H. Lundbeck A/S

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Operator

Ladies and Gentlemen, welcome to the Lundbeck financial statements for the first 6 months of 2018. For the first part of this call, all participants will be in a listen-only mode and afterwards there will be a question and answer session. Today, I am pleased to present Anders Götzsche Interim CEO and Executive Vice President, CFO and Anders Gersel Petersen, Executive Vice President, Research & Development. Speakers, please begin.

0.00.25

Anders Götzsche

Thank you very much operator and thank you all for your interest in Lundbeck and welcome to this Lundbeck teleconference covering our financial report for the first half of 2018. Together with me, I have our head of R&D, Anders Gersel Petersen, and to help me with the Q&A session I have also invited Peter Anastasiou, Executive Vice President of North America, and Jacob Tolstrup, Executive Vice President, Commercial Operations.

On slide 2, you can see the company's disclaimer which I presume you have read many times before and I will refrain from reading it out loud so I will go directly to slide 3. In the first six months of the year, we have seen continued, significant improvements in our overall profitability as well as shown solid growth in revenue in spite of the headwinds from exchange rate and generic erosion. We are therefore very satisfied with the progress of our operational performance. Revenue grew 9% in the period thereby reaching DKK 9.3 billion. Remember that similar to the first quarter also the second quarter has had some shipments that are positively impacting our results, especially to China on Lexapro. The six-month period is slightly some DKK 150 million better from that perspective. Our key products continued their strong growth and reported sales of these products have grown 21%.

In order for all of you to better assess our operational performance, we have split out the effect from hedging into a separate line instead of making a distribution or allocation to the individual products.

As the US dollar has declined since last year, we recognised a gain of DKK 277 million in hedging impact. In parallel with the sales growth, we have managed to bring down our costs and reported EBIT increased by 46% reaching a bit more than DKK 3 billion and the reported EBIT margin reached 32.4%. However, bear in mind that the hedging gain has a positive impact on the margin and there have also been some quarterly fluctuations in some of our costs and then on top of that we have also had DKK 165 million in non-recurring costs recognised under other operating items net.

As our tax rate is continuing to decline following the impact from the US tax reform, we have seen very strong growth in earnings per share of 83%.

In a minute, Anders Gersel Petersen will revert with a pipeline update, but just let me say that we are really happy with the progress in our development and registration work. It is important for me to note that the R&D effort not only should inventing and developing new molecules but also life-cycle management initiatives to intensify new additional growth opportunities for the existing molecules.

Please turn to slide 4. It is important to continue to point out that we have a portfolio of mature products and relatively stable products and we also have a portfolio of key brands which continue to generate substantial growth.

We continue to execute on our strategic growth platforms and we have seen a continued significant sales increase in our key products. In the first six months of 2018, our key products realised revenue growth of 33% in local currency, which is very satisfactory and all key brands have had double-digit growth numbers.

Sabril and Xenazine are down 34% combined foreign generic competition. Here some 3 years after the first generic versions of Xenazine were introduced, Lundbeck still has around 15% of the market in volume. Regarding Sabril, the generic versions have taken some 35% of the volume and it looks relatively stable. In local currency, all three regions are growing and are developing in line with expectations.

Please turn to slide 5. Our North American region is continuing the solid performance by growing 14% in local currency. It is still our key brands which drive the growth for the region. For the full year 2018 North America is expected to continue growing in local currency despite the expected negative effect from loss of exclusivity on Onfi in the fourth quarter.

Please turn to slide 6. International markets, which include our emerging markets business but also countries such as Japan, South Korea and Australia, increased 11% in local currency for the period and constitute 22% of our total revenue base.

This region is still early in the launch of our key products, which constitutes 14% of total revenue for the region. We expect to see significant long-term growth for these products in the region. In China, we recently launched Azilect and Brintellix. However, please note that especially China has been positively impacted by the major shipments in the first half of this year and we will see some destocking of Lexapro in the coming quarters.

Please turn to slide 7. Europe has seen a nice turn-around. It is now growing by 6% to DKK 1.5 billion, driven by the key products which now constitute 42% of sales. The key markets for Lundbeck in Europe are France, Italy and Spain which constitute around 43% of sales in the region.

Rexulti has been formally approved for schizophrenia in Europe, including Switzerland, and we expect to start launching in the first half of 2019.

Please turn to slide 8. Revenue from Brintellix, Trintellix reached DKK 999 million in the period of which 44% was generated in North America. However, countries in both Europe and in international markets also made valuable contributions to the total Brintellix revenue. In the three large European markets, France, Italy and Spain, we see volume market share getting close to or exceeding 2% and the value shares in the 5-6% range and with continued strong momentum.

We also see a solid performance in countries such as South Korea and Canada and then it has been recently launched in China. In the US, Trintellix has a volume share of 0.7% and a value share of close to 17% and both are still increasing.

Trintellix is continuing to grow significantly four years post approval reflecting strong appreciation of the value of that product. What that product provides in helping to address unmet needs for the patients with depression. I see a possibility for further upsides, especially following the revised labelling we received in the US earlier in 2018. A label that we expect to be further strengthened in October where we have a PDUFA date on a supplement NDA that we have submitted to include data on treatment-emergent sexual dysfunctions in patients with depression.

Please turn to slide 9. Rexulti is still mainly a US franchise and outside North America we have only launched in Australia. As you can see from the graph on the right side, the significant uptake continues and the momentum looks good in terms of revenue. Rexulti achieved DKK 752 million in sales for the period, which represents growth of 44% in local currencies and 28% reported.

