

H. Lundbeck A/S**Transcript: Conference call****Date & time: 07 November 2018 at 13.00**

Operator

Ladies and gentlemen, welcome to the H. Lundbeck interim report for the third quarter, the first nine months of 2018. 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. Today, I am pleased to present Debora Dunsire, the President and CEO, Anders Götzsche, the Executive Vice President and CFO, and Anders Gersel Pedersen, the Executive Vice President, Research and Development. Speakers please begin.

0.00.34

Deborah Dunsire

Thank you very much, operator, and thank you all for your interest in Lundbeck. Welcome to this Lundbeck teleconference covering our financial report for the first nine months of 2018. Together with me, our chief financial officer Anders Götzsche, our head of R&D Anders Gersel Pedersen, Peter Anastasiou, EVP of North America, Jacob Tolstrup, EVP of Commercial Operations.

On slide 2 you can see the company's disclaimer which I know you have read many times before so I won't read it out. Let us go directly to slide 3. Firstly, as this is the first time we are talking since I joined Lundbeck on 3 September, let me start with some comments on why I chose to join Lundbeck and how I see the future. Lundbeck has had a long and successful history of bringing new medicines forward in the fields of neurology and psychiatry to drive better outcomes for people living with these diseases. It is a company that is held in high regard by physicians and investigators in the field for our commitment to advancing care in these fields. It is also a company with a strong reputation for integrity, both in science and business practices. It is a privilege to be invited to lead such a company. It also fits with my personal objective as a physician working in this industry to spend my energy to tackle the areas of highest unmet need and bring forward transformative medicines. The patients with diseases in the area of neurology and psychiatry carry an enormous burden with their disease and the number of people affected is growing around the world. There is an absolute need for new and improved approaches to care. The first two months with Lundbeck have confirmed that I have joined a passionate, committed and highly skilled team of colleagues around the world. We have a very strong foundation for developing the company further as we pursue our vision to bring new medicines to people living with diseases of the brain and by doing so deliver long-term sustainable growth.

I would like to thank Anders Götzsche for his steady leadership during the transition which helped the company deliver a very strong first nine months. As you might expect with the arrival of a new leader, we are currently conducting a strategic review within the company. And we will be able to speak more about that the next time we talk at the time of our full-year results in February.

What I can say right now is that the company has an ambition to create sustainable, profitable growth through delivering new medicines to patients. We will look to maximise the opportunity with our currently available brands on the market, look to our internal pipeline for acceleration opportunities and the potential for transformative approaches and we will continue to seek to supplement the pipeline with external innovation that fits our strategy and core strengths in the central nervous system.

With that, please turn to slide 4. In the first nine months of the year, we have seen continued improvement in our revenue and profitability. Revenue growth has been solid despite headwinds from exchange rates and generic erosion as well as coming from a continued focus on cost and disciplined investment. While I have been here too short a time to claim credit for this, it is great to see the strength of execution and operational excellence driving these results. They enable us to raise our guidance on both revenue and profitability.

The revenue range will be DKK 17.7 billion to DKK 18.1 billion and on EBIT it will be between DKK 5.1 and 5.4 billion. Revenue grew 12% in local currencies in the period reaching DKK 13.9 billion. Our key products continued growing strongly across all regions of the world achieving 29% growth in local currencies. In parallel with the sales growth, we have managed our costs very effectively. Thus recorded EBIT increased by 28% reaching DKK 4.5 billion and the reported EBIT margin reached 32%. Finally, we see very strong growth in earnings per share of 56%.

Anders Götzsche will shortly discuss the financial performance in more detail and Anders Gersel will provide a brief pipeline update towards the end of the call. Before we go on, I will just acknowledge that the phase III outcome for 35700 announced two weeks ago was a tremendous disappointment for patients whose schizophrenia is not adequately treated with current therapy as well as for us here at Lundbeck. The results from the DAYBREAK Trial demonstrated that 35700 is a safe and well-tolerated antipsychotic medication having a similar efficacy as conventional therapy in this treatment resistant indication. Thus, not achieving the goal we set out for superior performance against current standards of care. We are in the midst of evaluating if there is a viable path forward for 35700.

Importantly, Lundbeck is in a strong financial position as I have already outlined. This gives us the ability to be thoughtful in ensuring that our strategies to drive profitable growth are implemented in the context of our strategic priorities and core capabilities building on the strength of our marketed portfolio and driving forward the strongest assets in that portfolio and selectively supplementing with external innovation.

Please turn to slide 5. We have a marketed portfolio of five key brands which are generating substantial growth up 29% in local currencies. Each of the brands has achieved double-digit growth. Furthermore, all three geographic regions are growing and developing in line with expectations.

China has become Lundbeck's second largest market. The growth in these key brands is a testament to the excellence in execution by the organisation both in development and in sales and marketing around the world.

Please turn to slide no 6. Our North American region is continuing to perform well achieving 10% growth in local currencies, reaching DKK 8.1 billion. Our key brands constitute around 80% of sales and grew 28% in local currencies.

