

H. Lundbeck A/S**Transcript: Investor Presentation, Q1 result 2018****Date & time: 08 May 2018 at 13.00**

Operator

Hello and welcome to the H. Lundbeck financial statement for the first three months of 2018. Today, I am pleased to present interim CEO and EVP and CFO Anders Götzsche, and EVP of Research and Development Anders Gersel Pedersen. For the first part of this call, all participants will be in listen-only mode and afterwards there will be a question and answer session. I will now hand you over to our speakers, please begin.

0.00.27

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 quarter of 2018. Together with me, I have our Head of R&D, Anders Gersel Pedersen, to help me with the Q&A session I have also invited our Head of North America, Peter Anastasiou, and Jacob Tolstrup, Executive Vice President and Head of Commercial Operations.

On slide 2 you can see the company's disclaimer which I presume you have seen many times before and I will refrain from reading it out loud. So we will go directly to slide 3. I will elaborate on the key performance measures in a minute, but please allow me to summarise on the strong financial performance we have had in this quarter. In the quarter, Lundbeck achieved its best financial result ever. We have seen a continued significant improvement in our profitability as well as shown solid growth in revenue in spite of headwinds from exchange rates and generic erosion.

We are therefore very satisfied with the progress of our operation performance. Revenue grew 9% in the period thereby reaching DKK 4.6 billion. Remember, though, that some of our products are tender-based and this quarter is likely close to DKK 100 million better from that perspective. Our key products continue their strong growth and reported sales of these products have grown 23%.

In order for you to better assess our operational performance, we have from this quarter chosen to split out the effect from hedging into a separate line instead of distributing them to the individual products.

As the USD has declined since last year, we recognise a gain of DKK 182 million in hedging impact which is in a separate line.

In parallel with the sales growth, we have managed to bring down our cost and reported EBIT increased by 64% reaching close to DKK 1.7 billion and the EBIT margin reached 36.1%. However, bear in mind that the hedging gain has a positive impact on the margin and there are also some quarterly fluctuations in some of our cost items.

As our tax rate continues to decline, following the impact from the US tax reform, we see very strong growth in earnings per share of 103%. Anders Gersel will revert with a pipeline update but let me just say that we are very satisfied with the progress in our development and registration work. It is important for me to note that R&D efforts not only address inventing and developing new molecules but also life cycle management to identify additional growth opportunities for the products already in the market. Here I think we have really been successful with the extension of the exclusivity of Lexapro in Japan and followed by the recent approved update of the US label on Trintellix and cognition.

Please turn to slide 4. It is important to continue to point out that we have a portfolio of mature and relatively stable products and we also have a portfolio of key products which generate substantial growth. We continue to execute on our strategy growth platforms and we have seen continued significant sales increases in our key products.

In the first quarter of 2018, our key products realised revenue growth of 23%, which is very satisfactory considering that we are beginning to see negative impact from depreciation of currencies. Sabril and Xenazine are down 29% combined following generic competition. Here 2½ years after the first generic version of Xenazine was introduced, Lundbeck still has close to 20% of the market in volume.

Regarding Sabril, the generic versions have taken some 30% of volume and it looks relatively stable. I will get back to you on our regional performance in a minute but it is our North American and European region that delivers growth in reported numbers.

In local currencies, all three regions are growing and developing in line with our expectation.

Please go to slide 5. Revenue from Brintellix and Trintellix reached DKK 467 million in the quarter of which 51% was generated in North America. However, countries in both Europe and in the international market also make a valuable and increasing contribution to the total Brintellix revenue.

In the three large European markets, France, Italy and Spain, we see value market shares getting close to or exceeding 5%. We also see a solid performance in countries such as South Korea and Canada with value shares between 3 and 4% and still increasing.

In the US, Trintellix has a value share of 18.5%. Trintellix is continuing to grow significantly 4 years post approval reflecting strong appreciation of the value that the product provides and helping to address unmet needs for patients with depression.

I actually see possibilities for further upsides, especially following the revised labelling we now have received in the US and which Anders Gersel will revert to in a minute.

Please turn to slide 6. Rexulti is still mainly a US franchise and outside North America it is only launched in Australia. As you can see from the graph on the right side, the significant uptake continues and the momentum looks solid. In terms of revenue, Rexulti achieved DKK 369 million in sales in the quarter, which represents growth of 32% and 51% in local currency.

We continue to have high expectations for this product as Rexulti has an attractive profile which is highly rated by the medical community. The week over week growth continues to outpace the branded market in general and the uptake is strong relative to prior competitive anti-psychotic product launches.