We continue to have high expectations for this product, as Rexulti has an attractive profile which is highly rated by the medical community. The w/w growth continues to outpace the branded market in general and uptake is strong relative to prior competitive antipsychotic product launches. The value market share exceeds 11%.

We have received Rexulti approval in Saudi Arabia in both indications and will soon start launching the product followed by launches in Europe, South Africa and Mexico in the upcoming quarters.

Please turn to slide 10. Abilify grew 16% to DKK 771 million primarily driven by Europe but we also see good growth in other regions. Abilify Maintena's volume share now exceeds 20% in most markets and is continuing to gain market share.

In the US, we have seen a positive effect from the approval of bipolar disorder last year and the volume share has reached 18%. Based on net sales, it seems that the LAI market has picked up somewhat compared to last year as the Y/Y growth now is around 13%.

Please turn to slide 11. We are pleased with the performance of these two products. Northera grew 16% to DKK 849 million for the period but in local currency the growth reached 30%. Onfi grew impressively 19% to DKK 1,762 million and in local currency reached 34% in its last year of exclusivity.

Please note that we expect introductions of generic clobazam in the fourth quarter and therefore we expect sales in that specific quarter to be 40-50% lower than we have seen in prior quarters in 2018.

Please to slide 12. Now I will turn to our performance of some of the financial measures. Cost of sales declined with 13% to DKK 1,711 million while at the same time growing the top line by 9%. Our gross margin has therefore improved following the change in product mix which reduced royalties and lower amortisation thereby reaching 81.6% for this period compared to 76.9% for the same period last year.

For the year, we expect that the gross margin will reach a level of 80-82%. The gross margin is expected to improve further in the coming years. The SG&A cost decreased from DKK 3.2 billion to 2.9 billion, which is a decline of close to 10% compared to growth of the top line of 9%. The SG&A ratio for the period was 31.6% compared to 38.1% the year before.

Please remember that the SG&A ratio for the full year 2018 is expected to improve compared to 2017, but we expect the level to be around 33-35% for the full year.

R&D costs increased by 16% to DKK 1.5 billion representing 15.8% of revenue. We expect the R&D ratio to increase to a level around 16-17% for the full year 2018.

Based on cost ratios, the EBIT margin has improved significantly from last. The margin improved from 24.3% to 32.4%. It is relevant to note that the first half year of 2018 has been impacted by the addition of shipments in international markets as well as non-recurrent items recognised in the line Other operating items, net.

In the first quarter, we recognised a gain from divestment of properties of 48 million. In the second quarter we had a gain of DKK 121 million from settlements in Australia as well as costs of DKK 334 million from the settlement with the Department of Justice in the US.

Next slide, please. Clearly the negative development in our main currencies is impacting our revenue performance, especially for North American and international markets. That is being visible in the table at the right side. In local currencies, we see solid growth in all regions and strong growth for our key products. The effective tax rate continues to decline and as a result we have seen strong growth in our net profit and subsequently our earnings per share which have grown by 84% and 83%, respectively.

Next slide please. Lundbeck continues to generate a very strong cash flow. Cash flow from operations has increased by 176% to DKK 3.3 billion. Net cash flow is impacted by the acquisition of Prexton in March and the increased dividend pay-out recognised in the first quarter. Our net cash flow reached DKK 416 million compared to an outflow of DKK 724 million last year.

We expect the net cash position to be between DKK 5 and 5.5 billion by the end of 2018, which is unchanged from the expectation we had in the last quarterly update.

Next slide please. We have had a very good start of the year and we expect continued growth for all our key products and the growth in all three regions in local currencies for the year will also continue. Additionally, we assume that 2018 will be impacted by the introduction of generic versions of Onfi and Sabril later in the year and the continued generic erosion for Xenazine.

However, we do see room for narrowing the guidance range. Therefore, the outlook for the 2018 revenue is now expected to reach DKK 17.6 – 18 billion versus previously a range of DKK 17.2 – 18 billion. We expect to see continued improvement in our profitability in 2018 and EBIT is now expected to be between DKK 4.9 and 5.2 billion compared to previously DKK 4.8 – 5.2 billion for the year, which indicates a margin of at least 27%.

For financial items, you should still expect a net amount of +/- DKK 50 million depending on the currency development. The reported tax rate is expected to be around 26-28% in 2019, which also will be the range in the foreseeable future. It is important to note that the cash tax rate is somewhat lower and we expect it to be around 20% and with that I will now hand over to Anders Gersel Petersen to go through the latest update from our R&D pipeline, so please Anders.

0.16.55

Anders Gersel Petersen

Thank you very much, Anders, and please go to slide no. 16. Firstly, I will say that I am very pleased that in the last 3-4 months we have been able to move 3 projects in the clinical testing within our core areas. We have also added Foliglurax to the phase 2 pipeline and see continued progression in other areas of the pipeline.

Additionally, we have a so far undisclosed internal project which is getting phase 2 ready and which I expect to be able to disclose more on in the coming quarterly updates. In June, Lundbeck and Takeda announced very positive results from the pivotal study with Vortioxetine in adults with major depressive disorders conducted in Japan.

Both companies intend to move forward with regulatory filing of Vortioxetine later this year to the Ministry of Health, Labour and Welfare in Japan. The clinical phase 3 placebo control study in MDD enrolled approximately 490 patients with recurrent MDD who were randomised to receive Vortioxetine, 10 or 20 mg or placebo. The primary end point was the change from baseline that is the start of double blinding treatment in the

Montgomery - Åsberg Depression Rating Scale (The MADRS Scale) total score after 8 weeks of treatment.

We continue the effort of getting across external innovation to support our own projects to get additional assets as well.

