Transcript

H. Lundbeck A/S

Transcript : Annual Report 2016

Operator

Hello and welcome to the H. Lundbeck Annual Report 2016 call. Today I am pleased to present President and CEO Kåre Schultz and for the first part of this call participants will be in listen-only mode and after this there will be a question and answer session. So please begin.

0.00.25

Kåre Schultz

Thank you very much operator. And thank you all for your interest in Lundbeck. Welcome to this Lundbeck teleconference call on our financial report for the full year 2016 released this morning. With me as usual I have our CFO Anders Götzsche and our Head of R&D, Anders Gersel Pedersen.

On slide 2, you can see the company's disclaimer which I presume you have seen many times before. I will refrain from reading it out loud 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 the year. Revenue grew 7% in 2016 thereby reaching close to DKK 16 billion. We have achieved a significant improvement in our profitability as well as growth in revenue and we are very satisfied with the development. Our key products have continued their strong growth and sales of these products have grown close to 80% in 2016. In general, all key products are performing nicely, but especially Northera and Rexulti are growing fast and all our key products are either exceeding or soon to exceed annual sales of more than DKK 1 billion. In parallel with the sales growth, we have managed to bring down our cost and have reached an EBIT margin of 14.7%. This means that we are on the path to achieve our long-term target of an EBIT margin of 25%. Our business is in such good shape that we now are in a positive net cash position. That is also the reason why we propose a dividend payout ratio at the high end of our policy and even feel confident raising the payout ratio further from 2017 and onwards.

Anders Gersel will revert with a pipeline update but let me just say that while I am obviously disappointed about the outcome of the phase 3 programme on Idalopirdine it was hardly surprising following the results from the first study announced in September last year. Again 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.

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Finally, we have provided our financial guidance for 2017 with continued growth on the top line and additional improvements in our profitability. Actually, 2017 is expected to provide Lundbeck with the highest sales level ever.

Please turn to slide 4. I think it is important to point out that we have a portfolio of mature and relatively stable products and we have a portfolio of key products which continue to generate substantial growth. During 2016, we realised revenue growth of 7% despite the handback of Azilect to Teva in Europe and generic erosion of Xenazine in the US. It is our US business that delivers most of our performance and foremost products like Onfi, Rexulti and Northera. The region is up 32% for the year and 31% for the quarter and constitutes 55% of our sales.

It is also relevant to mention here that around half of the growth in the US is driven by increased demand and if one excludes Xenazine where demand obviously is declining then demand actually drives more than 70% of the growth.

A second point to note is that now international markets are starting to grow again and it is my expectation that even Europe will stabilise and could even start showing modest growth, which would be a nice change.

Finally, I think it is worth mentioning the very strong improvement in our profitability and although recognising that 2016 was negatively impacted by the restructuring, you can see from the quarterly performance that we recognise a steady improvement.

Please turn to slide no. 5. We continue to execute on our strategic growth platforms and we have seen continued significant sales increases in our key products. In 2016, the key products generate revenue of DKK 6.5 billion corresponding to 42% of total revenue. We expect continued high growth for these products.

Please turn to slide 6. We will now look at our key products individually and let us start with Rexulti. As you can see the significant uptake continues and the momentum looks both solid and sustainable. The week/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 11% branded total script market share and some 12% branded new script market share.

In terms of revenue, Rexulti achieved DKK 826 million in sales in 2016, which represents growth of some 600% full year. Rexulti has an attractive profile which is highly rated by the medical community. The message of the attractive profile of the drug is also supported by a DTC campaign that was initiated in the beginning of 2016.

Additionally, we expect to see the first approvals outside the US during 2017, potentially starting with Canada followed by Australia. Additionally, we plan to file a product for schizophrenia in Europe and then we will hopefully be able to strengthen the profile of the product. Together with Otsuka we are conducting a pivotal programme in Alzheimer's agitation and we expect results during the first half of 2017.

Please turn to slide 7. Revenue from Brintellix/Trintellix reached DKK 1.1 billion in 2016 of which slightly more than half was generated in the US. However, countries like Brazil, Canada, Italy and Spain are beginning to make valuable contributions to the total Brintellix revenue. In Spain and Italy, Brintellix continues the encouraging start with volume shares exceeding 1%. In December last year, we were also able to launch it in France. In the US, Trintellix is continuing on a strong growth trajectory sustaining 42% market share amongst branded products in neutral brand prescriptions. Since the launch of the DTC in July, Trintellix has established its leadership in new therapy starts and share of patients switching to a new brand. New prescriptions share continues to significantly lead overall share signalling strong continued growth in new patient starts that will continue to increase overall Trintellix use. This growth is in part also driven by favourable formulary changes through the year. Over 70% of all anti-depressant prescriptions volume flow through commercial and Medicare Part D channels.