For the full year of 2018, North America is expected to grow in local currencies despite the expected negative effect from the loss of exclusivity on Onfi in October. Europe has seen a nice turnaround and is now growing by 7% to DKK 2.3 billion driven by our key products which constitute 43% of sales.

The largest markets for Lundbeck in Europe are France, Italy and Spain which constitute around 45% of sales in the region. REXULTI has now been formally approved for schizophrenia in Europe including Switzerland, and we expect to start launching it from the first half of 2019.

International markets increased 13% in local currencies reaching DKK 2.8 billion for the period. These markets constitute 21% of our revenue. This region is still in the early part of the roll-out for our key products. Those products grew by 41% in local currencies. We expect to see significant long-term growth for these products in the region.

The largest markets in our international markets arena are China, Brazil, Japan and South Korea. Japan is an investment area for Lundbeck as we will establish our own commercial organisation here for the expected launch of Trintellix pending approval next year.

In China, our second largest market, we have recently launched Azilect and Brintellix. We will now touch in more detail on each of the key brands.

Please turn to slide 7. Revenue from Brintellix or Trintellix reached DKK 1.5 billion in the period of which 55% was generated in North America. In the US, Trintellix has a volume share of 0.8% and a value share of 21% and both are still increasing. Brintellix in Europe and international markets is also growing nicely. In the three large European markets, France, Italy and Spain, we see volume market shares now exceeding 2% and value shares in the 6-7% range with continued strong momentum.

We also see a solid performance in countries such as South Korea and Canada and Brintellix has recently launched in China. Trintellix' strong continued growth five years post approval reflects the market's appreciation of the value it provides in addressing unmet needs for patients with depression.

We foresee the brand continuing to grow well into the future. As you are aware, we achieved revised labelling in the US earlier in 2018 regarding the inclusion of processing speed, a key marker for cognition in depressed patients. Most recently, the Trintellix benefit and tolerability versus some other medications vis-à-vis Treatment Emergent Sexual Dysfunction is now reflected in the Trintellix label.

Turning to slide 8. Rexulti is still mainly a US franchise and outside North America it is only launched currently in Australia but in the coming months, we will commence the launch in markets in Europe as well as Saudi Arabia and Mexico. As you can see from the graph at the right-hand side of the slide, the significant uptake continues and momentum looks solid.

In terms of revenue, Rexulti achieved DKK 1.2 billion in sales for the period representing very strong growth of 42% in local currencies. The w/w growth continues to outpace the branded market in general and the uptake is strong relative to prior anti-psychotic product launches. The volume share is approaching 0.6% in Canada and 1% in Australia. Both countries where Rexulti is only approved for schizophrenia.

In the US, the volume share has reached 1.5% and the value market share exceeds 13%. We continue to have high expectations for this product as Rexulti has an attractive profile and is highly regarded by the medical community.

Turning to slide 9. Abilify Maintena grew 23% in local currencies to approximately DKK 1.2 billion through the nine months, primarily driven by growth in Europe. Abilify Maintena's volume share now exceeds 20% in most markets and is continuing to gain market share. In markets such as Italy, UK and Canada, we even see shares exceeding 25%.

In the US, we have seen a positive effect from the approval of bipolar disorder last year and the value share has increased to 22%. Abilify Maintena is the second most prescribed long-acting injectable treatment for patients with schizophrenia in many markets. The overall growth in the LAI market is relatively stable around 13% reflecting the importance of this form of delivery in managing patients' illness.

I will now turn to slide 10. Northera grew 16% in local currencies to DKK 1.3 billion for the period. We see continued growth for Northera in the future although sales growth in Q3 was negatively impacted by a number of factors, including inventory fluctuations and a temporary backlog of patients in process awaiting therapy. The backlog is expected to clear in the fourth quarter.

Next slide, please. Onfi grew an impressive 30% in local currencies to DKK 2.7 billion. As expected, the product lost exclusivity on 21 October and we have already seen several introductions of generic clobazam for both tablets and liquid. Additionally, we see unusually aggressive pricing by the generic companies.

Given that we are only a couple of weeks into this process, it is difficult to assess the impact exactly, but we are monitoring it closely. As we have previously communicated, we will see a significant erosion of the product in the coming quarters.

I will now hand the microphone over to Anders Götzsche.

0.15.16

Anders Götzsche

Thanks, Deborah. Please turn to slide 12. Clearly, the negative development in our main currencies are impacting our revenue performance, especially in North America and

international markets, being visible on the table at the right side. In local currencies, we see solid growth in all regions and strong growth for our key products.

In order for you to better assess the operational performance, we have from the first quarter this year split out the effect from hedging into a separate line item instead of distributing them to the individual products. As the US dollar has declined since last year, we have recognised a gain of DKK 308 million in hedging impact. I will get to the cost ratios in a minute.