Next slide please. We have finished enrolling patients in the first pivotal study DAYBREAK on 35700. In the programme of 35700, we expect to be able to announce the first headline results in the second half of 2018. 35700 is an antagonist at dopaminergic, serotonergic, and α adrenergic receptors in clinical development for treatment resistant schizophrenia.

Unlike all currently available antipsychotics, 35700 has higher affinity for the human dopamine D1 receptor than it has for the human D2 receptor. This is hypothesised to result in a beneficial efficacy profile and a tolerability profile without the troublesome side effect associated with extensive dopamine D2 receptor blockade such as extra perennial symptoms.

Treatment-resistant schizophrenia is broadly defined in clinical guidelines as lack of response in target schizophrenia symptoms following treatment with more than 2 anti-psychotics. Treatment of adequate growth duration and of adequate medication also.

About one third of patients with schizophrenia have TRS with persistent core positive symptoms of at least moderate severity despite treatment with antipsychotics. TRS is among the most highly disabling psychiatric disorder with the greatest impairment in the patient's community functioning and psycho-social adjustment. TRS is associated with a pure prognosis and functional outcomes and individuals with TRS are at increased risk of hospitalisation, unemployment, homelessness, aggression, imprisonment and substance abuse. And finally also suicide.

As such, they constitute by far the highest cost factor among schizophrenic patients. Patients with TRS are today only reluctantly and very late offered treatment with clozapine as the only medication approved for TRS. This is because of the serious safety concerns and monitory needs associated with the use of this drug.

Please turn to slide 18. As you might remember we and Otsuka have a very broad life-cycle management programme ongoing for Brexpiprazole in various indications. Lundbeck

and Otsuka commenced a third clinical phase 3 study of Brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer type in June.

Approximately 300 patients are expected to be enrolled in the trial. The decision to initiate a third trial follows discussions with the US Food and Drug Administration, the FDA, regarding two phase 3 clinical trials for the agitation indication that were completed by Otsuka and Lundbeck in 2017. Results for the two completed trials were announced in May of last year and presented in poster sessions at the American Association for Geriatric Psychiatry's annual meeting in March of this year.

Additionally, it is my expectation that we can report headline results from phase 2 studies using Brexpiprazole in PTSD and results from the pivotal programme in bipolar mania during the first quarter of 2019. Especially the latter is interesting provided a positive outcome and subsequent approval as Brexpiprazole then will have the three pillars of psychiatric treatment, namely depression, schizophrenia and bipolar disorder, which represents a very strong product profile.

Next slide please. Lu AF20513 is an active anti-Abeta vaccine candidate against Alzheimer's disease. It is designed towards optimal immuno-genetic response in the elderly based on the hypothesis that cognitive function will be preserved through the early inhibition of Amyloid Abeta depositions in the brain.

Based on what we know about this project at this point in time, I am quite confident that we can start the proof of concept study in the first half of 2019.

Next slide please. Foliglurax was acquired by us in March of this year. Let me add a few comments on that. By acquiring Foliglurax, Lundbeck has obtained global rights of an attractive compound which currently is in clinical phase 2 testing for symptom treatment of off time reduction in Parkinson's disease and Dyskinesia including Levadopa-Induced Dyskinesia.

The first data from the ongoing clinical phase 2 programme is expected to be available during the third quarter of 2019, which is slightly later compared to previous announcement due to so much lower enrolment.

Next slide please. Just to conclude, we expect to have an interesting and hopefully positive news flow in the next 12 months or so and I feel confident that in that period we should

be able to establish better understanding and approved perception around our pipeline. With that I will hand back to Anders for concluding remarks.

0.24.04

Anders Götzsche

Thank you very much, Anders. And with that I would like to thank you all for your interest and we will open for the Q&A session. Please, operator.

0.24.13

Operator

Thank you. Ladies and gentlemen, if you have a question for us, please press 01 on your telephone keypad now so once again that is 01 on your telephone keypad if you have any questions. And our first question comes from Trung Huynh from Credit Suisse. Please go ahead, your line is now open.

0.24.37

Trung Huynh

Hi guys. Thanks for taking my questions. I have 3 if I may. Firstly, you are continuing to take out SG&A costs quite effectively. Can you let us know which areas you are doing this in and do you still – can you continue to effectively promote your products after you have given this lower SG&A investment? Secondly, in your outlook, you cautioned for increased stocking in the second half of the year. Could you let us know which products this could impact? And the magnitude of impact? And then finally, you note you commenced the third Alzheimer's agitation trial with Rexulti. Can you comment on the trial design and where the patients are based and your time and expectations? Thanks very much.

0.25.26

Anders Götzsche

First to you one, and then I hope that Anders Gersel can help me with the agitation. The SG&A cost, it is right that we have continued to lower the cost base but what we have also guided you guys about is that you should expect that it will over the upcoming years stay pretty stable and what we for the time being with our commercial folks looking very much into is the pockets of opportunities to create even more growth and that might lead to us hiring some reps in some different geographies with a change in our SG&A outlook? No, but you should not expect us to continue to drive down growth because you can see that all our key products actually have double-digit growth numbers and therefore of course

we want to continue to invest and it also comes along the lines that we have two newly approved products in China where we will invest in getting both Brintellix and Azilect being market leader as we have done with Abixa, which we have done with Cipralex and other products in China so we are going for actually trying to more than double our Chinese business within the next 5-7 years and therefore we will invest but if you look 4-5 years ahead, if you exclude potential launches of 35700, then you should expect that our estimate base will be pretty stable. Then you said that we had – I might have misunderstood your question – that we should be cautious about stocking. The only thing we have said is that in China due to some reallocation of facilities at our distributor in China we had to make a shipment in China in the first half that was.. all the shipments in China had a positive impact and therefore you should expect that we have an impact of around DKK 150 million from stocking in the first half and we will not be able to sell these products twice so you would have a negative effect of that in the second half. So that is what we have said and then of course I also want to emphasise again, we have guided the reduction in Onfi of 40-50% in the 4th quarter and that is of course due to the fact that if you see the very, very good performance we have had for the first six months we expect that to continue and therefore you would have expected us to make a huge upgrade if we did not see any generics for Onfi and that is still what we expect based on the fact there are tentative approvals for three generics already and seven are in line for getting approval so that is the reason for coming with these kinds of comments. And then, the last question I hand over to Anders Gersel to answer that, please.

