.

We are also able to add a new product to our neurology portfolio with the FDA approval of Carnexiv - a niche product which is expected to be launched early next year. Additionally, the US label for Rexulti has been strengthened by the recent approval to reflect clinical data from maintenance treatment of schizophrenia.

Please turn to slide 4. I would like to point out that we have a portfolio of mature but relatively stable products. And then we have a portfolio of key products which generate substantial growth. During the first 9 months of the year, we have realised revenue growth of 6 % despite the hand-back of Azilect to Teva and generic erosion of Xenazine in the US.

Again, it is the US operations that deliver most of the performance and foremost products like Onfi, Rexulti and Northera. The region is up33 % year-to-date and 32 % for the quarter and constitutes 54 % of our sales. It is also relevant here to mention that around half of the growth is driven by increased demand and if one excludes Xenazine where demand obviously is declining then demand actually drives around 75 % of the growth.

Please turn to slide 5. We continue to execute on our strategic growth platforms and we have seen continued significant sales increases in our key products. For the period the key products generated revenue of close to DKK 4.7 billion corresponding to 41 % of total revenue. In the third quarter key products are up 77 % reaching DKK 1.8 billion and constituting 45 % of total sales. We expect continued high growth for these products.

Please turn to slide 6. We will now look at key products individually and let us start with Rexulti. As you can see the significant uptake continues and the momentum looks solid and sustainable. The week-over-week growth continues to outpace the branded market in general and the uptake is strong relative to prior competitive anti-psychotic launches. Rexulti has so far achieved around 8 % branded total script market share and some 9 % branded new script market share. In terms of revenue, Rexulti achieved DKK 555 million in sales in this 9-month period, compared to DKK 58 million in the same period last year.

Rexulti has an attractive profile which is highly rated by the medical community. The message of the attractive profile on the drug is also supported by a DTC campaign that was initiated in the beginning of 2016.

Please turn to slide 7. Revenue for Brintellix or Trintellix as it is called in the US reached DKK 773 million in the 9-month period. Growth was primarily driven by the continued sales growth in the US which constitutes more than half of the sales. However, countries like Brazil, Canada, Italy and Spain are beginning to make valuable contributions to the total Brintellix revenue. In Spain and Italy, Brintellix has had an encouraging start with volume market shares of 0.5 and 1.1 %, respectively. In the US, Trintellix continues to demonstrate strong and consistent growth towards becoming the number one branded anti-depressant. The transition over the summer to the new name Trintellix has been successful with minimum disruption to patients and providers. Trintellix is continuing to grow within the branded anti-depressant segment achieving a 42 % market share amongst branded products in neutral brand prescriptions. Since the launch of the DTC in mid-July this year, Trintellix has become the branded leader in new therapy starts and continues to significantly separate from the other brands in terms of share of patients switching to a new brand. New prescription share continues to significantly lead overall share signalling strong continued in new patient starts, which will continue to increase overall Trintellix use.

This growth is in part also driven by favourable formula changes through the year. Growing market experience by psychiatrists and primary care physicians is strengthening the overall perception of Trintellix and helping to create a wider positive differentiation gap versus other therapies.

Please turn to slide 8. If we turn to Abilify Maintena, our long-acting anti-psychotic drug, this product is doing well in most if not all markets. The product still gains market shares and has approximately 13.5 % of the total atypical LAI market. The long-acting injectible market remains strong with double digit growth rates supported by a shift from oral to long-acting anti-psychotics as well as new product offerings.

Compared to the second quarter, the third quarter might look a little weak but we are confident that this is caused by quarterly fluctuations in both Europe and in the US. In the 9-month period, sales of Abilify Maintena grew 76 % and reached DKK 805 million.

Please turn to slide 9. Onfi just continues to impress. The product reached sales of close to DKK 1.8 billion following growth of 43 %. The main driver behind the growth continues to be increased demand.

Please turn to slide 10. Northera reached sales of DKK 774 million. Also for Northera, we continue to see increased demand, which again is driven by longer treatment durations and higher milligrams per patient.