Trintellix coverage continues to strengthen and is supported by strong growth in patient and prescriber demand. Growing market experience by psychiatrists and primary care physicians is strengthening the overall perception of Trintellix and is 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 close to 14% of the total atypical LAI market.

The long-acting injectable 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.

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In 2016, sales of Abilify Maintena grew 67% and reached DKK 1,114 million of which 60% was generated outside the US.

Please turn to slide 9. Onfi reached sales of DKK 2.4 billion in 2016 following growth of 37%. Northera reached sales of DKK 1,087 million. Both products look a little weak in the fourth quarter due to quarterly fluctuations and potential seasonality in the use of Northera. For both products we expect to see continued increased demand.

Please turn to slide 10. Lundbeck's fundamentals are sound and the balance sheet is strong. Based on the strong expected cash flow generation in the coming years, Lundbeck will continue its stepped reduction and in parallel establish a strategic cash reserve of approximately one year's free cash flow.

Furthermore, Lundbeck revises its dividend policy communicated in February 2016 and increases the dividend payout ratio from the current 30-40% of net profits to 60-80% of net profits from 2017 and onwards.

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

0.10.12

Anders Gersel Pedersen

Thank you Kåre. Please go to slide no. 11. First a comment on Idolapirdine. Lundbeck and Otsuka have now finalised the two remaining studies in the pivotal programme. In line with the results seen in the Starshine study which we reported from in September last year, the efficacy profiles observed in these studies do unfortunately not demonstrate efficacy as observed in the first positive phase 2 study and hence do not support a regulatory submission.

Regarding the FDA process around the supplementary NDA on Trintellix I do not have much new information to add. As you know, we had a positive assessment by the Advisory Committee a year ago and then a complete response letter that we received from the FDA by March of that year.

Since then we have pursued the dialogue with the FDA but until we get a final response one should not speculate about the potential outcome because it is not a simple topic. We understand that we are treading new waters in terms of trying to get this into the label

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and even if we do feel that the data are very compelling and we see a reproducible effect on cognition in patients with major depressive disorders it is not an easy decision to reach with the FDA so we will just have to patient with those discussions with them.

Let us turn to slide 12. Abilify Maintena has demonstrated efficacy in the bipolar 1 disorder study. This study is the result of one that we initiated back in August 2012 together with Otsuka. We randomised patients over 52-week treatment against placebo or Abilify Maintena.

The data were presented at the ACNP in December 2016 and now also is available in the Journal of Clinical Psychiatry.

Poor adherence is a big problem and significantly limits treatment outcome for patients with bipolar disorder. Patients with bipolar 1 disorder can benefit from a long-acting injectible which may help provide longer-term stability in patients who have difficulty in taking their daily medication.

I will not go into detail with the data as they have been presented already but the study demonstrates that Ability delays time to recurrence of mood episodes in adult patients.

As a consequence, on November 16, Lundbeck and Otsuka announced that the supplementary NDA for the expanded label of Abilify Maintena for the maintenance treatment of bipolar 1 disorder have been accepted and that the FDA has set a target date on 28 July 2017 to complete this review.

Please go to slide no. 13. Lundbeck and Otsuka have recently initiated a phase-2 study with Rexulti in individuals with post-traumatic stress disorders. The study is expected to recruit around 330 patients and evaluate the efficacy of Rexulti as mono-therapy or as combination treatment with Sertralin also known as Zoloft in adult subjects with PTSD.

The selective serotonin reuptake inhibitors paroxetine and sertraline are currently approved for the treatment of PTSD by the FDA in the US. Response rates with SSRIs in PTSD are moderate and a few patients achieve remission. Consequently, there is a need for additional treatment options.

Rexulti has previously been studied as adjunctive treatment in subjects with PTSD who had an inadequate response to treatment with paroxetine or sertraline. The study was however terminated early due to challenges with patient eligibility. This study aims to evaluate whether Rexulti as mono-therapy or a combination treatment is more effective than Sertraline alone or placebo in relieving PTSD symptoms in non-newly diagnosed patients.

Please turn to slide no. 14. Lundbeck has been quite active in entering early-stage partnership in recent years and here we have a line-up of partnerships entered in 2016. It is a broad list of both technologies and data-oriented deals as well as a couple of out-licensing deals. This level of activity is likely to continue going forward.

This was all from my side and I will now hand over to Anders Götzsche to go through the financial performance.

0.15.16

Anders Götzsche

Thank you very much, Anders. Please go to slide 15. As you can see from the slide that in the fourth quarter we had an increase in revenue of 12% and reached close to DKK 4.2 billion in sales, the impact from Azilect handback and the loss of exclusivity was therefore more than mitigated by the growth in the key products and you can also see that our gross margin has improved substantially following the improved product mix with reduced royalties.