0.28.35

Anders Gersel Petersen

Concerning the third study in agitation in Alzheimer's disease and Brexpiprazole, it is a similar design to the ones that we have already concluded except that we have included a higher dose of 3 mg and taken out the 1 mg dose, mainly due to the fact that since 3 mg is available in the US market already there was a desire to have that also evaluated in this population by the FDA and secondly that we are running it in the same countries as we did the previous studies with the exception of Russia.

0.29.15

Anders Götzsche

Okay? Next question please

0.29.19

Operator

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

0.29.25

James Gordon

Hello, thanks for taking the questions, a couple of questions, please. One was on US pricing – a couple of large cap pharma companies have had to roll back years' price rises in response to Trump pressure. Has there been any change to the year's pricing as you see it or are you still comfortable in doing something like 10% annual increase annually.

The second question would be 2019. You note the Onfi pressure that will impact the top line in 2019 released today. Looking at consensus, it seems like a mid-single-digit decline in revenues and EBIT next year. No EBIT margin contraction. Is it actually plausible that the growth margin improvement can offset the pressure from Onfi generics for the Sabril erosion and maybe also some headwind in terms of not having hedging income – or even having a hedging income headwind, or does that look optimistic?

And then a third question. Northera, just what is going on there? If I look at the IMF data, it suggests that the reduction in therapy resistance programmes is having some negative impact on the product, maybe because of the greater out-pocket costs to patients. But are you actually seeing that? Is the prescription data? Or is there for some reason more of a disconnect between the prescription data and what is actually going on because the sales data look better than the prescription data so why is that, perhaps?

0.30.40

Anders Götzsche

Peter, our head of our North American operation – he will answer the two questions about Northera and pricing, so Peter please go ahead.

0.30.48

Peter Anastasiou

Yeah, first on the US pricing. We always price our products consistent with the value they bring. The significant investments we have made and continue to make and we always carefully consider the volume market place and the competition. We don't intend to raise prices through the end of this year but we have not yet completed our evaluations nor made any decisions for 2019 and beyond so hopefully that answers your question on US pricing.

With Northera, as I think you heard from us in the past, because it is specialty-pharmacy distributed you are never really going to get a fully accurate view of the prescription data. Not all specialty pharmacies report to Symphony or the other data sources so it is not an accurate measure to use to understand the performance.

0.31.37

Anders Götzsche

And with regard to 2019, I am not willing to give any guidance for 2019 but what I can say is that of course Onfi is our biggest product for the time being but we have four other products that are growing with double-digit numbers so next year I will actually expect that that will continue but of course Onfi will have an impact and therefore I actually expect that we would see some kind of decline in revenue and also in EBIT but how big the impact will be I think it is way too early to speculate on that because we also have a very good momentum in the business so, you know, how that equation.. the result of that we need to see the upcoming months because the business is running really, really good.

James Gordon

Thank you.

0.32.29

Anders Götzsche

Next question, please.

0.32.32

Operator

Thank you. Our next question comes from the line of Sachin Jain from Bank of America Merill Lynch. Please go ahead. Your line is open.

0.32.40

Sachin Jain

Hi, thanks for taking my questions. A few, please. Firstly just a follow-on from the Onfi debate. 2H – sorry, full-year guidance implies that 2H you have a decline quite substantial versus 1H. Clearly two factors you called out are Onfi and the inventory destock. Is there anything else you would have us be aware of because otherwise we can sort of deduce

profitability of Onfi from the 2H versus 1H decline. Secondly, given the increasing focus on the next-year pipeline presentation, I wonder if you can just comment on implications for the mid-term R&D spend? And then finally on Lu AF. Could you confirm the expectations for regulatory filing i.e. because if a second phase 3 study is required and that is a base case, was there any prospect of you being able to combine with the second study you highlighted only for potential regulatory filing next year? Thank you.

0.33.34

Anders Götzsche

So, I can start. The mid-term R&D investments, this year we expect 16-17% but personally, I would be happy if we could increase our R&D spend to 18% because that means that we are successful in strengthening the pipeline. I think the organisation has been doing really well in driving their own innovation. Three new phase 1 compounds from my perspective it is actually the result of the focused strategy and very interesting products, of course. We know it takes a lot of years to get into the field with these but they could be a change in paradigm of treating patients. So I expect mid-term that it might be up to 18%. I definitely hope that we will be able to invest that and for Onfi I think the totality of the guidance is, as we have said, that you should expect that Onfi will continue the strong growth also in the third quarter. I have received some questions around why the second quarter was so weak for Onfi. It was only 23%. It is 7 years into the launch and we have delivered double-digit growth numbers and we had a fantastic start of the year with more than 30% so for me it is not a disappointment – 23% - there are movements between the quarters. I expect that we will see continued double-digit growth also in the third quarter and then when there is loss of exclusivity, the generics will enter the field and with this compound we expect it would be faster generic erosion than we have seen with Sabril and Xenazine and therefore we have guided with the 40-50%. I think it is more or less that and then there will be a lot of ups and downs but that is the guidance we are giving. And then for the last question, Anders please.