The value market share exceeds 10%. We have recently achieved Rexulti approval in Saudi Arabia in both indications and will soon start launching the product followed by potential launches in Europe, South Africa and Mexico in the coming quarters.

Please turn to slide 7. Abilify Maintena grew 15% to DKK 364 million so far in 2018, primarily driven by Europe. 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 and the value market share has reached 18.5% compared to 18% in December.

Based on the net sales, it seems that the LAI market has picked up somewhat as the year over year growth is around 13%.

Please turn to slide 8. We are pleased with the performance of these products even though they are quite impacted by the US depreciation. Northera grew 13% to DKK 396 million in the quarter but in local currency reached 29%. Onfi grew 27% to DKK 903 million and in local currency growth reached 46%.

We expect continued high growth for these products. Also, Onfi is expected to face generic pressure towards the end of the year.

Please turn to slide 9. Our North American Region is continuing the solid performance by growing 19% in local currencies. The reported growth is more modest. 4%. It is still our key products, which constitute around 80% of sales, which drive the growth.

In 2018, North America is expected to continue to be growing in local currency even with the effect from the loss of exclusivity on Onfi.

Please turn to slide 10. International markets include our Emerging Market business and countries such as Japan, Korea and Australia. And International Markets declined 5% in the quarter and constitute 24% of our revenue. In this region, it is still early in the launch of our key products which constitute 15% of total revenue in the region. We expect to see significant growth going forward for these products in the region.

In China, we have recently launched Azilect and Brintellix, but please remember in local currencies that we are still seeing growth and we have actually grown 5% in International Markets.

Please turn to slide 11. Europe has actually been a fantastic turn-around and after finalising the restructuring we are now growing by 5% to DKK 745 million driven by the key products which now constitute 41% of sales.

The key markets for Lundbeck in Europe are France, Italy, Spain which constitute close to 45% of sales in the region.

Please turn to slide 12. Now I will turn to our performance of some of the financial measures. Cost of sales declined from DKK 965 million to DKK 826 million or 14% while at the same time growing the top line by 9%.

Our gross margin has therefore improved following improved product mix with reduced royalties and reached 82% in this quarter compared to 77% last year.

The gross margin is expected to improve further in the coming years. SG&A cost decreased from DKK 1.6 billion to DKK 1.4 billion, which is a decline of 11% compared to growth in top line of 9%. The SG&A ratio for the quarter was 31.4% compared to 38.5% the year before. The SG&A ratio is expected to improve compared to 2017 for the full year and reach a level of around 33-35%.

R&D costs increased by 9% and we still use around 15.5% of the revenue in R&D. We expect the R&D ratio to increase to a level around 16-17% for the full year 2018.

The EBIT margin has improved significantly from last year. The margin improved from 24% to 36%. This means that the positive development we have seen in the last few quarters continues. However, it is important to note that this quarter has from a margin perspective been very good and is expected to be the best quarter for the full year – during the year.

Please turn to the next slide. Clearly the negative development in our main currencies is impacting our revenue performance, especially for North America and International Markets. As you can see at the right-hand side of the slide, in local currency we see solid growth in all regions and strong growth for our key products. Following the improvements in our cost ratios, our EBIT reached DKK 1.65 billion in the quarter and has therefore increased by 64%.

The effective tax rate continues to decline. As a result, we see very strong growth in our net profit and subsequently our earnings per share which have grown 103%.

Please turn to the next slide. Lundbeck continues to generate a very strong cash flow. Cash flow from operations has increased by more than 200% to DKK 2 billion. Net cash flow is impacted by the acquisition of Prexton in March and also the increased dividend payout which was also paid out in Q1 this year, but in Q2 last year. Therefore, our net cash flow was an outflow of DKK 380 million compared to an inflow of DKK 524 million last year.

We still expect net cash to be in a range of DKK 5-5.5 billion by the end of the year 2018.

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

Therefore, the outlook for 2018 is maintained for revenue in the range of DKK 17.2 to 18 billion. We expect to see continued improvement in our profitability in 2018 and EBIT is expected to reach between DKK 4.8 and 5.2 billion for the year, which indicates a margin of at least 26.7%.

For the financial year, you should expect a net amount of +/- DKK 50 million depending on currency developments. The reported tax rate is expected to be around 26-28% in 2018, which also will be in the range for the upcoming years. It is important to note that the cash tax is somewhat lower and we expect it to be around 20%.

I will now hand over to Anders Gersel to go through the latest in our R&D pipeline.