Furthermore, our EBIT reached DKK 751 million for the quarter and DKK 2.3 billion for the year and has therefore improved substantially, both looking at the quarter and for the year. This is partly driven by the top line performance and partly driven by the positive effect from the product mix and the restructuring programme.

The EBIT margin has therefore significantly improved from last year and even though we prefer to look at reported number it is worth adjusting 2015 for the impact from the restructuring programme and impairment. Looking at core EBIT, the margin has improved from 6% to 24% for the year but for the quarter the margin improved from 2% to 24%, which is very impressive.

Therefore, the positive development we have seen in the last quarters, we expect that to continue into 2017.

The effective tax for 2016 was around 44% compared to our previous expectation of 48%. The decline was caused by the increase in profit and by the reversal of valuation allowances on research and development credits arising from the acquisition of Northera and now acknowledged by the US authorities. The higher tax rate compared to the Danish corporate income tax rate is caused by amortisation of Northera product rights which are not deductible for tax purposes and Lundbeck's increased profit in the US at a higher tax rate so that is fully in line with what we have explained earlier. I also want to repeat what I have said last quarter regarding our forecast for the tax rate going forward into 2017 and onwards.

Please be aware that it is very dependent on our geographical mix as well as our product mix. If we start with the reported tax rate it is expected to be around 40% in 2017 and then it will further decline in the following years and by 2021 probably end up around 30% and beyond that we will go down to a long-term reported tax rate that is expected to be at a level around 23-25%.

If we look to the cash tax rates, it is somewhat lower. It is around 38% in 2016. We expect it to be around 30% in 2017 and 2018 and from 2019 the rate is actually expected to decrease to a level between 23 and 25 percentage points.

Please flip to the next slide. The very successful execution of the restructuring programme is best illustrated by the reduction in the number of FTEs from more than 6,000 people to less than 5,000, which is the lowest level ever for Lundbeck in 10 years.

Cost of sales has declined from around DKK 5.4 billion to around DKK 4 billion for the full year or from DKK 1.3 billion to DKK 1 billion in the fourth quarter.

SG&A cost has declined as well from DKK 7.9 billion to DKK 6.3 billion in 2016 or around 20%. In the fourth quarter, these costs were down some 15% to DKK 1.7 billion.

Please flip to the next slide. We ended 2016 with a positive net cash position of DKK 326 million. The strong improvement in our net cash of around DKK 2.5 billion is obviously a reflection of our improved cash flow mainly driven by our improved profit.

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Please flip to the next slide. Lundbeck returned into a positive net cash position at the end of 2016 and with this in mind we have proposed a dividend of DKK 2.45 for 2016, which is in the high end of our payout range. It is a priority to maintain a strong financial position including having an investment grade rating. This requires among other things a net debt/EBITDA ratio of less than 2. Going forward, we plan to repay the remaining debt we have on the balance sheet and to build a cash reserve corresponding to approximately one year's free cash flow.

By the end of 2017, we expect to have a net cash position of around DKK 2.5 – 3 billion and that is including repaying our debt in 2017.

Based on the strong cash flow we are generating and we expect to generate a very strong cash flow our intention is to raise the dividend payout from the existing policy, which is 30-40%, to a new policy, which is around 60-80% from 2017 and that will result in a higher dividend payout from 2018.

Please flip to the next slide. In 2017, we will likely be impacted by the loss of exclusivity on Sabril and we will see some continued generic erosion on Xenazine. However, with the expected continued growth for our key products, the outlook for 2017 indicates revenue in a range of DKK 16.3 to 17.1 billion.

We also expect to see a continued significant improvement in our profitability in 2017 and EBIT is expected to reach between DKK 3.4 and 3.8 billion for the year, which indicates a margin at at least 20%. For financial items, you should expect a net loss around DKK 50-100 million and with that it is concluding my presentation of the financials and I would like to hand back to Kåre for the concluding remarks.

0.22.13

Kåre Schultz

Thank you, Anders. We have listed our key priorities on the slide and they are hardly surprising but it is important to realise the full benefits of the restructuring programme and at the same time sustain the momentum we have for our key products. With that I would like to thank you all for your interest and open up for the Q&A session. Over to you operator.

0.22.35

Operator

Thank you very much. Ladies and gentlemen. If you wish to ask a question and you haven't already, simply press 0 and then 1 on your phone keypad now in order to enter the queue. And then after I announce you simply ask that question. And if you find your question has been answered before it is your turn to speak or wish to retract that question, just press 0 and then 2. And there will be a brief pause while questions are being registered.