0.35.31

Anders Gersel Petersen

Yeah, concerning filings I think it is too early to speculate on filing opportunities and obviously we need to look at the data before we can make any decisions on that. The 35700 is an area of high unmet medical need and I think that that is obviously something that we will have to take into consideration but we will see the data first and then decide on how to progress from here and obviously there will be no filings prior to having had discussions with agencies on that so our base line assumption is that we still need to run an additional antipsychotic schizophrenia study for 35700 based on a normal development programme

0.36.24

Sachin Jain

Can I start with clarification to the second question? Apologies. It was not really on Onfi, it was more on the 2018 guidance and the shape of 2H so 2H implied guidance about DKK 1 billion EBIT lower than 1H. Are there any factors to think about beyond the inventory destock in the fourth quarter, Onfi?

0.36.24

Anders Götzsche

You know, you should expect, you can do the math as I can and we have delivered DKK 3 billion in the first half and we are now guiding 4.9 to 5.2 and most .. and the number one factor actually taking down the revenue in the second half is Onfi and then secondly of course the destocking of – or destocking, actually that we will not have any sales in China for Brintellix because we have delivered, no for Cipralex we have delivered most of the shipments already in the first half. That's the two factors. If you adjust for them – if you adjust for the shipments for the first and then you take down the sales in the fourth quarter, then you will have a nice, easily understandable equation for the full year.

0.37.42

Sachin Jain

Thank you very much.

0.37.45

Operator

Thank you. Our next question comes from the line of Jim Race from Deutsche Bank. Please go ahead, your line is open

0.37.50

Tim Race

Hello guys. Most of my questions have been asked but I will ask two bigger picture questions. First of all of Anders Gersel, we are looking at severe depression and treatment-resistant depression-type products coming through that are great to use. You know, the cutting base-type products. I would be interested to know how you think these sort of products are going to change the paradigm in the depression market to perhaps more episodic type treatment, where that leaves you and your products? Also just a

bigger sort of picture question for Lundbeck is: Why are you not on the forefront of developing these given that you spend more on early-stage research than perhaps other companies and is there something else that you are working on in the field for use in new areas of depression and schizophrenia that should, you know, in the early stages that are exciting? To finish the question on Trintellix and Brexpiprazole and your SG&A spend, I mean one of the reasons for you outperforming specific expectations has been essentially better cost control but perhaps Trintellix and Brexpiprazole are not really performing to the levels that they could have performed that people expected maybe 2-3 years ago. I was just wondering aside from your indication, is there anything you can do on cost front in terms of more spending behind those two products to actually accelerate them further aside from the indications or should we basically use this as the level it should actually these products are now heading off? Thank you

0.39.16

Anders Götzsche

I can start and then the other guys can chip in but I would say you might have had higher expectations 2 years back but I think, you know, we have accelerated the Brintellix growth in the second quarter. I think Rexulti is, when you look at the underlying script both for Rexulti and Brintellix, we are extremely pleased with the performance. We have the possibility in the US, now we have the speed of processing in the label and we will hopefully also get treatment-emergent sexual dysfunction into the label in the second half so I think we are at a really good spot. What we are, of course, evaluating all the time is how much DTC should we do? And if we can see any opportunities to invest more or less we look at the return on investment all the time. We look into the optimisation of our sales force. How do we get return from that? So this sales effectiveness assessment we do month by month together with our partners but what is important also to say is that – as I said in the beginning – is that the SG&A from a totality point of view – you should expect it to be relatively flat over the next 3-4 years and then of course if 35700 makes it into the market then we need to find out what is the impact, how much synergies will we have with the other products in the sales force and how much do we need to invest in the launch phase and that could of course add some cost on top, but we are actually pretty pleased with both the performance in the US but I am also really pleased with the performance for Brintellix that we see it takes off in the rest of the markets and of course we will continue to push that performance also going forward.

And to the more holistic question which is a 1-day session, the question you asked, Tim, about the depression in the schizophrenia market. We will try to boil it down to 2 minutes.

0.41.26

Anders Gersel Petersen

This is Anders. Thank you for the question. First and foremost, in terms of the impact of having an NDA-like compound like Ketamine entering the market, I think it will be reserved for a very small segment of patients initially because of the very significant side effects associated with the use of such a molecule. And I think there is also from a development perspective a lot of concerns about the factor of blinding of patients in terms of the readout there. As you may know, some of the placebo effects that you do see in these studies can be quite significant for even patients with these severe conditions. So they are not easy to run. We do have programmes that are trying from a research perspective to address the more severe cases of depression including suicide areas and fast onset but it is not an easy entry into that area without having significant side effects associated with such molecules. So it is clearly an area of interest that we do continue to have research in and hopefully we will be able to deliver something in that area as well with a good profile. I don't think that it will have a major impact initially on the US market but we are currently seeing and currently can see on the horizon, but it is certainly something that indicates both the importance and the severity and also the cost of having patients that are severely depressed to see how these products will get to the market and that may change some of the dynamics in the marketplace, as you ask. For schizophrenia, I think these severe cases that are ourselves also address and some others also have got an eye to clearly is an attempt to make sure that people understand that treating these very severe cases with schizophrenia also has a huge benefit not only for the patients but also for the care givers and society and that that has an important role to play and the only way you can actually treat these patients is through medication. So we are working hard in that area and we do see that there are some opportunities to make some progress there but it is obviously too early for me to speculate on early-stage projects when they will materialise.