0.16.35

Anders Gersel Pedersen

Thank you, Anders. Please turn to slide 16. I will now first come back to Trintellix and Foliglurax in a minute, but make some brief comments about Rexulti and Alzheimer's agitation where we expect the third study to commence by the middle of this year with approximately 300 patients. I am also comfortable in expecting that we can start first in human testing for at least 2 and maybe 3 projects in schizophrenia and Parkinson's disease within this year. We continue the effort of getting access to external innovation to support our own projects or to get additional assets.

Please turn to slide 17. The Trintellix US labelling now includes data from the largest replicated clinical studies FOCUS and CONNECT that showed Trintellix had a positive effect on processing speed, an important aspect of cognitive function in acute depression. The prevalence of cognitive impairment associated with depression is high and as part of the comprehensive treatment approach it is important for clinicians to talk to patients about all symptoms associated with depression. Many depressed patients recognise the mood

symptoms of depression but they do not always by themselves recognise cognitive symptoms that may be related to this condition. Trintellix is the first anti-depressant with US labelling approved with digital symptom substitution test or DSST data that recognises as a clinical meaningful measure of acute major depressive disorders. This is an important milestone to us. This has to be seen in the backdrop of a recent meta-analysis published by Cipriani which indicates that looking at the core mood symptoms of depression Trintellix is considered the best available anti-depressant when you look both at efficacy and tolerability at the same time. With this updated Trintellix labelling, it gives the health care professionals important additional information about Trintellix to improve discussions with patients about their depression and also cognitive improvements associated with this depression.

Next slide please. We have furthermore submitted an sNDA regarding inclusion of data from 2 studies investigating Trintellix, an anti-depressant associated with sexual dysfunction of treatment. TESD it is called in abbreviation. The first of these studies was presented in 2014 and the second one is expected to be presented some time later this year. TESD tends to be underreported spontaneously and appears to be more prevalent when proactive measures are used.

For example, in some observational studies of patients taking an SSRI, the rate of spontaneously reported sexual dysfunction was around 15%. However, if one uses a validated scale to proactively measure TESD of patients taking the SSRI, rates range from 25% to 80% depending on the study.

Incidence of sexual dysfunction at any one visit for Trintellix was 38% for all doses and 32% for placebo.

In patients switched from SSRI associated with TESD to Brintellix, sexual dysfunction was improved while the efficacy in these patients was maintained.

Please turn to the next slide. Finally, let me add some comments on the acquisition on Prexton which was announced earlier on in March this year. By acquiring Prexton, Lundbeck has obtained the global rights of an attractive compound, Foliglurax, which currently is in clinical phase II testing for symptomatic treatment of OFF-time reduction in Parkinson's disease and dyskinesia, including levodopa induced dyskinesia or LID abbreviated. Foliglurax works by positively modulating a specific glutamatergic target (mGluR4) which activates a compensatory neural system in the brain which is largely unaffected in Parkinson's disease. This is a mechanism we also investigated some years ago internally and which we find very interesting.

Animal models have convincingly demonstrated positive effects in models of Parkinson's disease and the aim is to treat the motor symptoms of Parkinson's disease such as resting tremor, muscle rigidity and uncontrolled movements, also called dyskinesia. The first part of the ongoing clinical phase II program is expected to be available during the first half of 2019.

And now back to Anders for concluding remarks.

0.22.06

Anders Götzsche

Thank you very much. And now we will start the Q&A session and the first question comes from..

0.22.17

Operator

Yes, our first question comes from the line of James Gordon from JP Morgan. Please go ahead, your line is open.

0.22.24

James Gordon

Hello, thanks for taking the questions. One question was just on the CEO search. Just to hear if you talk about well it is the current issue you are encountering with the search in terms of it taking some time and the attributes you are looking for in terms of a new CEO and also just on that theme I think you normally have an annual strategy meeting in June where you come up with an updated medium-term plan. Is there a prospect that you have a new CEO by then? And if not, does that create an issue in terms of the ability to update the medium-term guidance or could that still happen even if you have not hired a new CEO? And the second question was just on the guidance and whether the EBIT guidance could prove conservative for this year based on the fact that you have done about a third of it in Q1? Can you talk about the headwinds? Are you expecting significant ex-US de-stocking and what sort of margin would you lose Onfi at? Can you just remind us how the economics work on Onfi, please?

0.23.18

Anders Götzsche

Thank you very much for the questions. There is not too much to say about the CEO search. It is ongoing. It is, the board of directors are making the search and I don't have any timeline for that so what we as a team are focused on is actually delivering still a performance and I think we have done a great job in the first quarter and that is basically what we are focusing on instead of focusing on when a new CEO will join.

