

H Lundbeck A/S**Transcript: Investor Presentation, Annual report 2018****Date & time: 05 February 2019 at 13.00**

Deborah Dunsire

Thank you very much operator and thank you all for your interest in Lundbeck. We welcome you to this Lundbeck teleconference covering our financial report for 2018. Together with me, our CFO Anders Götzsche, Peter Anastasiou, EVP North America and Jacob Tolstrup EVP, 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. Lundbeck has for 2018 delivered its best financial result ever and we have more than delivered on all our financial targets set in 2016 with solid growth in our top line driven by our key products and we have even stronger growth in our profit. Our R&D effort is also maturing, most recently with our PDE 10 inhibitor, 11167 entering phase 2 and we advanced three novel proprietary molecules into clinical development, though I am very aware that the failure of 35700 was a significant disappointment.

With that, please turn to slide 4. Anders Götzsche will discuss the detail of the financial guidance for 2019. I will simply highlight that the guidance accounts for the significant generic erosion, especially on Onfi, formerly our largest product. That erosion somewhat mitigated by continued solid growth for our other key brands. In the past months, we have been working on our corporate strategy to establish Lundbeck's path to future growth. And I will elaborate on how we will expand and invest to grow towards the end of this discussion. Suffice it so say now that the strategy is firmly rooted in our competitive strength in diseases of the brain across the value chain and continues a disciplined focus on profitability while acknowledging the need to invest in external innovation and internal acceleration to ensure future growth and sustainability.

Please turn to slide 5. In 2018, we have seen continued improvement in our revenue and profitability. Revenue growth has been strong despite headwinds from exchange rates and generic erosion. Profitability grew even more strongly due to continued discipline in investments and focus on cost efficiency. Revenue grew 8% in local currencies in the period reaching DKK 18.1 billion, especially driven by Brintellix, Trintellix and Rexulti. In parallel with the sales growth, we have managed our costs very effectively. Thus, reported EBIT increased by 20% reaching DKK 5.1 billion and the reported EBIT margin reached 29.3%.

Please turn to slide 6. We have a marketed portfolio of five key brands which are generating substantial growth, up 23% in aggregate in local currencies. Each of the brands have delivered double-digit growth in local currencies. 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. 7. Europe has seen a nice turn-around and has grown by 6% to close to DKK 3 billion in 2018. The European growth is a major part of our overall growth and it is driven by our key products constituting 44% of sales in the region. The largest markets for Lundbeck in Europe are France, Italy and Spain which constitute around 46% of the sales in the region. Rexulti has been formally approved for schizophrenia in Europe, including Switzerland where it has recently been launched. International markets increased 10% in local currencies reaching DKK 3.5 billion for the period or 20% of our revenue. This region is still in the early part of the roll-out of our key products which grew by 30%. We expect to see significant long-term growth for these products in the region. The largest markets in our international markets region are China, Japan, South Korea, Brazil and Australia – these markets constitute some 56% of regional sales. Japan is an investment area for Lundbeck as we will establish our own commercial organisation here for the expected launch of Trintellix pending approval towards the end of this year or early in 2020. In China, our second largest market overall, we have recently launched Azilect and Brintellix. Our North American region achieved 6% growth in local currencies reaching DKK 10.7 billion. Our key brands constitute around 80% of sales and grew by 15% in local currencies.

We will now touch on each of the key brands. Please turn to slide 8. Revenue from Brintellix, Trintellix reached DKK 2.2 billion in the period of which 57% was generated in North America. In the US, Trintellix continues as in all other markets to increase its market share. Since July 2018, the value share has increased from 20.8% to 23.1%. In Europe and International Markets, Brintellix is also growing nicely. In Italy, volume market share has reached 2.9% while France and Spain now approach 2.5%. Value shares are in the 6-7% range with continued solid momentum. We also see good growth in countries such as South Korea and Canada. Brintellix/Trintellix continues stronger five years post approval and reflects the market's strong 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 in 2018 for both inclusion of processing speed, a key marker of cognition, as well as Trintellix benefits in tolerability versus some other medications vis-à-vis treatment-emergent sexual dysfunction.

Please turn to slide 9. Rexulti is still mainly a US franchise and outside of North America it is only launched in Australia and Saudi Arabia. The European roll-out commenced on 1

January this year and in the coming months, we will launch in additional markets in Europe and in South and Central America. As you can see from the graph at the right-hand side of the slide, significant uptake continues. In terms of revenue, Rexulti achieved DKK 1.7 billion kroner in sales for the period, which represents growth of 44% 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. In the US, Rexulti's value share has increased from 11.8% to 13.6% in the last six months. We continue to have high expectations for this product as Rexulti has an attractive profile and is highly valued by the medical community.