0.44.03

Tim Race

Okay, thanks for the detailed answers.

0.44.07

Operator

Thank you. Our next question comes from the line of Michael Novod from Nordea Market. Please go ahead. Your line is open.

0.44.15

Michael Novod

Yes, hello. It is Michael from Nordea. Just two housekeeping questions. Going back to the Onfi erosion you guide for. Guiding 40-50% - the exclusivity does not run out until 21

October, so mid-quarter or close to mid-quarter but you know you only have two months then of generic pressure or do you expect with that guidance that there will be some kind of destocking already in October, i.e. early in the quarter or how should we thing about it? Otherwise it seems very aggressive, the slump that you are expecting in November and December. And then just secondly to the tax, Anders, you are guiding for 26-28% in the foreseeable future is that like 3-4 years forward and should we expect it to decline gradually down to the 26% just for modelling purposes?

0.45.09

Anders Götzsche

Thank you for your question, Michael. From a reported tax rate if for the next 3-4 years you expect, you know an average of 27%, I have said 26-28% reported and then from that from 2022 and onwards it will be, the structural reported tax rate will be 23-24%. If you look at the cash tax rate then you should expect for the next 4 years that it will be around 20% and then it will be, going forward, the same as the reported because the Danish tax rate will be 22% and most of our products at that point, from 2022, will be taxed in Denmark and then we will have some non-deductible items that will add and then we have a global tax will tax it up so it might add 1-1.5%. For the Onfi question, I will hand over to Peter to give some more details

0.46.07

Peter Anastasiou

Yeah, and just for clarity, the exclusivity ends 21 October and in terms of our assessment of the erosion, we certainly have looked at a number of analogues to try to assess this and there are differences between Onfi and the erosions that you have seen with Xenazine and Sabril most notably is the fact that Onfi is retail distributed where both Xenazine and Sabril are specialty pharmacy distributed so that is an important differentiating factor that we believe also leads to faster erosion. And also the number of generic competitors that we expect at the time of exclusivity ending. There are already four that have tentative approval from the FDA. That means that they cannot launch before exclusivity period ends but we expect them to launch quickly thereafter and our estimate is that is another six waiting and so those also could be approved by the time of the loss of exclusivity so those are the factors that lead to the more significant erosion that we expect with Onfi than what we have seen with Sabril and Xenazine.

0.47.15

Michael Novod

Okay, thank you

0.47.18

Operator

Okay, our next question comes from the line of Wimal Kapadia from Bernstein. Please go ahead. Your line is open

0.47.24

Wimal Kapadia

Thanks for taking my questions, Wimal Kapadia from Bernstein, so just coming back to Northera. Can you just describe what the impacts have been of longer and higher dosing of the drug as a growth driver and the recent cortef and then is that now coming to an end? And is patient recruitment now the main challenge? And then staying on to that, how are Lundbeck actually targeting the cardiologists? Does this require more investment from the sales force? Our second question is on Rexulti. On the slide that you have you did not really mention how long-acting injectable sub-key version. Is that still something that the company are looking to progress into phase 3 and if you are just deliver the context or colour around now what sort of demand there is for a product like that and then my final question is on Onfi, a comment on Onfi again. Epilepsy drugs could have a reasonable tail revenue. How does Lundbeck think about that for Onfi? Thank you very much

0.48.16

Anders Götzsche

I can start with Onfi and then Peter can chip in. You know, just to be very transparent, we of course have not been very good in predicting Sabril and Xenazine and we have also, we are pretty surprised by the fast erosion for Xenazine and then in actually the first month there was a decline of 50% and then you all know that it regained momentum, but it is as Peter said, it is a different distribution and we have looked at multiple analogues and that is the reason why we actually expect it to be faster, but of course what we have also discussed with all of you, you know, it is a severe indication that Onfi is treating so we cannot rule out that you are more right but this is basically based on all analogues we have been looking at. This is actually our best guess. And Peter you can make a comment about Northera.

0.49.22

Peter Anastasiou

Yeah, Northera. As you know this is the first treatment approved for neurogenic autostatic hypertension so there is a market development aspect in helping to highlight the disease,

the unmet needs, the symptoms, to help doctors detect that and that is actually we have seen nice advancements in the ability of doctors to detect and intervene and treat. As you point out, the relevant target audience is in terms of prescribers are both neurologists but also cardiologists that are often used as consults so it is a combination often time a treatment team approach between neurologists and cardiologists and we have many sets of customers in both categories and all of our promotion is reflective of that and the investments that we made of the connections and the promotion that we do to both sets of customers and also there remains a significant unmet need while we have really helped the customers understand better about NOH and intervening and treating and we have seen many, many patients be added, put on Northera. We still think there is a lot of significant opportunity that still remains untapped and so that is our focus area. And then you talked about dosing and length of therapy. Dosing and length of therapy are on track with what we expected. Maybe on the length of therapy, it is actually a little longer than what we expected and I think that is reflective of the fact that patients are getting the clinical benefit that they desire from the therapy and are therefore staying on longer than our original expectations. I hope that answers your questions.

0.51.00

Anders Gersel Petersen

This is Anders here, with respect to the Rexulti long-acting injectable. We are still looking into formulations that will be optimal for this product to take forward and until we have convinced ourselves that we have the right formulation we will not move ahead with that but bear in mind that some of the developments with that kind of projects are somewhat faster than a classical development programme.