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

0.08.36
Anders Gersel Pedersen
Thank you very much, Kåre. Please go to slide 11. FDA has recently approved the labelling of Rexulti to reflect the clinical data for maintenance treatment of schizophrenia. The approval was based on results from long-term randomized withdrawal trial in adults with schizophrenia. Additionally, the FDA has approved Carnexiv injection as a short-term replacement therapy for oral carbamazepine formulations in adults with certain seizure types when all administration is temporarily not feasible. Carnexiv has received orphan drug designation from the FDA for this indication and will be the first available intravenous formulation of the anti-epileptic drug Carbemazepine. Lundbeck plans to make Carnexiv commercially available in the US in early 2017.

Lundbeck has also announced headline results from the first clinical phase III study or Starshine in the ongoing phase III programme evaluating the effect or the efficacy of the investigational drug Idalopirdine for the symptomatic of patients with mild to moderate Alzheimer's. In the study, Idalopirdine failed to meet the efficacy endpoint and thereby replicate the encouraging phase II data that we have earlier reported on.

Regarding the FDA process around the sNDA on Trintellix, I do not have much additional information at this time. As you know, we received a complete response letter from the FDA in March following a very successful advisory committee meeting with an 8 to 2 vote in favour of including cognition data in our label. We are still working with the FDA to get this information included in our label and we expect feedback on this effort during the first quarter next year.

Additionally, we have finalised the phase II trial in ADHD in adults. Vortioxetine unfortunately failed to achieve significance in separating from placebo. The study was compromised by more than 30 % of patients having extremely low or no exposure to the drug. For patients with exposure to Vortioxetine a clear signal versus placebo was seen suggesting that the drug could be efficacious in this population. In spite of these setbacks it is my opinion that we have a solid pipeline which can generate solid value creation for the future. We have several life-cycle management projects which I expect to be able to elaborate more on in the upcoming quarters. We also have a maturing early stage pipeline which will generate new flows in the coming 12-18 months.

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

0.11.34
Anders Götzsche
Thank you very much, Anders. Please go to slide 12. As you can see from the slide in the third quarter revenue increased by 8 % and reached close to DKK 4 billion in revenue. The impact from Azilect hand-back and the loss of exclusivity were therefore more than mitigated by growth in the key products. Our EBIT reached DKK 589 million in the quarter and 1,541 million for the 9 month period and therefore improved substantially both looking at year-to-date and on the third quarter. The reason for the good result is partly driven by the top line performance and also partly driven by the positive effect from the restructuring programme. The successful execution of the restructuring programme is thereby already visible and best

illustrated by the reduction in the number of FTEs from more than 6,000 people to less than 5,000 people. The lowest level in more than 10 years.

The EBIT margin was significantly improved from last year and even so we prefer to look at reported numbers. It is worth adjusting for the third quarter last year - adjusting the third quarter last year for the impact from the restructuring programme and impairment and if you look at the core EBIT the margin improved from 11.9 % to 25 % and has therefore continued the positive development we have seen in the last few quarters as well. The effective tax for the third quarter is around 48 % and the reason for the higher tax rate compared to the Danish corporate tax rate is amortisation of Northera product rights which are not deductible for tax purposes and Lundbeck's increased profits in the US due to the fact that the corporate tax rate in the US is higher than the Danish tax rate and not fully offset by the tax loss realised last year in Denmark.

Please also let me repeat what I have said in previous quarters regarding our forecast for the tax rate and please be aware that it is very dependent on our geographical mix as well as our product mix. The reported tax rate is expected to be around 48 % in 2016 and around 40 % in 2017. The change in 2016 to 48 % is due to the increased earnings estimates for 2016 so we are lowering the expectation from 50 %. Going forward, the reported tax will continue to decline and by 2021 we will probably end up between 25 and 30 % impacted by the relatively high profit contribution by products held by Lundbeck US and by Northera product rights amortisation not deductible for tax purposes.

When you come beyond 2025, the long-term reported tax rate is expected to decline to a level between 23 and 25 %. It is important to note that there is a material difference to the cash tax which is somewhat lower being around 40 % in 2016 and 30 % in 2017 and it will decrease to a level around 25 % from 2018.

Please turn to slide 13. As you can see, all cost ratios have improved compared to the same period last year, also some of the cost items last year are impacted by the restructuring programme. Adjusting for these items, cost of sales has declined from around DKK 3.7 billion to around DKK 3 billion for the 9-month period and from DKK 1.2 billion to around DKK 900 million in the third quarter.