We will now get Carsten Madsen at SEB. Please go ahead Carsten, your line is now open

0.23.20

Thanks a lot. Carsten Madsen, SEB, here. Two questions to start out with on Trintellix and this potential for getting the cognitive data recognised in the label. When we then also see in this release today that you had an ADHD study that failed to meet the end point and that is after all about attention and ability to focus. What does this mean for your ability to get cognitive data into the Trintellix label? And then if you could maybe talk a little bit more about top and low end of guidance. Is this another story like 2016 where Xenazine generic erosion did not really happen? Will that also be the case for 2017, for example for Sabril? Could this be the thing that leads you to getting to the top range of your guidance? Thanks

0.24.17

Kåre Schultz

Thank you very much for those questions, Carsten. I will hand the first one to Anders Gersel and then I will answer the second one myself. So Anders, over to you.

0.24.26

Anders Gersel

Yeah, thank you. It is quite correct that we had a proof of concept study in ADHD which was not successful in the primary end point that was concluded during the quarter. The details of that study are such that it does not support the overall view but the main driver of similar problems in the study of this kind is basically very, very poor compliance by patients in the study. It is a phenomenon that has been seen by others but was very significant in this study and we have measured it through plasma concentration so I think our own conclusion that it does not in any way counteract the viewpoint that the drug has the effects that we are asserting that it does in depressed patients. That is the first point. The second point is that I do not believe that this has any impact at all on the discussions

with the FDA because they both recognise the problem as a targeted indication within depression as we know by now and they also recognise the findings that we have had in depressed patients in the very, very large studies that we have been running in this area. so I don't think it will have any influence on these discussions at all.

0.25.51

Carsten Madsen

And then just in the release you also mention – you are very specific about getting data into the data section. Should we read this as a sign that you are now rather progressed in your discussions with the FDA compared to the results that you gave during 2016?

0.26.10

Anders Gersel

No that has been our strategy all along. There are some technical reasons as to why that is the case but we have done that from day 1 in our application with the FDA – looked for getting it into the clinical trial section, so – and we have had no discussion with the FDA on this over the past many, many months.

0.26.32

Carsten Madsen

Okay, thanks

0.26.34

Kåre Schultz

Thank you to Anders for those answers. Now, I will address your question, Carsten, on the top and low end of the guidance for the sales line and you are absolutely right that one of the key uncertainties for 2017 that is the erosion pattern for the continued erosion of Xenazine and it is the entry of generic competition for Sabril. We estimate that we will see further erosion of Xenazine and we estimate that we will see generic competition on Sabril and following that we will see erosion. However, it is very difficult for us to predict both the erosion curves of Xenazine and Sabril and the exact timing of the competition in the generic space with generic Sabril. So that is why we are giving a relatively wide range. On top of that there is of course the normal uncertainty on the mature products but they are relatively stable and have been so for a while and the growth rate of the five key products but they are also very stable in terms of their volume progress in the US and Europe so overall the key uncertainties are related to Xenazine and Sabril.

0.27.52

Carsten Madsen

Okay, thanks.

0.27.55

Operator

We now go to the line of Diana Na, J.P. Morgan. Please go ahead, your line is open

0.28.00

Diana Na

Hi, thanks for taking my questions. It is Diana Na from J.P. Morgan. I have two questions please. First, I am wondering if you have been approached by any more companies for sharing the Sabril advanced programme and consequently what does the guidance assume in terms of the number of generic competitors for Sabril in 2017? And then, secondly, in the case of a positive readout for Rexulti in Alzheimer's agitation how confident are you that you have the black box warning in elderly patients removed and if the warning is not removed is this likely to limit the commercial opportunity in this indication? Many thanks.

0.28.39

Kåre Schultz

Thank you, Diana. I will answer the first question and then I will leave it to Anders Gersel to answer the second question.

With regard to Sabril you are absolutely correct that there is a REMS programme which was modified last summer and we have been asked to make a shared REMS programme that can be shared by any generic manufacturer that achieves approval from FDA. To the best of our knowledge, there are two companies who have approached FDA but we do not know, of course, that for certain whether that is the correct number but our assumption right now is that during the coming year, we will probably see two generic launches of generic Sabril. Anders?

0.29.28

Anders Gersel Pedersen

And with respect to the black box warning I can tell you that the black box warning around antipsychotics for this area is a class labelling and therefore it normally means that the FDA does not take a particular stance on any given project, but basically has it as a general labelling for all drugs in this class. So our expectation is that this will not have an impact on the black box warning. It may seem ironic to you that at the same time as you can get an indication, you can have a black box warning around the use of such a molecule in this particular population but that is seen elsewhere also so I think a likely outcome that we have expected is that it will be with a black box warning with the indication and we don't think it will have a limiting impact on our promotability here.