The effective tax rate has declined and consequently we see very strong growth in our net profit and subsequently our earnings per share which have grown by 57% and 56%, respectively.

Cost of sales declined 11% to DKK 1.6 billion while at the same time growing the top line by 8%.

Our gross margin has therefore improved following improved product mix with reduced royalties and lower amortisation, thereby reaching 81.3% for this period compared to 77.3% for the same period last year.

For this year, for the full year 2018, we still expect the gross margin to reach a level of 80-82%. The SG&A cost decreased from DKK 4.8 billion to DKK 4.4 billion, which is a decline of 7.6%. The SG&A ratio for the period was 31.7% compared to 37.1% the year before.

The SG&A ratio for the full year 2018 is expected to improve compared to 2017 and we still expect to reach a level around 33-35%. R&D costs increased by 19% to DKK 2.3 billion, representing 16.4% of revenue.

We expect the R&D ratio to increase to a level around 17% for the full year and will likely increase further next year. Based on these cost ratios, the EBIT margin has improved significantly from last year. The margin improved from 27.1% to 32%.

Next slide, please. Lundbeck continues to generate a very strong cash flow. The cash flow from operations has increased by 70% to DKK 4.6 billion. Following the strong increase in the company's operating profit and decline in tax rate, Lundbeck has also shown a

significant improvement in our return on invested capital. Net cash increased to DKK 5.4 billion by the end of the quarter, up 46%.

Our operations have generated 5.3 billion kroner in positive cash flow. Investments include the acquisition of Prexton as we did in March 2018, of EUR 100 million and the EU approval milestone of Rexulti of \$ 50 million.

We expect net cash to be around DKK 5.5 billion by the end of 2018.

Next slide, please. We have had a very good performance so far though 2018 and we expect continued growth for our key products and growth in all three regions in local currencies for the year. 2018 and especially the fourth quarter will be impacted by introductions of generic versions of Onfi and continued generic erosion on Xenazine and Sabril. However, we do see room for erasing the guidance – the outlook for 2018 revenue is now expected to reach DKK 17.7 – 18.1 billion versus previously a range of DKK 17.6 to 18.0 billion.

We expect to see continued improvement in our profitability in 2018 and EBIT is now expected to reach between DKK 5.1 and 5.4 billion compared to previously DKK 4.9 to 5.2 billion for the year, which indicates that the EBIT margin will be at least 28%. Please note that the EBIT in the fourth quarter will benefit from the gain from a settlement made in Australia.

For the financial items, you should 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 2018 which will also be the range in the near future.

It is important to note that the cash tax rate is somewhat lower and we expect it to be around 20%. I will now hand over to our head of R&D, Anders Gersel Pedersen to go through some updates from our R&D pipeline.

0.21.09

Anders Gersel Pedersen

Thank you, Anders and please turn to slide no. 16. First, let me start by saying that the outcome of the 35700 was a disappointment and illustrates how difficult it is to reach

significant superiority with new medicines, especially for treatment resistant patients and I will get back to that project in a minute.

35700 aside, I am pleased that we have been able to move the portfolio forward and we have in the last 5-6 months been able to take three projects into clinical testing within our core areas. In addition, we have added Foliglurax to the phase 2 pipeline coming in from our acquisition of Prexton Pharmaceuticals in March 2018.

We also continue progression in other areas of the pipeline. Our immunotherapy project for Alzheimer 2513 will start a phase 2 proof of concept study early next year. And in addition, 11167 is about to start phase 2 this year.

We continue the effort of supplementing our pipeline through accessing external innovation, support our own project or to bring in additional assets.

Next slide, please. The headline results are here graphically illustrated and as you know the 35700 programme was designed to tackle the major unmet need of finding a new treatment for patients resistant to conventional therapies. The results demonstrated 35700 to be safe and well tolerated and similarly effective to conventional therapy in this indication. We did not achieve the goal of superiority performance against the current standard of care. This is clearly disappointing news for our patients and the clinical centres that work with us as well as for us internally in Lundbeck.

The 35700 team is now working to fully analyse and better understand the totality of the data. Given our strong financial position, also for the coming years, we have the ability to continue to drive our interesting pipeline forward and we will continue to look at how we can potentially accelerate the programmes within our internal portfolio.

Next slide please. To conclude, we have had a good year on many fronts, both advancing and expanding the pipeline. We are also driving the increased use of big data, machine learning and advanced analytic tools with the goal of streamlining our approach to drug development. This helps us in addressing patient trajectories and in different indication as well as to evaluate key symptomatology development for a lot of patient groups. We also expect that we will have interesting and hopefully positive news flow in the next 12 months or so and we look forward to discussing the advances as they occur in 2019.

Well, now, I will hand back to Deborah for concluding remarks.