And you are fully right that every year in June we have a strategy meeting and what is also obvious that before we have a CEO we will not come out with any long-term financial targets but our goal as a management team is of course to over-deliver compared to what we have already laid out as financial targets and you can see that we started pretty well in the first quarter. Then it is obvious, we get a lot of questions about guidance and there is no doubt that we have had an extremely strong start of 2018 but I think it is also cautious to – you know, we need to be cautious because we know that we might face – we don't fully know the trend for the genericization for Sabril, Xenazine and by the end of the year Onfi, but it is also fair to say, you know, if the really good start of the year – the fantastic numbers – is rolling into the next quarter then we need to look into the guidance. That is how it is.

And then for Onfi, of course Onfi is a very profitable product. It is a neurology product and it is very profitable so it is in the high end so of course it will also hurt some of the earnings in Q4 if we get kind of what we say fast generic entrance and we expect that there will be multiple, we know that there are multiple generics ready for launching. How fast it will take off we don't know. So that is actually, I hope it answered your question James.

0.25.28

James Gordon

Yeah, thank you.

0.25.31

Operator

Thank you. Our next question comes from the line of Trung Huynh from Credit Suisse. Please go ahead, your line is open.

0.25.36

Trung Huynh

Hi, thanks for taking my questions. A couple from me please. Firstly, can you tell us which products were positively impacted by seasonality shipments and the actual impact of these? Secondly, thanks for giving us the prevalence of the cognitive symptoms that MDD patients have. Can you give us an indication what proportion of these cognitive patients suffer from processing speed issues and finally will Lundbeck increase its DTC advertising for Trintellix off the back of this label update? Thanks very much.

0.26.13

Anders Götzsche

I will let Anders answer your question on cognition

0.26.18

Anders Gersel Pedersen

Yeah, I can tell you that the impairment on DSST is quite prevalent amongst patients with cognitive deficiencies. We have not in the study selected patients based on a DSST score but basically had patients that had some reductions in their cognitive capability as such in one of the studies. And in those studies, it is quite clear and in general population studies that across the board there is a decline in the DSST scale when cognitive impairment is present. But there will clearly also be individuals for whom this is not the case. The importance of the DSST testing is that it is a change sensitive metric which basically tells us how can patients improve if you improve on the cognitive functioning and that is why it has been quite important to have that put into the label because you could have other measures that would be measuring cognitive impairment but that would not be really change sensitive to the same extent as this one is so this is an important and sensitive metric to have included in the label and as you may be aware it is one that has been very widely used basically since the 1930s as a part of a lot of different test batteries in many different clinical situations.

0.27.55

Anders Götzsche

Jacob – seasonality?

0.27.56

Jacob Tolstrup

Yeah. This is Jacob, so you are absolutely right. As we also mentioned we have about 100 million in additional shipments affecting the quarter positively and without going into too

many details on which products, I can say that it is primarily Cipralex, Lexapro and it is countries like China, Saudi Arabia, Egypt and also a country like Lebanon that are positively impacted in the quarter.

28.26

Trung Huynh

Thanks very much.

28.28

Operator

Thank you. Our next question comes from the line of Michael Novod from Nordea Markets. Please go ahead, your line is open.

28.35

Michael Novod

Yes, hello, it is Michael from Nordea. A few questions. So first of all, back to Cipralex – can you try to comment on how long a tail you see because even though we are just for these additional shipments it still seems to be performing quite well so maybe you could try to give us in a – I don't know – 3-5-6-year perspective where you see this drug going, whether we should see it staying around 2.5 billion or where you see this going? That was one, the second thing on Onfi, is there something that we are not catching in terms of the pricing? We try, of course, to monitor pricing and volumes and so underlying growth local currency is 46% for Onfi, volume growth was 12-13% at least the stuff that we are tracking, so is there something that we are missing or is something happening to the gross/net and should we expect you to be able to do the same price hikes if it is price that can offset some of these significant generic impacts potentially happening in 2019? And then lastly on M&A because Anders you are quoted for in the media saying that you have now USD 900 million by the end of the year providing M&A power. How much M&A firepower would you actually be able to have in total when you judge the situation now?

0.30.03

Anders Götzsche

Thank you for the questions. You know, the strategy is definitely still that we want to focus on our own internal pipeline and as much value we can create from that, that is the number one priority. But of course, if we get into a situation like we had with Prexton and Foliglurax then if we can strengthen the pipeline, we would definitely do that again. But

our preferred option is to invest in the internal pipeline and then if we can find some external opportunities, we hope that they would be early stage so we can get the full value upside. And we are definitely not speculating in what is the potential, how large acquisition could we do because it is definitely not the main focus area for us. The main focus area is to try to get the most value out of our own pipeline and then add some early stage products. And then Onfi, Peter?