0.51.29

Wimal Kapadia

Great, thank you very much

0.51.32

Operator

Thank you. Our next question comes from the line of Peter Sehested from Handelsbanken. Please go ahead, Peter, your line is open.

0.51.40

Peter Sehested

Yeah, it is Peter from Handelsbanken. Thank you for taking my questions. A couple to Anders Gersel. Just want to follow up on 35700 and how you are going to communicate about this, I mean, you stated that you will not inform about or provide any filing update after you have spoken with the FDA but I mean are there scenarios where you could communicate that based on this data etc. etc. I mean you will go to the FDA with an ambition of seeking approval etc. on the back of one study only, if that is possible in the way that you communicate around the announcement.

And secondly, with respect to the Alzheimer's vaccine – you seem pretty confident in being able to move into phase 2 in the first half of 2019. Peter commented on the positive titer development etc. etc. so is that still the basis for your high confidence and secondly your progression into phase 2 are you also anticipating that to be done in collaboration with a potential partner here? Those were two questions for now. Thank you very much.

0.52.58

Anders Gersel

First and foremost, with respect to 35700, we do not have any expectations that we can file based on a single study if that is what you are alluding to. The demands for that are very significant and I don't think it is realistic to plan for that. We have no plans for that. We will look at the data when we get them and based on that we will obviously formulate our plans going forward. I do not think you should expect us to announce any revised filing strategies from what I have said before until we have sort of come to a conclusion with the FDA in such a respect with that opportunity arises. We need to look at that when we see it. At this date, our operative mode is that we need to do an additional study and that is what we will be doing and when we have the results of these two studies then we have a filing and that is what we have in the plans for the time being. With respect to the immune therapy vaccine programme, we are pretty confident in moving forward with an approval of concept study in the sense that that we have a titer 0.54.22 that we think looks sufficiently intriguing for us to move ahead with. We have obviously no way of knowing whether it does what it should be doing without taking the next step so that is why we are pretty confident that will do that and we have had interactions with agencies to discuss the extent to which we sufficient data to move into these next study levels and have had the go-ahead to be able to do that so we are in the process of finalising those programmes so that we can initiate them in the first part of 2019. We will initiate those programmes alone or together with Otsuka. We have not at this stage had any discussions with them on that. We still have the data in confidence inside only Lundbeck so we haven't had any discussions with anybody else on that.

0.55.24

Wimal Kapadia

Okay. Thank you very much. I can jump actually to..

0.55.30

Operator

Thank you. Our next question comes from the line of Emily Field from Barclays. Please go ahead your line is now open

Hello, Emily, your line is now open for your question.

Hello

0.55.45

Emily Field

Can you hear me now?

Hello

0.55.49

Emily Field

Yeah, I was just wondering if you could walk us through again, sort of the guidance that you expect for the gross margin extension, some thought of what will be done to the Onfi and then just what the drivers are in particular for that extension in the out years and then also just for Trintellix with the label update. Have you been able to detail most of the prescriber base which are likely to have a nice uptake that you had expected and then just on TEFD potential waiver update. Are there any other jobs that have that in the label? And if you could maybe quantify what you think the opportunity is there? Thank you.

0.56.22

Anders Götzsche

Peter, could you go through Trintellix?

0.56.25

Peter Anastasiou

Yeah, with Trintellix as you know we received the label update in the second quarter and shortly thereafter we started educating physicians and the response has been very positive. I think the speed of processing claim is one that resonates and that they understand, they see these types of issues in patients with depression, slower processing speed in terms of thinking and decision-making. But it is important to note that this is not our exclusive focus. One of the real areas of strength that I think is creating the strong momentum that we have with Trintellix is that it is the most complete anti-depressant. It is very, very effective. You can see that from the remission rates. The efficacy is also bolstered by the speed of processing claimed but it also has a very strong tolerability profile which will soon hopefully be bolstered by the treatment-emergent sexual dysfunction claim so it is the totality of the anti-depressant effect and the tolerability that is leading us into this great momentum and speed of processing really supports that and we believe that TSD will also support it. Our TSD in terms of how we think that fits in we certainly won't quantify what we expect this will be. We certainly think that it is already understood that Trintellix has a good sexual dysfunction profile but now we will hopefully be able to add in the label some data that will help us promote and educate doctors more on the great tolerability profile that it has with TSD.

0.57.59

Anders Götzsche

And for the gross margin question, we expect 80-82% this year and within the next 5-7 years we expect it to be improved to 86-88%. Okay, next question, please.

0.58.20

Operator

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

0.58.27

Peter Welford

Hi, thanks. First just on the mid-term outlook. I appreciate that that was not yet in place but have you a plan with regard to when we could tentatively envisage you giving a new mid-term target on the margin etc. and should we anticipate that in 3Q or do you think that it is more right actually that we need to wait longer and that it is more likely to be the 4Q results for the 2019 guidance in the media?

Secondly, then on 35700, is it possible that you could decide to enlarge the new trial and turn that into a phase 3 within your new trial using the current format. And then finally, just housekeeping, could you possibly detail for us what the income from the Australian settlements particularly was during 2Q and the Carnexive impairment which I don't think was excluded from core earnings. Thank you.

0.59.25

Anders Götzsche

The Australian settlement was DKK 121 million in the first half and the gain from buildings was some 40 million and then you have the totality of that. What was the connection that the write-off was around 40 million so then you should have every one-off, single one-off item in your paper and with regard to financial long-term targets I think we should not speculate in when that will go out to you guys because Deborah needs to start on 1 September and what I can promise you is that I believe that she will be building on the existing strategy and then she will get into the business and then when she is ready then she will make the appropriate communication. And with regard 35700 you will soon get an expert answer on all these questions, Anders.