0.24.29

Deborah Dunsire

Thank you, Anders. Please turn to slide 19. To summarise, we are delighted to announce very strong sales and earnings for the first nine months of 2018 and upgraded guidance ranges for the full year. Today's financial report confirms our strong financial position with Lundbeck being on track to deliver its best financial results ever. We will face headwinds on revenue growth in the coming quarters as we weather the expected decline in Onfi sales. While the setback with 35700 is obviously a great disappointment, we have also had good progress in our earlier R&D work with four new projects moved into the clinical pipeline. We will continue to build our future strategy on Lundbeck's core strength, our skills and knowledge in disease biology and technologies within psychiatry and neurology. We will optimise the company's ability to create long-term sustainable growth by capitalising on the marketed brands, advancing and indeed accelerating assets within our internal R&D pipeline and supplementing those with high-quality external innovation as we refresh and replenish our pipeline. We are looking forward to presenting the conclusions from our strategic review with the annual report in 2018 early next year. With that I would like to thank you all for your interest and open the question and answer session. Thank you.

0.26.06

Operator

Thank you. Ladies and gentlemen, if you have a question for the speakers, please press 01 on your telephone keypad. And our first question comes from the line of Trung Huynh of Credit Suisse. Please go ahead. Your line is now open.

0.26.24

Trung Huynh

Hello. Trung from Credit Suisse. Thanks for taking my questions and congratulations to Deborah on joining the team. I have three if I may. So firstly, you have been in your new role now for two months. Can you tell us your initial impressions? What surprised you positively or on the flip side, what surprised you negatively since joining Lundbeck? Secondly, you note you are conducting this thorough review of the company. Just on your priorities for cash, could you give us an idea of what areas of focus you are looking at? Lundbeck has spoken about doing smaller deals in the past, returning more economics. Has that view changed? And then finally, just a product question on Northera, sales were lower Y/Y, you mention an inventory fluctuation and administrative burdens causing this backlog to patients. Can you give us more colour to these issues? And what gives you confidence in reversing them and potentially what size is this backlog? Thanks very much.

0.27.31

Deborah Dunsire

Thanks for your questions. The first two months at Lundbeck I think have confirmed what I saw from the outside. It is a company with a great heritage, a real passion and commitment around the patients facing the burden of diseases of the brain and that heritage is built on really strong skills and understanding in the area. It has been tremendous to get to know the people within the company and see those skills and that passion manifest really throughout the organisation. Not only here in Denmark, but also around the world. So, nothing that I saw from the outside has been refuted when I came to the inside. In fact, my perceptions have been strengthened.

Your second question with respect to the review ongoing and our priorities for cash. I would not pre-empt that review by coming up with any conclusions but I reiterate we need to invest for growth and we will need to invest behind our marketed brands to be sure that we can capitalise on the right patients and the best patients for those brands, accelerate the internal pipeline and look for opportunities and indications where we may be able to streamline and accelerate development and then on the external innovation side look at all potential avenues for growth be it licensing, partnership or acquisitions. We don't only have one thing in mind. What is critical is that any investment we make, we need to consider in the framework of creating long-term profitable growth for the company so with every investment we will be asking ourselves the question: How will we gain a return for our shareholders based on this investment.

We are on a very strong financial foundation so we can afford to be thoughtful and disciplined in our criteria for return as we approach both internal and external investments.

A third question on Northera I am going to hand over to Peter, our head of the North American business to take that in detail.

0.29.46

Peter Anastasiou

Yes, first I want to reiterate that there was clearly underlying demand growth for Northera and so on the two specific issues that you ask about are in terms of inventory fluctuations. Of course, there are always fluctuations that occur between quarter to quarter. That clearly happened in our view between Q2 and Q3 that affects Q3 numbers and then also on the backlog let me describe that for a second. So, we have a call centre that does the

intake of prescriptions and processes those prescriptions. That call centre moved from one location to another and there were unexpected issues with that move that led to the backlog of patients being processed. And we are on track as we said in the release to have that backlog resolved in the fourth quarter and then to your question about what to expect for the future, certainly our guidance that we issued as part of this release incorporates what we expect for Northera in Q4. Finally, I would end by saying on Northera that there still remains a tremendous unmet need in the nOH market. There is a growing recognition of nOH, neurogenic orthostatic hypotension as an issue in neurologic diseases like Parkinson's and the drug continues to deliver great results and is very tolerable and is of course the only product that is indicative for symptomatic relief of nOH.

0.31.16

Trung Huynh

Thank you very much

0.31.19

Operator

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

0.31.26

James Gordon

Hello, thanks for taking the questions, a couple of questions, please. One was a question about R&D reinvestment and not looking for exact guidance but just more generally, you stated that the DKK 2.6 to 3 billion that Lundbeck has invested in R&D or reinvested in R&D is efficient to drive the sort of top-line growth that you desire for the company or is it a fair assumption that with your R&D background and ambition that we should assume a significant step-up in investment in R&D over the next few years? The second question was just about balance sheet optionality and the sort of timing with which you might deploy that in a meaningful way. Is it fair to assume you would want a long time to go through the existing business or could a conclusion in February be that you are already ready to start deploying the balance sheet in a meaningful way in 2019? And then just a follow-up on Northera, is it possible to quantify at all the impact of the destock and quantify the magnitude of the patient backlog so can we say something like how many patients are in the backlog relative to how many patients are in therapy and what the magnitude was so we can try and work out what the cleaner growth rate was for the quarter?