0.31.04

Peter Anastasiou

Yes, Onfi, the strong quarter that we had is a combination of both demand and inventory. Our number shows that we had 16% increase in demand which is very strong, especially for a brand that has been on the market for 7 years. But we also did see some inventory build that emanates mostly from some wholesaler issues that we had and we had to stock up some alternative wholesalers for a period of time so you do see some inventory build there. But overall, we see very strong demand coming from Onfi and we expect to see that continue.

0.31.40

Michael Novod

How much was the inventory build-up, maybe you can spell it out for us so we have a feeling of where it is going?

0.31.47

Peter Anastasiou

Yeah, we typically don't release that kind of specificity, so I think that is all the information that we can provide right now.

0.31.58

Michael Novod

Okay.

0.32.00

Jacob Tolstrup

And Michael, this is Jacob regarding your question on CipraleX/Lexapro so I think you should probably divide the world into something like three categories, so for Europe we expect to see a continued decline and that decline will over time become less and less but we do expect to see a continued decline in Europe in general. Then of course you have these quarterly fluctuations. If you look into International markets, we actually have many markets, especially in Southeast Asia, the Middle East and also to some degree in Latin America where we can uphold the sales of CipraleX/Lexapro and also some places do continue to promote Lexapro in some markets. That means that we expect to see a decline but to a less degree than what we see in Europe and then the last country is obviously Japan, so Japan we now expect to be able to uphold our sales for a longer period in Japan expecting generics by the end of 2022.

0.33.03

Michael Novod

So, before that it is realistic to see it staying around the current levels when you net it all out?

0.33.09

Jacob Tolstrup

Well, I mean, you should expect a decline going forward.

0.33.15

Michael Novod

Okay. Thanks.

0.33.18

Operator

Thank you. Our next question comes from the line of Wimal Kapadia from Bernstein. Please go ahead, your line is open.

0.33.26

Wimal Kapadia

Hi, thanks for taking my question, I am Wimal Kapadia from Bernstein, so two please. For the first one, just following up on James' question earlier in the call and given the high margin nature of Onfi, should we expect 2019 to be a declining year for earnings or do you think that Lundbeck has enough elsewhere to maintain some level of growth in earnings? Then I guess, just following on from that, you know a similar question for Northera in 2021. And then my second question is around the injectable anti-psychotics so I am now aware that you have several.. you are looking at developing generics already in the injectable market. I guess, given the amount of infrastructure outside of the drug itself, how much should we think about the impact from generics within this market? Thank you.

0.34.13

Anders Götzsche

I can start with the Onfi question. I think it is reasonable to believe that we might have a decline in both revenue and earnings in 2019 because Onfi is our biggest product from a revenue perspective and if it goes as we anticipate, that there will be fast generic entrance, then it will hurt our earnings in 2019 as well as our revenue, so that goes without saying. Northera is a bit more tricky to predict. If it goes fast, then it will of course depend on what is the size of the product at that point of time but that might also give a dip and that is how it is. What we will continue to focus on is the profitability and all the products that we have control over, we will continue to grow with these double digit growth rates, we really believe that is possible. Generics, was it generic Abilify? Yeah.

0.35.23

Peter Anastasiou

Yeah, so we believe we have very strong pattern coverage for Abilify and we don't expect generics any time soon so I am not sure what generics you are referring to, if you are talking about just in general in the marketplace.

Wimal Kapadia

In general, yeah, just in general..

Peter Anastasiou

Yeah as you know, there hasn't been a generic LAI launch in the atypical LAI space so we haven't seen that yet. Certainly, that could happen with RISPERDAL CONSTA in the coming years, I guess, coming months even potentially but we believe we have a very differentiated molecule in Abilify Maintena, it is also once monthly and the presence of a twice monthly, CONSTA for example, we don't see as having really much impact and one other point is in addition to being a once monthly treatment for schizophrenia, we are also

the only once monthly treatment for bipolar disorder so we feel like not only do we have a great IP, but also some strong clinical differentiation that allows the brand to continue to grow.

0.36.25

Wimal Kapadia

Okay, great, thank you.

0.36.27

Operator

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

0.36.35

Peter Sehested

Yeah hi it's Peter from Handelsbanken I have actually just one question relating to the commercial potential of the Trintellix label update. I mean, you are giving us some prevalence numbers and I mean that is also appreciated and we can play around with those in the model but could you just dwell a little bit on your strategy for potentially capturing that additional volume that you are quantifying for us? Thank you very much.