The sNDA cost has declined from DKK 5.1 billion to DKK 4.6 billion in the 9-month period or 8.6 % decline. In the third quarter, these costs were more or less unchanged. They were around DKK 1.5 billion. Finally, the R&D costs, as you can see from the slide have been impacted by an impairment charge on Idalopirdine in the third quarter this year. When looking at the cost ratios for the full year, we still expect our cost of sales to reach a level around 25 % and R&D is expected to stay around 20 % of revenue for the year. sNDA is likely to end the year at a percentage close to 40 % of the expected revenue.

If you flip to the next slide, slide 14, you can see our development in cash flow and it is obviously a reflection of our improved profitability that we have seen a very, very good cash flow. We can see improvement in the operational cash flow. We can see improvement in working capital and by having such a strong quarter we now expect that in 2016 we will finish - we will end 2016 with a net debt around zero.

If you go to slide 15, as a result of the good ... or the third quarter result we have upgraded our guidance for the year and you can see that we now expect DKK 15.3 to 15.7 billion in revenue and a reported EBIT of DKK 2.1-2.3 billion and that means that we would at least deliver an EBIT margin of 13 % for 2016.

I just went through the cost ratios and the tax ratio for 2016 and onwards and now the only thing to comment on is the net financial where we also expect to use a little less so the net loss for the year is expected to be around DKK 100-150 million for the year.

This outlook is of course based on unchanged exchange rate for the remaining part of the year and this concludes the financial presentation and now I would like to hand back to Kåre for the concluding remarks.

0.18.08
Kåre Schultz
Thank you Anders. With that I would like to thank you all for your interest and open up for the Q&A session. Over to you operator.

0.18.16
Operator
Thank you. Ladies and gentlemen, if you have a question for the speakers, please press 01 on your telephone keypad. And please hold until we have the first question. Our first question comes from the line of James Gordon from J.P. Morgan. Please go ahead. Your line is open.

0.18.38
James Gordon
Hello. Thanks for taking my question. My question will just be about the pipeline so no one thought Idalopirdine was a sure thing to definitely be positive but looking at the pipeline chart without Idalopirdine there is not that much in terms of late stage effort at the moment so only one NCA and that doesn't have data until 2019 and then the phase II you show hasn't been successful. So with the rest of the business doing so well from an operating perspective and you are having more cash could you actually look to do more in-licensing to build up the late stage pipeline or is it very much a plan you stick to only doing internal development?

0.19.10
Kåre Schultz
Thank you James for that good question. I will address it overall and then I will let Anders comment on the opportunities we see in the existing pipeline so we have a strategy where we have decided to go for a focused R&D strategy. As you know, we focus on Alzheimer's disease, Parkinson's disease, schizophrenia and depression and we are focusing on organic research and development which basically means that we want to develop our own products and the reason why we can do this and why we came up with that strategy is of course we have the competences to do it and we also have the time to do it because we are looking at a very strong portfolio of key products with a long duration of protection for Rexulti and for Brintellix and that basically means that the next 10 years we are seeing a positive outlook on our total business, which means that we can fund the organic R&D effort where we will of course in-licence early but where we have no plans of acquiring late-stage assets that are either very close to or at the market in some geographies but Anders please give some comments on where you see the excitement in the longer term in the pipeline.

0.20.21
Anders Gersel Pedersen
Yes we have as we have given comments on we have a number of projects both within the Alzheimer's and Parkinson's area that are maturing and going forward we expect to be able to take some of these projects and we have not yet decided fully which of them into further development at some time over the next 12-18 months and I think it is important that we spend the time to secure not only that we have a good molecule but also that we know exactly how to select the right patients and also to de-risk the approach that we go into these very significant projects with molecules in these areas. So we are making good progress in them and are not concerned at this moment about the lack of a phase II project as such and in some of the areas we will probably even bridge between some phase I/II projects and into phase III due to

the nature of the molecules that we are dealing with. So I think we have a good portfolio with good opportunities to actually replenish the pipeline when we think we need it.

0.21.36
Kåre Schultz
Thank you Anders

James Gordon
Thank you.