0.32.33

Deborah Dunsire

Thanks for your questions, James. I will start on R&D investments and then Anders Götzsche and Peter Anastasiou will answer. I think that for R&D investment, both internally and in the external innovation, will be guided by the potential ability for contribution to long-term profitable growth, so within our own pipeline, we will be looking for those acceleration opportunities and products that we bring in from external innovation may need development resources, so I think that we will continue to deploy our resources against building new growth into the pipeline and we will use the capital thoughtfully and sensibly so I am not suggesting a huge step-up or a step-down but we will be making decisions to invest for the future. Anders, do you want to comment?

0.33.32

Anders Götzsche

Yeah and along these lines, what Deborah is illustrating, what we have said earlier is I think, what I can hear from Deborah, she is very much in alignment with that, you know, if we find good opportunities where we can see value creation, we have also said in the past, would we be scared to death to go to 20% of revenue or a nominal value beyond 3 billion which is kind of the magnitude of the investments? Definitely not. But of course, as Deborah also described, we will of course make proof testing of is it something that creates value in the long run? And we are in a very good position and we have guided you that we expect to use around 18% and it is always good to have kind of a threshold or a bar where we say if we want to go above that, then we need internally to discuss thoroughly what are we investing in because we are in for the long run, we want to create value for the investors and for the company and then if your question is, James, what about the balance sheet? We have a strong cash position and we are making the strategic review and then we will find out the different ways of creating growth but definitely, as we have been seeing for the last 3-4 years, we have created a lot of growth and we have a strong financial position and of course we can leverage on that when we want to create even more nominal growth to the business.

0.35.02

Deborah Dunsire

I think it's a great position to be in, a strong financial foundation that means that we can find interesting assets, we can be outwardly looking, invest in the internal pipeline but not have to do anything in a rush and immediately, so you can count on us to be very disciplined in our investment criteria and our return criteria.

0.35.26

Peter Anastasiou

And then, James, this is Peter, I will try to give a little bit additional colour to your question, so first of all, we don't give specific details on inventory and patient levels and that sort of thing but I will say that the backlog is expected to be resolved in Q4, there was demand growth in Q3 and we expect continued demand growth and the specific numbers are embedded in our guidance that we just issued and I reiterate that this backlog issue is a temporary phenomenon.

0.35.59

James Gordon

Thank you

Operator

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

Wimal Kapadia

Great, thanks for taking my questions, Wimal Kapadia, Bernstein, just a couple, please. For the first one on the pharma revenues, clearly you continue to do quite well driven by contract manufacturing, can you provide a little more colour here, how should we think about this line moving forward? My second question is on 35700, just your thoughts on whether a longer study would have led to a superior outcome and is this something that the company may consider moving forward and then just a follow-up on Northera again, so I appreciate that inventory and distribution issues drove some of the weakness in the quarter but could you touch on the high patient out of pocket cost and the administration burden for physicians and is that something that will continue to be a drag on the products moving forward? Thank you very much.

0.36.58

Deborah Dunsire

Thank you, Wimal, for your question. I am going to hand over to Anders Götzsche to take the question on contract manufacturing and then Anders Gersel Pedersen will respond on 35700. Peter Anastasiou will respond on Northera.

0.37.14

Anders Götzsche

Okay, I can start with the other revenue. You are fully right that we have seen very good growth in that and that is of course, as you know, that what we are doing with our manufacturing sites is that we primarily produce our own products but of course we try to optimise whatever we can all the time and we have seen solid growth and we actually also have good margins on that business and it will also continue to grow in that you see that the growth for the full year will be pretty substantial. But it is also, you know, we get contracts in, we are losing contracts, so you cannot, you should not build into your financial model that it will continue to grow but we expect it to continue with the levels that we see in 2018 into 2019, if it will be flat or growing, it is too early to speculate in that but we will not continue to see this very high double digit growth rate going forward because there is also a limit to how much we can actually take into the factory but it will be very profitable so that is nice.

0.38.21

Anders Gersel Pedersen

This is Anders Gersel, I will just comment on the 35700, your question as to whether a longer-term study would be more successful than the current one that we have conducted. First and foremost, we clearly would not know because we would have to do that to answer the question but if you look at the data that we have seen so far, we do not believe that that is the case. We think that we have already with a ten week study compared to normally running these studies in schizophrenics for about 6-8 weeks that we have extended it that clearly did not indicate a trend toward an increased separation when you went out at the longer time points so we have no reason to believe that and therefore we are also pretty clear on the fact that we don't expect to be able to go forward with TRS treatment-resistant schizophrenia as an indication but obviously we will look at the data, do the best we can in terms of understanding there but I don't think that that is a viable path forward.