0.30.22

Diana Na

Great, thank you very much.

0.30.26

Operator

We are now over to the line of Michael Novod of Nordea. Please go ahead, Michael, your line is now open.

0.30.32

Michael Novod

Yes hello it is Michael Novod from Nordea. Two questions, the first one being to Northera. Maybe you could walk us a bit through, say, the volatility or the seasonality in Northera? Also regarding the use of Northera in terms of stay time and dosing, just to understand sort of the volatility we see in that product's sales, Q/Q. And then the second thing regarding the cash carry you are going to have on the balance sheet. Have you changed anything regarding how you look at business development? Is it still smaller, say, potential pre-clinical or academia collaboration that you are after or are you also considering perhaps smaller build-up??? of early-stage biotech or perhaps profitable companies in small size? Thank you very much.

0.31.29

Kåre Schultz

Thank you Michael for those two questions. I think I will try and handle both of them. With regard to Northera, we do see seasonality pattern. It is not like we can give you a precise analysis of it because as you probably know, there is a limited number of patients on Northera, only a few thousand. But there seems to be the tendency that as the weather in North America is significantly colder in the winter than in the summer, that people are more active outdoors and seek more possibility of being mobile and getting outside in the summer half of the year. And since the drug works in the way that it avoids that you faint or you pass out and it therefore is some way of securing that people especially with Parkinson's have a chance of moving more freely around than otherwise possible. There seems to be this tendency of a higher growth rate so to see in the summer months. Underlying we have seen a very strong development since the launch of Northera. So if you take an MET number and do that math then you will see that there is a very strong momentum on the product. I personally think there is some kind of combination here where the weather does play some role but where we also see some random fluctuations based on the relatively low patient number there is on the product.

With regard to your second question on the cash carry on the balance sheet there is absolutely no change to our business development strategy. We have a focused strategy where we want to organically do the research and development of our products. That means that we are looking for early stage so pre-clinical or very, very early clinical assets that we can in-license and then we can develop worldwide. The reason for the cash carry is basically both operational and then to secure that we have some kind of freedom, should whatever situation arise and we have not changed the long-term objective of returning all the positive cash-flow we generate to the shareholders.

0.33.44

Michael Novod

Okay, thank you.

0.33.49

Operator

We are now open to the line of Trung Huynh of Credit Suisse. Please go ahead, your line is now open.

0.33.55

Trung Huynh

Hello, two questions from me, one on Brintellix and one on Sabril, first one for Brintellix we saw for 2016 Takeda net sales grew 6% Y/Y but the prescriptions were up 43%. Should

we expect another step-down in net price or is now price at an acceptable level so that prescription growth will feed into the net revenues? And secondly on Sabril, growth in Q4 was 20% higher than Q3. Is that a case of putting your rebates ahead of generics or is that seasonality or volume acceleration? Thanks very much.

0.34.33

Kåre Schultz

Thank you, Trung, for these two questions. I will try and answer both of them. With regard to Brintellix, we did see increased access in 2016 and we did also see a marginal increase in the absolute rebate level. We are expecting to see a more steady development in 2017 without any major changes in both access and rebate levels. With regard to Sabril, it is pure you could say random logistical swings between Q3 and Q4. So if you want to have, and we didn't do anything to sort of change rebates or do anything in order to incentivise anybody to do anything, so if you want to have a sort of picture of what is really going to be the next couple of months for Sabril, I recommend that you take the 12 months moving annual trend and use that because there is not the same kind of change in underlying demand as you see from the book sales.

0.35.38

Trung Huynh

Excellent. Very helpful. Thank you.

0.35.41

Operator

We are now over to the line of Sarah Thomas at Deutsche Bank. Please go ahead.

0.35.44

Sarah Thomas

Hi there, it's Sarah from Deutsche. A couple of questions, please, just firstly on your guidance, can I just clarify the upper hand is there a no-generics to Sabril this year? Would that get you to the top of your guidance range or would this be upside - and then just on post traumatic stress disorder trial could you remind us of the reasons why you abandoned this indication last time and what you are doing differently this time? Thank you.

0.36.09

Kåre Schultz

Thank you, Sarah. I will answer the guidance question and then Anders Gersel will take the PTSD. If we were to have absolutely no generic competition on Sabril in 2017 then we would be exceeding our guidance. So the guidance takes into consideration what we think is a realistic timing. For competitive reasons we will not reveal what we think this realistic timing is and we will not reveal exactly what curve of generic loss of business we are predicting. But we do include in our upper guidance that we will see generic competition on Sabril. And then Anders, will you answer the PTSD question?