0.21.42
Operator
Our next question comes from the line of Michael Novod from Nordea Markets. Please go ahead. Your line is open.

0.21.48
Michael Novod
Yes, hello, it is Michael from Nordea. Just a few questions. If you look at Carnexiv that you are launching I know you don't give say sales or pre-sales potentials at least but what kind of say product category sales class are we looking at here in terms of sales over the next 3-5 years? Maybe you can elaborate a bit more where you see this is going. And then secondly on generic erosion of key products like Xenazine - it has been significantly lower than expected on the sales level. Is it the same thing we should see for Sabril and maybe you will also talk about Onfi and then also Northera so are we more looking at generic erosion rates of the 30-50 % per year than traditional rates of 80-90 % per year? And then lastly on the margin side. We have seen also these cost reductions feed faster into your P&L than expected so are you targeting perhaps not 25 % already in 2017 but say somewhere above the 20 % level?

0.22.58
Kåre Schultz
Thank you very much, Michael. We will try to address all your questions. I will cover the first two ones and then I will ask Anders Götzsche to cover the question on the margins, so if we look at Carnexiv then it is a niche product because it is for people who go into the hospital and have some situation where they use this anti-epileptic drug and they cannot take the tablet formulation and therefore they can use this IV formulation as part of being in the hospital so I would say it is clearly a niche product and talking about a niche product it is hard to say exactly how big it will be. We think we will benefit patients in that specific life situation but it is of course not a product that will have any general use for people with epilepsy so a niche product but I am sure that it will be also a product that will add to sales and profits but not in any magnitude similar to what we see with some of our other five key products.

Then if I jump to the very good question about generic erosion and what we have seen on Xenazine and what we can expect over the coming 5-10 years in terms of other products that go off patent. It is very, very hard to predict. I think what we have learned is that there are specific elements of importance to each generisation so to speak and a couple of the elements are what patient segment are you talking about, how many generic versions of the drug will be launched, how fast after it goes off patent and what are the sort of mechanisms mandated by the FDA sort of is there a REMS, is there not a REMS, how complicated is it to market the product? What are the support programmes that are normally in place in the market place for this segment so all these elements seem to play a role and we have been surprised that the generisation of Xenazine has been very rapid the first month - you remember August last year when it went off patent and we got generic competition, we had a very steep drop, then it sort of levelled off and now it has been sort of slowly eroding over the last 6-8 months so it is hard to say and we will have this discussion for quite

some years because next year at some point in time there is a risk that there will be generic competition for Sabril and my expectation is that we will have the same complicated discussion about exactly how fast is that going to go and we will be happy to share all our insights with all of you. But I think we will all find it a challenge to estimate it precisely and the reason why we cannot really do it is that we don't have full insight into how many generic companies are actually going to launch and at what time are they going to launch? So it is hard to predict also for the coming years. Anders will you address the margin question?

Anders Götzsche
Yes. We said last year that we would reach 25 % within 3-5 years and of course we can see that the pace that we are increasing our profitability with is going faster than anticipated so of course there is a higher likelihood now that we will reach the 25 % earlier than later so of course we could have an ambition to do it within 3-4 years from the original announcement instead of 5 years. That is definitely possible.

0.26.35
Michael Novod
Okay super. Thank you all.

0.26.41
Operator
Our next question comes from the line of Martin Parkhøi from Danske Bank. Please go ahead. Your line is open.

0.26.47
Martin Parkhøi
Yeah hello gentlemen. Just a couple of questions of a financial character. Firstly, now you are saying the net debt - you will be in a net debt position of around zero by the end of the year. Could you comment on what kind of war chest that you would actually like to have before you are starting to pay out all your excess liquidity to the shareholders? Then secondly I just have to understand a little bit on your guidance upgrade of the DKK 700 million that you upgrade sales by. Could you try to give some kind of ballpoint figures on the product category - which one has been - how much is from Xenazine and how much from Northera and the new key products. And then also with respect to the guidance you of course said you are upgrading your EBIT by DKK 600 million but of course excluding the write-down, then it is actually DKK 740 million you are upgrading by and that is more than sales so how much of the EBIT guidance is driven by lower costs and then a final question. I know, of course, things have changed since you gave your guidance in 2015 where you said your cost base will go down from 15 to 12, of course sales are much higher now so that really makes sense but if we just say where are we now? Because at that time you said we will be half the way in 2016 but where are we now? Are we half or are we more than half the way down the road?