1.00.27

Anders Gersel Petersen

Yeah, the 35700 study. It is correct that immune study is up and running and it can and will actually be expanded to include some more patients into it. It has a design that is somewhat different than the 35700 DAYBREAK study so to the extent to which it will suffice to support study in what way it could ever help in the filing I think it is too early to speculate on that.

1.01.03

Peter Welford

Thank you.

1.01.06

Operator

Thank you. Our next question comes from the line of Jacob Lademann from Carnegie. Please go ahead your line is open.

1.01.13

Jacob Lademann

Hello. Thanks for taking my questions. Actually I only have a few left regarding the Alzheimer trial you expect to commence next year. Could you talk about what sort of data you have already to sort of probably go into yeah Proof of Concept trial. Do you have anything else other than scanning of amyloid Beta levels and also what type of end points do you expect for the trial to commence. Will you have any clinical evaluations as well as I would expect you to report amyloid Beta levels and finally could you talk about I guess a little bit more about the mode of action here. What differentiates it from it of course raising the polyclonal antibodies against the amyloid Beta but in what way particularly molecularly does that differentiate against existing other programmes in this base? Thank you.

1.02.14

Anders Götzsche

Thanks. Anders

Anders Gersel Petersen

The activity of an active immune stimulant therapy, as this one is, is very different from an antibody in the sense that you rely on the poly-clonality of the inherent antibodies in the body so you are not targeting a single species of types of a Beta but we obviously want to have a profile that looks right and targets predominantly the ones that you are wanting which are in our case the oligomers that we have as our focus so that is a differentiating factor between that and certain of the other antibody or vaccine therapies that are out there. The other part is that if you have an antibody administrative then you will have a certain proportion of patients who will generate neutralising antibodies against that so you will lose the effect for some patients after a year or two, which is a natural thing for mainly antibodies to see that happening. And that obviously will not happen in this case where you raise internal antibodies within the body itself. Just to be correct, you assume that we had scanning pictures. At this stage, we do not have analogue scans at this stage. What we do have is we have the titers that allow us to do the PoC study which includes both clinical and scanning at baseline and at read-out in these patients so that is the plan with that programme.

1.03.56

Anders Götzsche

Okay?

Jacob Lademann

Thank you

Anders Götzsche

Next question, please

1.03.58

Operator

Thank you. Our next question comes from the line of Marietta Niemitz from Prime Avenue Please go ahead. Your line is now open.

1.04.07

Marietta Niemitz

Yes good morning. Thanks very much for taking my questions. The first one is on Q4-Q2. I realise it is very early days but very high level, could you give us a feel what an efficacy trial could look like? The MoA suggest that you probably want to do that earlier like in the prodomal phase and it could also mean it could take quite some time before you see an effect on this use progression so any colour there would be helpful. And then I just wanted to follow up Sachins question on the R&D spend, I mean I was actually very surprised that you are only expecting about 18% now. Actually in the next year, I mean, you could potentially be moving 3-4 projects into phase 2 and the need to be made into your pivotal trial and then I believe in the past you have also been quite open to add another project through a deal if the opportunity presents itself so do you really expect to do all of that and keep the R&D spend at 18%? And don't your first target of 20% still hold? Or would you be willing to go above 20% in individual years temporarily? Is that also to be decided by your new CEO or do you really just expect to have to prioritise in 2019? And then a commercial question on Rexulti and the European rollout, please. Should I infer from your comments on time lines that you won't be launching in Germany at all? Or will you simply await an agreement there on the long-term price before you launch? And why are the time lines generally so protracted given this drug really serves very high unmet needs in schizophrenia? Is that because there is potential scope for off-label use that is complicating the negotiations or are these sorts of time lines just normal even in straightforward indications with very high unmet needs? Thank you very much.

1.06.09

Anders Götzsche

We need to give fast answers here. The R&D percentage I expect it to be around 18%. You are fully right, it could be 20% in a year, it could be lower in another year. We have for 3 years in a row been lower, but it could of course, I hope that we will have good traction and if possible if we can see value then of course we would be willing to go above 20% but as an average you should count on 18%. Rexulti, Jacob will elaborate on that

Jacob Tolstrup

Yes, very brief Marietta. Thanks for the question so for Rexulti we are evaluating basically on a country by country basis where we can get what we believe is an acceptable price that will lead to a business case that is viable for us. That is why we will not communicate today in which countries we plan to launch but don't expect it to be full-blown European launch. We will go selective in certain countries that we will be able to talk about as we progress closer to launch. So it is all a matter of getting to that point and I think the first launches will take place during the first half of 2019 and when that exactly happens is still to be finalised.

1.07.24

Anders Gersel Petersen

Alfa synuclein compound, the A2 compound that you refer to that is quite correct, you will have to introduce that fairly early in the disease to get an impact on patients there. A lot of work is ongoing as we speak to enhance our ability to detect the right patients and to monitor the progression of Alfa synuclein in these individuals along clinical metrics so it is not a fast programme, the Alfa synuclein programme, but as we have also seen over the past 45 years in the Alzheimer area then you can certainly get some breakthroughs in some of the technologies that allows you to actually monitor and decide on patient flow in a much more intelligent way than you have done before and we know there is a lot of work going on that both we and others conduct in that area.

Marietta Niemitz

Thank you

Operator

Thank you. This brings us to the end of our Q&A session and will now hand back to our speakers for any closing comments.

1.08.39

Anders Götzsche

Thank you very much to all of you for listening in and your interest in Lundbeck and have a great day. Thank you very much.