0.36.49

Anders Gersel Pedersen

Yeah. The PTSD study that we stopped prematurely was simply because that the enrolment of patients was very, very difficult to do in the way that we had designed the protocol with a number of criteria. We got a number of patients willing to get into it but then as we tried to validate them to move into the programme, we lost virtually all of them so it was impossible with the design we had on that programme to actually get patients that were of the kind we wanted into the study. So we had no signal, no data, no anything that made us make this decision. It was simply a feasibility phenomenon that made us abandon the programme.

0.37.37

Sarah Thomas

Great, thank you.

0.37.40

Operator

We are now over to Peter Welford at Jefferies. Please go ahead.

0.37.43

Peter Welford

Hi yes thanks just a couple of quick ones. Firstly, just returning to the busy development in the cash point. I just sort of wonder, I guess, which is your harder strategy in the sense that you say you are trying to keep the investment grade status and net debt/EBITDA less than two times but also obviously the pay-out ratio is now up to 80%. So I guess if there is

an attractive opportunity that presents itself, how do you sort of assess that given the only one year of cash that you are planning to keep on the balance sheet long-term? And then just two points of clarification, firstly on the pipeline slide, the AF82422, I think it is called, is that the A2A that you have had for a while? And secondly then just on the repaying debt during the course of this year, I presume that excludes the mortgage and this is purely the bank debt that you are paying down during 2017? Thank you.

0.38.45

Kåre Schultz

I will answer your first question and then Anders Gersel will take the pipeline question and then Götzsche will take the debt repayment question. In terms of the business development strategy then as I said before it is totally unchanged and that means that we are not going for any sort of transforming acquisitions or M&As or anything like that and obviously if we were going for that then it would be debt ratios that would be far exceeding what we are discussing here. So what we are talking about is just the fact that we are going to be very cash generating the coming many years and we want to signal to the investors that we are not going to hoard that money, we are going to return the cash flow to the shareholders, that is why we are sort of doubling the level of the dividend pay-out ratio in our policy and that is also why we are explaining that we will create the necessary flexibility for the minor business development elements that we need to use for our organic R&D activities in the four therapeutic categories where we operate. So that is really how you should see it, that we are still going for organic R&D, we are going for returning all the cash to the shareholders, but we will have some strategic cash level that makes it easy for us to operate in the marketplace, also with minor business development activities. Then Anders, on the pipeline?

0.40.18

Anders Gersel Pedersen

Yeah, the AF82422 that you asked about is the programme which is an antibody programme that we have developed with the help of Genmab so it is an antibody that is targeting Parkinson patients or Lewy Body Dementia and is planned to go into man sometime in 2018.

0.40.47

Kåre Schultz

Thank you, Anders. And then Anders Götzsche, on mortgage debt?

0.40.52

Anders Götzsche

It is important to highlight that by the end of 2016 we have a mortgage debt of DKK 1.8 billion and we have a cash position of DKK 2.5 billion. That means we have a net cash position of DKK 300 million. So what we will repay is the mortgage debt in 2017 and so when we end 2017 we will have only a cash position and no debt. So we expect to have these DKK 2.5-3 billion in cash, that is how we expect 2017 to end.

0.41.35

Peter Welford

That is great. Thank you. I guess just to understand what the rationale I mean the mortgage debt seems to be at a pretty attractive rate so what is the rationale for paying down that debt given I think it is less than 1.5% even.

0.41.50

Anders Götzsche

Yeah but the rationale is that we will be very, we will have a strong cash generation for many years going forward and therefore there is basically no need to have these close to 2 billion on our balance sheet and paying the interest. We think it is more value creating to actually repay it and then say that we will keep close to one year of free cash flow and everything above that we will allocate that back to the shareholders.

0.42.23

Peter Welford

Okay, thank you.

0.42.29

Operator

Before we go to Marietta from Avenue, if anyone has got any further questions at this stage, please do press 0 and then 1 on your phone keypad now to enter the queue. And while waiting for any further questions, Marietta Miemietz from Primavenue, please go ahead to your question, your line is now open.

0.42.49

Marietta Miemietz

Yes good afternoon a few questions please, one on your Alzheimer's strategy. So your commitment to Alzheimer's as part of your four focus areas seems unchanged despite the Idalopirdine results but your disease modifying pipeline assets are fairly early stage, so how should we think about the medium term? Do you think you can maintain the relationships with the prescribers and run a profitable Alzheimer's business on symptomatic treatments including Brexpiprazole for extended periods of time? And I mean are you basically ruling out any acquisition of a mid-stage asset in Alzheimer's based on your previous comments? It would be great if you could confirm that please. Second question just on the dividend, I mean the upper end of your pay-out ratio really seems unusually generous in this industry and I guess it is partly explained by your business development approach but it would be great if you could help us think about a progressive dividend policy in that context which is really the norm in the industry and which I think you were also always expecting. So should we expect the pay-out ratio and maybe even the absolute dividend to fluctuate from year to year based on the opportunities available or are you actually committed to flat or rising absolute dividends year after year, despite the high pay-out ratio? And then just a very quick one, pushing my luck on Trintellix and the cognition claim. I appreciate that you can't really go into much detail but is it fair to conclude from the amount of time this is taking that a dedicated study with some sort of a new end-point on cognition is not off the table yet? Thank you very much.