0.28.22
Kåre Schultz
Thank you very much Martin. I think in order for Götzsche not having to answer all four questions I will cover the last first and then the first one and then Götzsche can cover the different questions on the upgrade. If we just take this thing about the famous DKK 3 billion then you are absolutely right that when we looked at this 1½ years ago we had basically a plan where we were going to sell 14 billion and spend 15 billion which would lead to a reported loss of 1 billion so that basically means that we had to cut the 15 billion in cost down to 12 billion and that is a 3 billion reduction of the total P&L - all cost in the P&L. In the meantime we have of course ended up in a situation where we are selling fortunately more than 14 billion this year and hopefully also more than 14 billion next year which means that you have to take the cost element of the additional sales and of course add on top of the 12 billion but if I should give you a best estimate of how much we are reaching this year then you are absolutely right we said probably around half

1½ years ago or a year ago. I would say now we are probably closer to two thirds so my guess would be this year on a comparable basis we are probably reaching around 2 billion and next year we will still on a comparable basis reach the 3 billion. So that was your last question.

Then the first question about net debt. It is correct that we will be net debt neutral at the end of the year and of course we need to have a discussion with the Board of Directors on what kind of war chest if any we think is necessary? What kind of payback policy do we foresee going forward? What do we see in terms of dividends? What do we see in terms of potential share buybacks? We have not concluded this discussion with our Board of Directors. We will bring out an updated set of communication and policies on this in connection with our full-year results in February so I have to get back to you on that but I will say that in general I am of course in favour of returning if not all then the majority of the cash flow generated to the shareholders but more specifically we will get back to you in February. And now over to you, Götzsche, for the two upgrade questions.

0.30.46
Anders Götzsche
Of course as we have stated in the release the reason for the upgrade is of course three elements. It is less decline on Xenazine and that is of course a major component and then it is going better than we actually anticipated for the key products so Onfi is going really well, Rexulti, Northera as you have seen also - very, very strong data for these and Trintellix is doing well in the US so that is one part and then we can just see that you know we are moving faster with the restructuring programme and taking more people out than anticipated also just reducing the capacity cost in general so it is these three components that have materialised and that is also why your conclusion that we have actually taken the underlying upgrade is of course higher than the revenue upgrade so you are fully right, it is a combination of all three elements. I think you had 6 or 7 questions Martin. Did we cover them?

0.32.00
Martin Parkhøi
Oh, I think you have covered all of them.

0.32.02
Anders Götzsche
That is great. You had 7 questions and we answered with three.

Martin Parkhøi
Thank you, that was great.

0.32.11
Operator
Our next question comes from the line of Trung Nguyen from Credit Suisse. Please go ahead. Your line is open.

0.32.14
Trung Nguyen
Hi, thanks for taking my questions. I have got three. The first one. Three thirds of your Rexulti US sales are in depression but you are only filing for schizophrenia in Europe - what is the reason for this? Is this simply down to price or between the core data you have in-house? My second question is on Northera. Very impressive sales this quarter. You mentioned duration could be an issue why this was better. Is there any other reasons why you think Northera did better this quarter than everyone's expectations? And finally on

Idalopirdine. Do you think you will consider during another study of this using a similar dosing regime from the phase II trial? Thanks very much.

Kåre Schultz
Thank you very much Trung for these three good questions. I will cover the first two and then ask Anders Gersel to cover the last one so you correctly state that in the US we see the majority or the bigger part of sales coming from MDD and the rest coming from schizophrenia and that our strategy in the US is to file in schizophrenia and the basis of this is a commercial analysis that we have done together with our partner Otsuka where we have been analysing the price points and the behaviour of the regulatory and reimbursement authorities in Europe and we had to conclude that the reimbursement authorities they set up their own independent ways of looking at things which are not aligned with the studies we do to provide EMA with clinical evidence of our drugs so we have concluded that the best way forward and the best price point which makes the most sense for us in terms of getting a positive commercial case on Rexulti in Europe is to file it in schizophrenia so this is a commercial decision we have taken and which we will follow up on and to be more practical about it the price point for anti-psychotics in Europe is in general significantly higher than the price point for anti-depressants.