0.37.06

Peter Anastasiou

I will comment on that. We won't give specific numbers about what we expect the impact to be but basically our strategy continues to be to establish this as the most complete antidepressant without compromise so that means we have to continue to drive the core efficacy of the product but also differentiate that efficacy with this additional new labelling which, as Anders pointed out, is a very prevalent symptom in depressed patients and then of course we have strong tolerability as well and some additional data coming, as Anders also mentioned, that we expect on the sexual dysfunction profile, so we believe our strategy should be to maintain the course and utilise this data and incorporate it to continue to build this as the most complete antidepressant.

0.37.53

Peter Sehested

Okay, just perhaps one follow-up because in the meantime, for the past couple of years at least, I have seen you and your partners sponsoring some CME activities relating to cognition etc., I just wondered whether you in your interaction with physicians etc. have seen increased interest for this given your activity in the space? Thank you.

0.38.17

Peter Anastasiou

Yeah, I will just make one additional comment on that. Yes, it has been an effort for us to help clinicians understand that cognitive symptoms including slow processing speed are an important part of the disease presentation and so certainly those educational efforts have been helpful and we have seen in our interactions with physicians that there is a growing awareness of that symptomatology being present and an increase in certain clinicians looking for and asking for those symptoms and we would expect that to continue to progress.

0.38.51

Anders Götzsche

But it is important to say that we have not in the past been able to talk about in the field about cognitive improvement. It is only because we have a label update now. The extension of the label gives us the opportunity to now go out to the physicians and talk about cognition.

0.39.13

Peter Sehested

Thank you.

0.39.16

Operator

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

0.39.23

Emily Field

Uhm, hi, following up on the comments you made on Onfi's impact, the genericization impact on the margins, I was wondering if you could give some additional clarification on your expectation that you expect gross margins to continue to improve over the coming years since it looks like that won't be linear? And then also if you could quantify the impact, that positive impact that hedging had on the margin, has that played into the decision not to raise guidance? And then also just following up on the second generic entrance for Sabril, if you have seen changes in terms of the market dynamics and if you have any visibility into any forthcoming generics in the pipeline?

0.40.02

Anders Götzsche

I think Peter, maybe you could start with the question regarding Sabril?

0.40.05

Peter Anastasiou

Yeah, as you probably know, a second generic just entered the supply chain. It is important to note that so far we have two generics but it is only for the sachet version, there is no generics yet for the tablet version. It is too early to say what impact that has but up until this point, we have been able to hold onto roughly 70% of the branded business, so how that will progress is an uncertainty, as Anders had mentioned in the beginning of his presentation.

0.40.38

Anders Götzsche

Okay and for the hedging, what we have said explicitly is that we expect up to DKK 400 million in hedging gain this year and we have realised DKK 180 million in the first quarter and based on the majority of the impact from hedging is of course the USD and if you look into the USD curve compared to Euro and DKK last year, then you will see that the really declining pattern started in May and therefore the biggest impact from hedging gains will be basically in the first half of 2018 and then they will be declining. So from a profitability point of view you can see that we have booked DKK 182 million and you can take them out from the top line and the bottom line or the EBIT line then you can see what is the impact on the profitability. So, and from a gross margin point of view, we expect that we can more or less improve our gross margin with 7-8% from now on and it will take kind of 5-7 years before we reach that.

0.41.55

Emily Field

Okay, thank you.

0.41.58

Operator

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

0.42.03

Peter Welford

Hi, thanks for taking my questions. Just firstly with regard to Onfi, I wonder if you could quantify the amount of OPEX that there is approximately behind that product at the moment just so we can think about what sort of could be taken out there and any, is there any sort of synergy between Onfi and any other products? Going on then to the TESD indication for Trintellix, I am just curious as to what took the time delay between the initial study reading out and then pursuing the indication with FDA. Was there sort of initial discussions with the regulator that prompted this or perhaps you could just sort of explain what led to the decision to file this sNDA. And then just on the cognition. I know you have already been doing sort of DTC campaigns, talking about the sort of cloud if you like, that people experience and presumably doctors are sort of aware of the publications that are already out there. So I guess from a practical point of view, how do you think this now is going to have a big impact on your both DTC and marketing of the drug and perhaps you could just outline sort of what is it you are planning to do on the get-go. And then finally, did you say 5-8 years to improve both margins 6-7%? That is great. Thank you.

0.43.21

Anders Götzsche

We believe that we can improve our gross margin 7-8% within the next 5-7 years. And then marketing, promotional thinking around cognition, Peter?