0.44.34

Kåre Schultz

Thank you Marietta for those questions. If we take the first one then I will answer part of it and then I will ask Anders Gersel to elucidate on the projects we do have and then I will handle the dividend one and then we will let Anders Gersel handle the Trintellix question at the end. So on the Alzheimer's business we are totally dedicated to Alzheimer's through our whole Research & Development activities and through the products we have in the marketplace and we will continue to be so. We will not go out and acquire any late stage, mid-stage, already launched assets in order to get more activity in this area. So there is no change to our strategy. We believe that with what we have in our pipeline we can stay highly relevant for the specialists and the doctors in this field and we believe that we have good connections with the neurological field, both in research development and clinical practice worldwide. And we do have some very, very exciting products that are also creating this interest. Maybe Anders you could just briefly mention the products we have under development in Alzheimer's.

0.45.45

Anders Gersel Pedersen

Yes. First and foremost, we have a number of very different approaches to Alzheimer's disease modification, we have the base molecules which are targeting the synthetic pathway of the A beta toxic elements, then we have the Tau antibody programme which is targeting the Tau protein spindles and then finally we also have the vaccine programme which is also targeting the A beta molecule but clearing it from the brain. All of these are disease modification aspects but obviously clearly with an early symptomatic possibility in particular with potential with the Tau molecule. The interest that we have in this area is strong. We think there is a very good biological rationale and that has been confirmed also to some extent with the aducanumab data that came out early on in terms of the link between protein deposit changes, spinal fluid changes, symptomatology changes, we know it is a small study but that was the first time there is a very clear link between these three and also even if this (??? 0.47.03) data were not the best that were, there were some indications there was some link to the hypothesis there. So we think it works, we think it is a matter of getting the right patients and also finding the right time and the metrics to evaluate them by. This is going to take some time but I don't think it is going to help us to in-license something and I think particularly in the Alzheimer's area, mid-stage products are not really going to be relevant because we will probably move more rapidly from larger phase I with POC type endpoints in some of the patients to show that we have the target engagement and then go into phase III.

0.47.54

Kåre Schultz

Thank you Anders. On the dividend you could say we are moving from being sort of below the average of the industry to probably having a dividend policy that starts at the average and then goes slightly higher. It is clearly not our plan to have fluctuating levels of absolute dividends. It is our plan to have stable and increasing dividends so you should not see it such that we will sort of be fluctuating based on the specific year or a specific situation on any other parameters. So we are expecting to have a steady increasing business, steady increasing earnings and also steadily and stable increasing dividends over the coming years. Then on Trintellix, Anders maybe you can comment again on the discussions with the FDA and the changes of a dedicated study?

0.48.37

Anders Gersel Pedersen

Yes, I think there is nothing specific on the table or off the table. We are negotiating with the FDA based on the filings that we have already made and we have gone into some discussions and re-analysis based on our own views and learning also a request from the FDA and that is what they are looking at at this stage, to see if they will follow the

recommendations of the advisory committee based on some of those further analyses and understandings there. We have not been into any discussions at all as to the appropriateness or likelihood of any subsequent studies that have to be done.

0.49.18

Kåre Schultz

Thank you Anders.

0.49.20

Marietta

Okay, it is very clear, thank you very much.

0.49.23

Operator

Okay we now go to the line of Peter Sehested at Handelsbanken, please go ahead Peter, your line is now open.

0.49.29

Peter Sehested

Thank you it is Peter from Handelsbanken I thank you for taking my questions. I have two, one for Anders Gersel, I think we are looking at the base readouts in Alzheimer's I think the first one later this year. Would you consider a negative outcome of that to be a class effect? And then a question for Kåre or whoever might want to answer this. You have delivered a string of earnings surprises, the market typically likes that but and then there is of course a clientele of the market which likes dividend so they will be happy with your dividend but those who also want a bit of share price appreciation they would sort of look at the potential for surprises coming out of Lundbeck over the next couple of years. So Kåre could you just elaborate a little bit on what you see as potential for the top line potential relating to current consensus numbers and also in terms of the bottom line? Are you completely finished with your programme or is there any potential for more? So sort of a bit you know candies for those in the investment community who actually like to see some share price appreciation based on potential upside to what is expected in the market right now. Thank you very much.