If we then look at Northera, then you could say that overall it is just a positive volume story so we see higher volumes and that is most likely a combination of both the milligrams used per person, the number of persons using the product and also the duration of use so all in all a very positive story, a very positive development we are seeing right now.

And then the last question on Idalopirdine. Over to you, Anders.

0.34.47
Anders Gersel Pedersen
Yes, in terms of decision as to how to progress or if to progress with Idalopirdine is something that we obviously will look into when we get the remaining two studies. That is one thing. But we are also trying to understand further based on what we know today in terms of the exposure and some of the receptor profiling to try to get a better grip around why we got such negative results out of the just concluded Starshine study. And when we have finalised that review together with our partner Otsuka in this area we will make a decision on that but up until then we will assume that we are not progressing with it given the negative results we had of the first study.

Trung Nguyen
Thank you very much

Kåre Schultz
Thank you

0.35.41
Operator
Our next question comes from the line Peter Welford from Jefferies. Please go ahead. Your line is open.

0.35.48
Peter Welford
Thanks for taking my questions. I've got three left. Firstly just sticking with Northera a minute. I wonder whether we are seeing the average dose on drug beyond the 400 milligrams TID per patient that was seen in the long-term extension or whether or not that is to be the level to which we are trending to in commercial practice as well.

Secondly then, just on the DTC, for Brintellix in the US. Curious to know what sort of feedback you had from that in states where it is active and what potential could be seen from you - I guess on the ground efforts I mean in terms of the potential imposition practices, if any, based on that.

And then thirdly, given obviously the Idalopirdine setback and therefore you do have perhaps a little more flexibility in the OPEX line. Are there any plans now to accelerate 35700 and what potentially could be done with the extra flexibility now if you were to decide to invest in 35700 more? Thank you.

0.36.49
Kåre Schultz
Thank you very much Peter. I think again I will try and cover the first two questions and then I will ask Anders Gersel to cover the last question on Idalopirdine. So in terms of Northera, we don't have that specific data so we cannot really provide it to you because we don't know exactly. We have rough estimates of how many patients are on the product and we have rough estimates of how long they stay but we don't have like you know full data insight into this so therefore I cannot really say but only say that we are very sort of positive about the total inflow of patients and also the volume that we see in terms of demand in the marketplace. In terms of the DTC campaign on Brintellix which was started after the summer we see a very positive reaction in the marketplace so we can clearly see in the script data that the DTC campaign has a positive impact. It is, I would say, too early to sort of predict exactly the long-term effect of it but it is not too early to say that it definitely has a positive impact. The majority of it is television but there is of course also some online digital media where we promote the product so that is very positive. And then Anders on Idalopirdine.

0.38.08
Anders Gersel Pedersen
Yes actually the question was whether we would invest more in 35700 given that we have less to invest in Idalopirdine now. I think we are already investing quite significantly in 35700 and had that as our plan already. The most important thing for us here is not necessarily whether we can cut a quarter or two on the total programme but to optimise the programme for success. We are planning other studies while the ongoing phase III study is running to learn more about the molecule in particular populations and we will continue those things but we have not made any plans to start address large-scale studies earlier than we had planned before even if we financially could do that.

0.39.06
Kåre Schultz
Thank you Anders

0.39.11
Peter Welford
Okay thanks for taking that..if you have got good data on Northera on patients I guess would you be willing to share how many patients are currently held on Northera? Thank you.

0.39.22
Kåre Schultz
No normally we would not share that kind of granularity on the products and by the way we don't have the specific number either so but you are right even if we had it we would not share it - but we don't have it. Thank you.

0.39.34

Peter Welford
Okay thank you.

0.39.37
Operator
Our next question comes from the line of Olivia Capra from Barclays. Please go ahead. Your line is open.