0.43.35

Peter Anastasiou

Yeah, so as I mentioned before, our approach is to incorporate this into what we have been doing because core efficacy in depression is the key area that clinicians want to hear

about and this is added information that, as Anders pointed out, we were not able to speak to clinicians about. The publications have been out but now this is the first time that we can proactively speak to the data that is in the label so certainly we will be incorporating that and in terms of DTC and other things, you should expect us to continue to do the types of things that we have been doing that have led to the strong continued growth, four years into the launch of the product we still see very strong growth and you should expect us to continue that type of work of course through the part of that effort we will be evolving our messaging over time to incorporate all of the great bits of data that we get, not just cognition but also hopefully if the sNDA is approved, treatment-emergent sexual dysfunction as well.

0.44.37

Anders Götzsche

And Anders Gersel would like to explain about the treatment of sexual dysfunction.

0.44.45

Anders Gersel Pedersen

Yeah, the study that was published in 2014 was in itself not a sufficient study. We needed to have another study concluded and that has been part of the package that has been submitted to the FDA so it is following a fairly regular cycle, we haven't been waiting on submitting anything here. So we are basically seeing that as going through the process now and expecting with the PDUFA date to have the results out in, I believe it is October.

0.45.19

Anders Götzsche

Onfi?

Peter Anastasiou

Yes, so with Onfi of course we won't get into the specifics of how much SG&A we have behind the asset but of course we will continue to promote the product all the way up until we lose exclusivity because it is continuing to grow very strongly, as you see, and then certainly over time we will identify synergies and economies that exist with our other business and as you know from a neurology point of view, we still have a very important product that we need to promote and is doing quite well in terms of its growth in North America so we will continue our neurology focus on continuing to establish that product in the treatment of NOH.

0.46.08

Anders Götzsche

Okay. Next question?

0.46.10

Operator

Thank you. Our next question comes from the line of Marietta Miemietz from Primavenue. Please go ahead, your line is open.

0.46.16

Marietta Miemietz

Thank you. I have a few product questions, please. The first one is on Trintellix life cycle management. Can you just update us how we should think about the scope and timelines as any potential additional studies and potential big indications like anxiety? Second question on Foliglurax, can you just share with us very high levels sort of the gating factor for phase III decisions? Should we expect that if the phase II that is currently ongoing pans out really well, you might actually go straight into a phase III or what would you really need to have confidence on before you go into a phase III in this relatively difficult indication and very high level, I mean what would a phase III design potentially look like in terms of scope, end points, follow-up time, timelines overall? And my final question is on Carnexiv, can you just give us any pointers as to how you might be able to monetise this asset? Is there any reason to assume that another player might be able to fix the manufacturing issues more easily or could afford to spend more time and money on this? Thank you so much.

0.47.27

Anders Götzsche

I can start with Carnexiv, you know, we have tried a lot to solve the production issue and we just need to say that we don't have kind of the solution for actually getting this back to the market but I can rule out that somebody else can help us doing that and then we will of course try to sell the product or whatever but you shouldn't expect huge income from that. And then Trintellix life cycle management initiatives, we are for the time being discussing with Takeda what is the next step and we are not willing to disclose what kind of things that we, we have some thinking around life cycle management but what we are focusing on is actually that we get these TCD data approved and also that we now have cognition as extension in the label and that gives us a really, really good hook for actually

going out to the physician, being able to explain why this is an extremely or maybe the best antidepressant in the world and why we believe that more patients should actually have a benefit from Trintellix. Foliglurax we will after, when we have seen data, Anders will in a minute elaborate what will it take to go into phase III but we expect to get data in the first half of 2019. Then we might do some formulation work and then it will take approximately, please rectify me, Anders, if I am wrong, a year before we go into phase III. But maybe you can give a bit more flavour into that.

0.49.07

Anders Gersel Pedersen

That is correct. We expect, even with positive phase II data, that we will not be initiating the phase III programme until sometime in 2020 simply because of optimising production formulation elements around the molecule. In terms of what exactly we will see on the on-time/off-time question in this study, we have not set a solid one point in terms of reduction that we will see but we are absolutely certain that we will take it into phase III directly if we see a sufficiently large impact on the on-time in these patients and we will also, even if it is not the easiest thing, we will carefully monitor the dyskinesia impact on this patient population that we have in this study and on the balance of those two parameters basically decide exactly on what the phase III study should look like to achieve as attractive a label as possible. It is too early without those data for me to go into details about the design of the phase III study but given the nature of the problems that we are talking about, it is fairly short-term studies that we have to do so we expect that it will not be really long-term studies that we have to conduct in these patients.

0.50.43

Marietta Miemietz

Great, thank you.

0.50.47

Operator

Thank you. Ladies and gentlemen, as a reminder, if you do wish to ask a question, please press 01 on your telephone keypad now. Our next question comes from the line of Carsten Lønborg Madsen from SEB. Please go ahead, your line is open.