0.50.40

Kåre Schultz

So Anders will you handle the base question?

0.50.42

Anders Gersel Pedersen

Yes, first and foremost I think the studies that are ongoing in this area are so complex and so huge so it is very difficult to give you a yes or a no in this area. I think it depends a lot on what you see. First you also have to recognise that base molecules are not identical so it depends quite a bit on what exactly we see from even a negative study or a positive study but we cannot draw exact conclusions from one base molecule to another because they may have different strengths on different sub-units of the receptor there.

0.51.25

Kåre Schultz

With regards to the share price then as a CEO you should never speculate on that. We can conclude of course based on facts that it has probably roughly doubled within the last 12 months so at least that has been some fun for those people who are looking for growth in the share price. With regard to the coming year you could also say where are the key sort of uncertainties where there can be a positive or a negative outcome and we have discussed a couple of them already. There is the ongoing discussion with FDA on the Trintellix label for cognition. It will not have a huge impact on the earnings of this year but of course long term it could have a positive effect if we do get it, probably no real negative effect if we don't get it. In terms of Rexulti, then the results of the agitation in the Alzheimer's study also will not have a dramatic effect this year but of course it could have a significant effect on the long-term upside for Rexulti, in terms of Abilify Maintena and bipolar indication then I guess it is somewhat anticipated that it will get approved because the data is really good so you could say it would be positive if it gets approved, negative if it doesn't So I think the sort of swing factors are more related to these specific events, given that I feel we have a really good plan for our cost which we have well focused under control. We have really good momentum on our five key products so you could say the things I just mentioned combined with the uncertainty of when and how competition will be there on Sabril is probably the things that will have sort of the biggest development impacts this year. And then of course at the end of the year we would love to see Azilect and Brintellix get approved in China but again that will be a longer-term financial impact, not short term. Thank you.

Transcript

0.53.23

Peter Sehested

Thank you.

0.53.35

Operator

We are now back to Carsten at SEB, please go ahead, your line is open again.

0.53.28

Carsten Lønborg Madsen

Thanks. Carsten Madsen. Thanks for my follow-up question here on the US depression market. With Trintellix and Rexulti, you now in total have 45% of the branded market so it also seems that you need to expand the market a lot and I know you will probably say that there is a lot of patients to take from so it is definitely possible to do but could you just try to highlight some initiatives that you could do with Lundbeck Inc. in order to sort of further accelerate the size of the branded market and on top of that maybe also talk a little bit about Trintellix during 2016 where at least when you look at prescription data you accelerated your year growth during the year? Thanks.

0.54.13

Kåre Schultz

Thank you for that question, Carsten. Yeah what we are talking about here is that the antidepressant market in the US is huge, there are millions of users every day and that 98% of the market is generics. But you have to see it this way that it is not generics necessarily as seen from the prescription point of view because the doctors are actually writing the brand names so doctors are still writing script for Lexapro but when the script gets to the pharmacy then because the product has gone generic the script gets filled with a generic. So in the mind of doctors it is the perception of which products that are efficacious, safe and relevant for their patients. Now in the minds of payers it is often trying to get the cheapest therapy possible and therefore they will make as many blocks as they can on new and better therapies. Trintellix is in my opinion the world's best antidepressant and right now it has 0.6% volume share in the US antidepressant market. Now I think there are two reasons why it doesn't have more than 0.6%. One reason is that the interaction with physicians has been reduced because we are all in strict compliance and that means that we interact less frequently than we did 20 years ago with physicians so that means the dissemination of the clinical information happens slower and the other element is that payers are making more restrictions step edits, co-pays and so on trying to delay the use of new and innovated medicines in the antidepressant field. However, it is

hard to argue against the fact that the clinical effect from Trintellix is extremely good and that means when people get on the product, when doctors get experience with the product, we do see accumulation of sales, accumulation of patients and increased prescription levels. And in the second half of last year we also started a DTC campaign with TV advertising to make people aware of this better treatment option. And that is potentially why we are seeing this quite strong dynamics on the TRx in the last part of 2016. So my expectation is that we will see very long and continued growth in the volume share of Trintellix. Exactly the end point is hard to predict but I do expect the product to keep on growing basically all the way up until loss of exclusivity. So I hope that explains it. Thank you.

0.56.50

Carsten Lønborg Madsen

It does. Thanks.

0.56.55

Operator

Okay as there are currently no further questions, gentlemen may I please pass it back to you for any closing comments.

0.57.03

Kåre Schultz

And here from Valby we would just like to thank you all for dialling in and listening to what we had to say and thank you for all your good questions. Goodbye.