0.39.44
Olivia Capra
Yes, hi, Olivia from Barclays. Thank you for taking my questions. I have got three please. Just firstly, you just related the desire to focus on organic and house pipeline development which makes sense If I can just come out from a different angle can you help us think about what would have to happen to make Lundbeck change the strategy and become more aggressive on late stage pipeline M&A and then secondly on pricing. In light of all your pricing concerns right now for the whole sector how much of your US portfolio is driven by volume and how much by price? And how should we think about this number going forward. And then I am just saying if the US pricing went to zero normally you have volume growth in this region. Do you think that would be enough to put your 25 % EBIT margin target at risk?

And then lasty, a financial question if I can. Looking at the key three cost of goods sold ex amortisation, ex royalty payaways assuming I did the math right it looks like it took a meaningful step down both in absolute and margin terms in the quarter. Is this part of your efficiency programme and should we expect this to continue going forward?

0.40.48
Kåre Schultz
Thank you, Olivia for these three good questions. I will address the first two ones and then ask Anders Götzsche to address the last one.

So you are absolutely right. We have a strategy where we do you could say in-house/organic R&D. Of course in collaboration with our partners and with early stage in-licensing, but we don't have any plans to acquire late stage assets or products that are already in the marketplace. And then your question is: What would have to happen for us to change this? And I don't really know, I don't think we will change it. I think we will stick to the strategy. I think we have proven over the years that we can innovate and that we have generated the world's three best anti-depressants in a row, Cipramil, Cipralex and Brintellix and that we can continue to do that so I am pretty confident in our organic R&D strategy and that is what we are going to pursue and I don't see any triggers that would change that in the foreseeable future.

Then if we jump to your second question which is about the pricing and what would happen in terms of our business if we were not to see any price increases in the US, then first of all I would say that our 25 % operating profit target is not based on any significant price increases in the US. So this we will reach no matter what happens in US presidential elections and in the US pricing scenarios. That being said it is also quite clear that this year if you look at our five key products the majority of growth is coming from volume. We should make no mistakes on that. We do have positive net pricing developments after list price, rebates, and so on we still see positive net prices but on our key products that is of a size where by far more than half of the growth is coming from actual volume increase, basically more patients going on Trintellix, more patients going on Rexulti, more patients going on Northera, on Onfi and so on and that you can also see if you follow the script data for these products. It is very clear if you look at the script for, for instance, Rexulti or Trintellix that the number of patients every week on average is going up and that is basically why we are growing so we will keep on growing no matter how the pricing scenario is going to end

up looking in the US. But then the last question on the cost of goods sold and those ratios. Over to you Anders

0.43.22
Anders Gersel Pedersen
We have seen a drop in the COX percentage in Q3 and you should also expect to see the same level in Q4 and it will also improve in 2017 but of course there will be fluctuations between the quarters so you cannot say that one quarter is the precise expectation for also the upcoming quarters but we have seen a shift in the level also compared to Q1 and Q2 and that is due to product mix that the key products are growing at a very, very good pace and they have a much higher profitability and that will also lead to a substantial improvement or a COX percentage next year.

0.44.12
Kåre Schultz
Thank you Anders

Olivia Carpa
Okay, thank you.

0.44.17
Operator
Our next question comes from the line of Carsten Lønborg Madsen from SEB. Please go ahead. Your line is open.

0.44.24
Carsten Lønborg Madsen
Yes, thank you very much. I just have a sort of a little bit about strategic or fundamental question to maybe Gersel. When you talk about this with the bridging phase I, II trials or phase II, III trials so essentially trying to skip a phase in the development of new products and we all know that CNS can be challenging. I would just like to hear your thoughts on whether or not you are not increasing risk here I mean sometimes doing a small phase I study can be a really good idea because it saves you a lot of money instead of going directly into a larger phase I, II trial so which type of products will you utilise this strategy on and which type of products will you not and how confident are you that you have some answers that fit this strategy and then secondly on sort of the tail products you can maybe call this for Cipralex - would you mind sharing some colour on Europe and ex-Europe - Europe seems to have stabilised around 200 million per quarter. Is there any dynamics in this number going forward or should we just more or less expect it to be stable here and maybe also the same outside Europe? Thanks

0.45.34
Kåre Schultz
Thank you very much Carsten. The first question goes to Anders Gersel and I will take the second question.