0.39.32

Peter Anastasiou

And then, Wimal, on your question about Northera, first, I just want to point out that the questions you asked about a high cost and administrative burden are not new phenomena. If you go back and look at past releases, we have referenced these and those have been embedded in the performance we have observed in the past and are not new phenomena and certainly, we have been working through all those challenges and as it relates to administrative burden, most of that refers to, of course, the resetting of high deductibles and a number of different factors at the beginning of the year and some of the seasonality that we have observed with Northera but those are not new phenomena.

0.40.12

Wimal Kapadia

Great, thanks very much.

Operator

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

0.40.22

Michael Novod

Yes, thank you very much, it's Michael from Nordea. Just one question on the guidance you implicitly give for Q4 on EBIT, somewhere around DKK 650 million to 1 billion and that includes possibly DKK 100 million in one-off, so if we look for 2019, could you comment on whether you see it as sort of an annualisation if you do that, is that a fair level or should we expect that the Q4 2018 also includes an excessive amount of costs for additional promotion etc.? And then secondly on Onfi, you see in the pricing, of course, which you also mention, do you see anything in the channels that we can't see, i.e. should we also expect some sort of destocking going into Q4? And then lastly on the potential competition from Epidiolex because we did see with Xenazine that as long as there were only generics, I know there is not as many as on Onfi, there wasn't the greatest impact and then came some branded new products into the market, so where do you see Onfi in terms of Epidiolex competition?

0.41.42

Deborah Dunsire

So I think on the fourth quarter, I am gonna ask Anders Götzsche to comment on how we are thinking about the fourth quarter cost structure going forward, it has traditionally been a quarter where promotional costs have ramped up as people come back in from the summer but I will hand to Anders for that and then Peter will take the Onfi and Epidiolex questions. Anders?

0.42.06

Anders Götzsche

And Deborah is fully right, you have also seen that in the past. We have a high activity level ongoing in the commercial business, actually starting in September after coming back

from holiday in Southern parts of Europe and other places so we see a high level of activity which also means cost but of course, I still think it will be a pretty good quarter, if you see 3-4-5 years back, it was much lower but of course, it will not be one of the best quarters in the year and of course, there will via the broad range revenue-wise, it is also a signal that we basically don't know how fast the erosion is going for Onfi, you know, we can see what you can see, that a multiple number of generics are ready to launch or are making pipeline filling but we do not have any insight into how will the numbers actually play out and that also means, I think it is way too early for us to speculate in 2019 before we have seen the data in November, December and until mid-January before we start to take any conclusion and of how fast will the erosion actually be.

0.43.24

Peter Anastasiou

Yes and I will also add, with regards to your Epidiolex question, so it's a different situation with Epidiolex and Onfi than with Xenazine and the other products that you were mentioning. With Xenazine, those products would be potential replacements or will be instead of Xenazine, it would be unlikely that a doctor would use both tetrabenazine and deuterated tetrabenazine. In the case of Epidiolex, it's an adjunct treatment to Onfi, actually the trials were done in utilisation with Onfi, so we don't see Epidiolex displacing Onfi, we see it being used concomitantly so we don't expect an impact.

0.44.05

Michael Novod

Okay, thank you

Operator

Thank you. Our next question comes from the line of Martin Parkhøi of Danske Bank. Please go ahead, your line is open

Martin Parkhøi

Great, thank you very much, I have two or maybe three questions. Firstly, it is to you, Deborah, you comment that you want to create a company with stable growth. If you look at the past 20 years, since Lundbeck was IPO'ed, stability in growth has not really been there, you have some very good years and then you have some very bad years. Isn't this just the nature of operating within the central nervous system diseases, that it is very product-driven so you have to live with the fact that you come through these very rough times sometimes and it would be misleading to direct the company within CNS to be a sustainable growth company? Then, second question is to the pipeline in general. I think

it's a couple of years back, you made this rather rigid pipeline strategy meaning that you only had these four core areas where one of them is depression where you don't have one single product in your pipeline, I don't know if you can see any external candidates which are interesting within depression but is there any chance that you believe they will be more proper now to maybe divert a bit for this strategy and maybe also look at external candidates which are outside your four core areas?

0.45.42

Deborah Dunsire

Thanks for your question, Martin. So, first of all, I think that creating long-term sustainable growth is really taken over a collection of years and I think Anders Götzsche has made the point before, I think it's over the last ten years, this company has increased in value something like three times? Am I correct, Anders?

Yes

And so, when I think about the long-term sustainable growth, it is over that long a period, does it mean every year is going to be a linear progression? No, it does not necessarily and suddenly, we face the year of 2019 with the Onfi expiry so that we will have that headwind in 2019. In the CNS, as you point out, it is very difficult but I think, building a balanced pipeline across all the phases from our own internal discovery and supplemented from externally, we should be able to over the long term create a company that can go forward. This company has over 100 years of history. It is our job as the leadership team to enable it to continue into the decades ahead. With respect to the pipeline and the strategic project ongoing, I don't want to pre-empt it. What we have said is that we will build on Lundbeck's core strengths in knowledge and understanding in psychiatry and neurology and so, let's talk about that more in February when we come together. When I think about growth strategies, I think about building on our sources of competitive strength and our competitive strength is really in the central nervous system area.