0.51.04

Carsten Lønborg Madsen

Thank you very much and then Anders, in relation to this gross margin improvement of 7-8 percentage points, just in order for you not to change your long-term targets on this call, could you perhaps also maybe talk a little bit about the other ratios, sales marketing, R&D sales etc., how they will move because otherwise you are getting likely above 30% in terms of the reported EBIT margin. And then also on the US market you report, not report but in local currency you have 19% growth. Are there any other products where you are seeing inventory build-up or something like that? So, if possible, you could maybe break it down in demand and price. And finally on Onfi, do you expect a reversal of this inventory build-up in the coming quarters? Because it sounds a little bit odd that inventories are increased ahead of a patent expiration. Thanks.

0.52.03

Anders Götzsche

From a cost ratio perspective, I think you should anticipate that going forward we would be closer to 18% in our R&D ratio but it will of course be very dependent on what kind of products we have in the portfolio so as you can see, we are using 15.5% of revenue in R&D and we anticipate between 16-17% but I definitely hope that we are so successful that we can move our percentage up to around 18% because that also means that we have more growth perspective going forward. Then from an SG&A point of view, we are expecting a level of SG&A to be pretty, from a nominal point of view to be at the same level in the years to come we are ramping a bit up in China, adding 100-200 additional folks to actually promote Azilect and Brintellix but except for that then you should expect it to be pretty flat.

0.53.19

Carsten Lønborg Madsen

... and the year-end number? I was just.. SG&A, you say, pretty flat, was that from the year-end number or is it compared to the 31.4% of sales?

0.53.34

Anders Götzsche

No, I am not referring to a percentage. What I am referring to is a nominal value so what we expect this year is to have a SG&A margin of around 33-35% and when we get to that number, we expect it to be, for the next 3-4 years to be only increasing very little and that is the increase we might have is only due to that we are adding some more folks in China to take, to continue to grow there. But if you exclude that, then it is a very modest or a small increase.

0.54.16

Carsten Lønborg Madsen

Okay.

0.54.20

Operator

Thank you. Our next question comes from the line of Marcus Koch from UBS. Please go ahead, your line is open.

0.54.26

Marcus Koch

Hi, this is Marcus Koch from UBS. Thank you for taking my question. One on Trintellix, so Trintellix still came in below market expectations so what are in your view the key challenges for its commercial uptake in the US? Are they primarily reimbursement related, formulary coverage, does patient affordability play a role? I particularly think of the Medicare population and what are you going to do about that? Thank you.

0.54.57

Anders Götzsche

I can start, you know, we are definitely not disappointed or believe we come in below our own expectation for Trintellix. If you look into the script numbers, we actually believe that every time, you have seen for the past years that when you come into the first quarter, you will see a small dip due to the high deductible new insurance plans, all that kind of stuff. So we are actually exceeding our own expectations and we actually believe that the growth numbers that we are seeing for Trintellix in the US are where they should be and for the remaining part of your question, I will hand over to Peter to actually elaborate if there is anything but basically, or I can also conclude it, we do not see any market access issues, you know, we are actually where we want to be, we are back at formulary at UnitedHealth with full coverage, we have taken price increases as we have done in the previous years and the gross/net percentage has only increased slightly so basically there is no fundamental change for Trintellix in the US and we are extremely happy with the uptake that we are seeing and then we get, we have this very surprising news about getting extension to the label so I think we are good to go for a nice development during 2018.

0.56.33

Marcus Koch

Okay, thank you.

0.56.36

Operator

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

0.56.50

Jacob Lademann

Now it is unmuted, thank you, thanks for taking my questions. Two questions on Onfi, please. You mention in the report that you have seen the first generic being tentatively approved by the FDA. Could you just confirm that you only know of one generic or how many you know of in that case? And also, could you also just please confirm that this generic does not qualify for 180 days exclusivity under the Hatch-Waxman Act. Thank you.

0.57.21

Peter Anastasiou

Yes, we can confirm actually that there are two now, generics that have tentative approval and I want to emphasize what tentative approval means. We have orphan regulatory exclusivity with Onfi so there is no risk that generic could launch sooner than that. What the tentative approval just means is in the FDA's view that the product is sufficient to be launched but cannot launch until the exclusivity ends.

0.57.53

Jacob Lademann

That's great, thanks.

0.57.58

Operator

Thank you. As there are no further questions, I will hand back the conference to our speakers.

0.58.03

Anders Götzsche

So thank you very much for your interest in Lundbeck. Thank you very much for taking the time to listen to the teleconference and also coming with all these great questions. So have a great day. See you soon.