0.45.40
Anders Gersel
Yes, I think in terms of the strategy that would take you into not necessarily doing a phase II would obviously mean that you would do a more extensive phase I study but it could also be a typical scenario where your ultimate read-out for confidence in a - on a primary end point would be so long that it would have a negative impact on your overall development time and if you had sufficiently robust surrogate markers you would rely on then that would enable you to make some of these decisions at an earlier time point and you would not gain much by having completed a complete phase II study as an interim there so I

think from a complete end point perspective you are obviously right that you don't know if you have reached that in a phase II and then repeated that but on the other hand it could take you 4-5 years to do that and repeating it then you may want to increase your risk but doing it knowing that you have reached some very specific surrogate marker signals that you are actually looking at what you are aiming for

0.46.58
Carsten Lønborg Madsen
But are there any others that are more suitable for this than others? I am guessing Alzheimer's is maybe not the best place to do stuff like this.

0.47.06
Anders Gersel Pedersen
That could be areas within any US genitive area where you had sufficient strong markers that you would be looking at, yes, you could.

0.47.14
Kåre Schultz
Thank you, Anders. Then I will try and address the tail product question and what you are referring to is that of course there has been a dramatic reduction of sales of Cipralex and other off patent products. But then at a certain point in time it seems to sort of level off and that is attributable to the right in the EU. We do see sort of a levelling off. It does not mean that the products are not still declining - there will be a slow decline in the coming years but then you have to combine that with the fact that in countries such Japan where the product is still under protection and in China, we continue to see growth and there is this phenomenon that you take markets, emerging market like China, Brazil, Middle East and so on there is quite a big segment of the market that prefers to get the originator products and the reason is that people are often paying quite a lot out-of-pocket themselves and when they are going to pay for something they would like to know what they are buying and in some of these countries you will have 10-20-30 generic copies of a product like Cipralex and the customers will actually prefer to get the original product where they know the quality is right, the efficacy is right and that sorts of creates much longer tails than we probably have been used to in for instance the US marketplace and that is underpinning that our mature products as we call them are relatively stable also on a long-term basis.

0.48.47
Carsten Lønborg Madsen
Okay, thanks

0.48.48
Operator
Our next question comes from the line of Jacob Lademann from Carnegie. Please go ahead. Your line is open.

0.48.58
Jacob Lademann
Thank you. Two questions please. If you look at Abilify Maintena in the last couple of quarters you could actually see a lot of fluctuation as you say, but could this also be a result of increased competitive pressure and perhaps if you could say specifically how you see that developing in the future. That was the first question. The second question in terms of top line growth from a strategic perspective. You say that you are not really dependent on Idalopirdine post 2019 but could you then try to pencil out what you see are strategic growth drivers after that period? Thank you.

0.49.34
Kåre Schultz
Thank you, Jacob. I will try and handle both questions. If we look at Abilify Maintena then it is absolutely true we have seen some quarterly fluctuations and last quarter was relatively weaker than we would normally expect but it is primarily in the EU that we have some swings that are related to product movements and so on and then a little bit in the US. If we look at our market shares they are very, very steady and growing so if we look to the US we have steady growth in our market share, which you can also see if you get hold of any of the sort of IMS numbers, TRx, NRx and so on so we are not seeing any change in the competitive landscape in the third quarter that is affecting our US sales. It is more random swings and we are very confident that the strong growth we had year-to-date nine months will also be repeated in the 12-month result, basically meaning that we will also have progress in our sales in the fourth quarter of Abilify Maintena both in the US and in the rest of the world.

Then with regard to top line growth your question: What is going to drive the top line growth sort of beyond 2019 and it is of course a combination of you could say the mature portfolio staying relatively stable, a couple of products going off patent, phasing out and then strong continued growth of some other key products such as Rexulti and Brintellix which have a very long patent life in front of them so we are basically seeing that some of the products we have ourselves developed are taking over from other products where we have bought them in or where we are paying higher royalties that is replacing the turnover we are losing and in that combination we both see total growth in turnover and a significant improvement in profitability and that is what we expect will be the case also past 2019.

0.51.34
Carsten Lønborg Madsen
Thanks

Kåre Schultz
Thank you very much for all your questions. Are there any more?

0.51.40
Operator
There are no further questions at this time. Please go ahead.

Kåre Schultz
Thank you very much for listening in on this teleconference and thank you for your interest in Lundbeck. Goodbye.