0.47.37

Martin Parkhøi

Can I just have a follow-up question? Maybe that is for Anders. Anders, now you are talking about speeding up your own pipeline. Can you give some kind of examples on what you could do differently with the products you have today and maybe give some kind of indication and how much time would you actually gain by doing that?

0.48.00

Anders Gersel Pedersen

Well, first and foremost, Martin, I am not going to go into great details of what some of the opportunities are but we know that there are, you can take products forward for example in more than one single indication as a way to go forward, that is a way of doing it, and you can decide how are you going to, often with regulators also, can you advance programmes and get to earlier POCs and potentially build on that and that are some of the things that we are actually working on right now and I think with respect to your particular question about depression then I think it is quite clear that that is a very tough area because of the very generic label that currently exists across that area but we are working diligently in that, trying to understand what are segments and groups that you can actually tackle there and potentially get some differential position. But we will not take molecules into the clinic until we have a clear view on what would be a winning strategy in that respect. We do still have, as you full well know, the Trintellix on the market for depression for quite some years with data and patent protection on that so we do have time to accelerate other products that we think would potentially be able to come back on that and on top of that, we also have Rexulti for adjunct therapy, as you know, so it is not that we are abandoning the depression per se but we don't want to take molecules into an area if we don't see a clear differential position there.

0.49.35

Martin Parkhøj

But I guess you are also bringing in more risk by speeding up the pipeline, I guess it would also be a possibility for you to do a DayBreak 2 and a DayBreak 1 at the same time, you didn't decide to do that and now it appears to be a very good idea because then you have used a lot of money, so in reality, it also means if you do more indication at the same time, I guess you are also bringing in more risk?

0.49.56

Anders Gersel Pedersen

Yeah, in theory, you could say yes, but the reason that we have done them the way we have and I think the notion about the DayBreak was that if you move into a study like the DayBreak study, the difference between doing a classical prove of concept study and actually doing it as a pivotal study, given the way the design of these studies run, it is that you would actually lose a lot of both timing but also money in selecting out patients in underpowering a study simply for going for a prove of concept-round making pivotal immediately, so that is some of the decisions we made at that time, clearly knowing that we did not have a POC before we went in there. There are other ways of doing POC studies that lead to a position where you can decide to move on from and they may not

be pivotal in themselves but just supportive or indicative of where you are heading so that does not necessarily increase your risk, even if you go for more than one indication.

0.50.57

Martin Parkhøi

Thank you very much

Operator

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

0.51.09

Tim Race

Okay, thank you, thanks for taking my questions. Just looking at the things that you can control in terms of spend to 2019, with Onfi and Sabril obviously losing exclusivity, are there further costs that you can reduce here? And how should we sort of look at SG&A versus the additional spend you need to make in Europe for Rexulti? Should we expect SG&A to be relatively stable next year, up, down? I mean, where are the offsets here? Because essentially, you are implying, I think, that R&D is going up to the percentage of sales which, do you mean that in terms of other absolute percentages next year as well? Anders, just try to help us understand the cost structure of the business and within the current forecast in the sales. Thank you.

0.51.56

Deborah Dunsire

So, I think, your question going into 2019, with respect to Onfi and Sabril, I am going to actually turn it over to Anders Götzsche to comment on that.

0.52.08

Anders Götzsche

So, Tim, what you should expect and that is totally consistent with what we have also said during the last year is that you should expect SG&A to be pretty much at the same level as we have this year and how come that we expect that? It is that we are investing in Japan and China, we are ramping up there and then we are taking out cost in other parts of the

business, we are taking some cost out in the US and in general, we are looking at cost, which means that we will be able to ramp up in China and Japan without increasing our cost base. And from an R&D perspective, what I meant when we were commenting on the slides was that you should expect basically the same percentage of sales as R&D costs but of course, if there is anything that we find out that instead of using 18% that we can move something forward, that would mean that we need to use a bit more of R&D costs, we would not be scared to do so but for the time being, it is our intention to use around 18%.

0.53.24

Deborah Dunsire

And Jacob, would you like to comment at, I think that Tim had raised Rexulti in Europe, as we go through the launches there?

0.53.30

Jacob Tolstrup

Yeah, sure, absolutely. So, you know, we have the approval, Tim, of Rexulti in Europe and I think also the last quarter, we said that growth will take place or sorry, launch will take place of Rexulti in Europe in the spring of 2019 and that is still the case, so we are rolling out Rexulti to more and more countries, we will be launching in Saudi Arabia this month and then in early 2019, in Mexico and then the first launches will take place in Europe so that is about 13 markets that we will launch Rexulti in from now on and in 2019.

0.54.05

Tim Race

Thank you

Operator

The next question is from the line of Peter Sehested of Handelsbanken. Please go ahead, your line is now open.

0.54.16

Peter Sehested

Yeah hi, it is Peter from Handelsbanken. Yeah, I guess most of my questions have already been answered so I will be so polite as to jump back out of the queue. Thank you.

0.54.26

Operator

Okay, if anyone else has any question and they are in the queue and they want to remove themselves from the queue, just press 0 and then 2. So, we now go to Marietta Miemietz at Primavenue. Please go ahead, your line is now open.

0.54.38

Marietta Miemietz

Yes, thank you very much for taking my questions, just a couple of points clarification on Lu AF35700, please. I always thought that Lundbeck originally really just wanted to position this as a safe alternative for patients with treatment-resistant schizophrenia without the horrendous side effects that the standard of care has and that superiority in terms of efficacy was never actually expected, so I am just wondering how your view of the profile that the treatment-resistant schizophrenia drug needs to have evolved and why is that the case? Why don't you think that the current profile could potentially be attractive in the marketplace if the safety is very good? And then, given you have terminated treatment-resistant schizophrenia, what could an alternative development plan potentially look like? Because if I remember correctly, Lundbeck also never really thought it made a lot of sense to take such a potent antipsychotic into depression and I am kind of struggling to think of any other indications and also, I am just wondering what do you make of the counter-intuitive dose relationship curve and is there a chance that the low dose you used in the study was actually too high? Thank you very much.

0.55.56

Deborah Dunsire

Okay, so I will start and I will hand over to Anders Gersel Pedersen. I think, to gain a label that includes the words treatment resistance, we have to compare to the currently available therapies, what a patient might otherwise get and we did work with the FDA on the study design and brought in these active comparators so we showed a similar efficacy and a very good safety and tolerability profile but didn't see the superiority and that is what makes us say we wouldn't get a treatment resistant label with the product. With that, I am going to hand it over to Anders Gersel to comment further.

0.56.42

Anders Gersel Pedersen

Yeah, first and foremost, the regulatory path for getting a label as we sought is actually to do the study that we failed in so that is a clear no-go, if you don't win on that, you won't get the label and therefore, you will not have that place in therapy, so I don't think that there is any discussion about that. Then, your next question about the dosing, we think this was the correct dose, we think the 10 mg dose was our ideal target dose that we took forward here and as you normally do with studies of this kind, you have to do some other dosages, notably a higher dose to show that you have reached out what the molecule can cover and that there is no particular side effect so physicians, if you had been successful, would increase the dose and that is why we picked the dosages we did here. We have no reason to believe that a lower dose would be more effective in this particular population. With respect to other indications, I will not preclude what we potentially could consider going forward with this molecule, I would not have great hope for some of your suggestions in that respect but I would just leave it up to the team to look at the data and analyse that and then we will see what comes out of it. At this stage, we would say that the treatment resistant schizophrenia indications as such is not one we will pursue, the likelihood that we will find another one, I will not guess on but obviously having a programme that has failed as this one has, it is always a higher hurdle to make sure you move forward. On the other hand, with a good safety profile, you have reduced certain risks in a programme like this.

0.58.27

Marietta Miemietz

Great, thank you.

Operator

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

0.58.38

Michael Novod

Yeah, I just had a follow-up question on Trintellix. We heard Takeda say that they reported softer Q.. what was that, Q1 or Q2 for them, equal to your Q3, due to a true-up or a prior period adjustment on the rebate. Is that something we then should model in for Q4 in your numbers? Because there is no real correlation between Takeda numbers and Trintellix US sales and US royalties in the US.

0.59.04

Deborah Dunsire

I will ask Anders to take that question.

0.59.07

Anders Götzsche

The clear answer is no, Michael, we don't expect any true-up in the fourth quarter, so what you can see from, we don't normally comment on Takeda's numbers but they have, their expectations for Trintellix in the US is double digit growth continued, which you also are seeing that we are delivering, and you can see that the script trend is continuing to be very nice so we expect that our US organisation will continue together with Takeda to deliver a stellar performance with Trintellix, also in the light that we have two good events this year with treatment-emergent sexual dysfunction coming into the label and the same with speed of processing, so I think we have a lot of good news to go out with in the field and I know that Peter and the team will do their utmost to actually create the same growth numbers next year as we have seen this year in the US, so that is definitely what we aim for so we don't expect any kind of negative surprises.

1.00.14

Michael Novod

And I agree there are a lot of solid growth signs, I was just thinking that that number is of course on the absolute sales number and then your royalty number had to converge at some point in time, unless the royalty rate changes.

Anders Götzsche

We don't expect that

Michael Novod

Okay.

1.00.38

Deborah Dunsire

... Questions. I would like to thank everybody for their interest in Lundbeck and look forward to meeting many of you over the months ahead.