Please turn to slide 10. Abilify Maintena grew 23% in local currencies to approximately DKK 1.6 billion in 2018, primarily driven by growth in Europe and North America. Maintena's volume share now exceeds 25% in markets such as the UK, Italy and Canada and it is continuing to gain market share. In the US, the value share has increased from 18.9% to 19.8% over the past six months. The volume share is approaching 19%. Abilify Maintena is now the second most prescribed long-acting injectable treatment for patients with schizophrenia in many markets.

Turn to slide 11. Northera grew 15% in local currency finishing the year at DKK 1.8 billion. There have been quite a few moving parts for this product throughout 2018. Most recently, with the patient backlog in the third quarter. The backlog has now normalised, I am glad to say, and we see continued growth for Northera in the future.

Next slide please. Onfi has been an amazing growth driver for Lundbeck, but it has lost exclusivity as of October 2018. Sales grew 12% for the year in local currency achieving close to DKK 3.2 billion. In the fourth quarter, sales were down 40% in line with our expectations following the introduction of several deeply discounted generic versions in October.

Please turn to slide 13. Our early to mid-stage pipeline has some very interesting molecules and we brought three novel medicines into the clinical pipeline in 2018. We also strengthened the phase II pipeline with the acquisition of Foliglurax for Parkinson's disease. And the advancement of 11167 for negative symptoms in schizophrenia late in the year. We anticipate the outcome of the Phase III programme for bipolar mania in Q1 of 2019. 35700 is still under evaluation to assess if there is a feasible development path forward. With respect to 20513, our immunotherapy for Alzheimer's disease, we are evaluating the antibody titres needed to progress the Phase II trials and we will decide on the path forward during 2019 as we further understand the link between titres and desired effect.

Next slide, please. In November last year, Lundbeck and Otsuka announced the achievement of positive clinical results as measured by significant improvement versus placebo in the CAP-5 total score change from baseline for the combination of brexpiprazole with sertraline. The overall safety and tolerability of brexpiprazole were good and comparable to previous data when administered either as a single agent or in a combination of brexpiprazole with sertraline. The companies plan to meet with the US FDA during the first half of 2019 to discuss the results of the Phase II study and the design requirements for a potential Phase III programme. PTSD is an important and growing unmet medical need. As you know, this disorder is precipitated by a range of traumatic events. The core features of PTSD include flashbacks and nightmares, hyper vigilance and irritability to name just a few. And these suggest that treatment with an atypical antipsychotic in addition to an SSRI could be beneficial for these patients.

Next slide, please. Lundbeck has initiated a Phase II proof of concept study with the compound 11167 to confirm its potential as a treatment for patients with schizophrenia who are experiencing persistent negative symptoms. Effective treatment of negative symptoms represents a huge unmet medical need for people with schizophrenia. And no treatments are specifically approved for this indication today. Negative symptoms such as reduced social drive, lack of enjoyment, poor motivation are often the most troublesome for patients and prevent patients from returning to a productive life even if their positive symptoms are controlled. 11167 represents a new and potentially very interesting approach to treat negative symptoms of schizophrenia in patients where positive symptoms are stable. It works by inhibiting the activity of the PDE10 enzyme in the brain. This affects the signalling of neurotransmitter dopamine in a manner that may specifically improve negative symptoms while enabling positive symptoms to remain controlled even in the absence of treatment with a D2 antagonist.

I will now hand the microphone over to Anders Götzsche to expand on the corporate financial picture.

0.14.05

Anders Götzsche

Thanks, Deborah. Please turn to slide 16. Deborah has already elaborated on our revenue performance so no need for me to do that as well. Cost of sales declined 11% to DKK 3.5 billion while at the same time growing the top line by 5%. Our gross margin has therefore improved following improved product mix with reduced royalties and lower amortisation thereby reaching 80.9% for this period compared to 77.5% last year. For the next two years, we still expect the reported gross margin to reach a level of 80-82%. We still have good control over our operational cost, the SG&A costs decreased from DKK 6.5 billion to DKK 6 billion which is a decline of 7%. The SG&A ratio was 33.3% compared to 37.6% the year before.

R&D costs increased by 21% to DKK 3.3 billion representing 18% of revenue partly driven by additional cost moving the early stage pipeline forward and 35700 including cost related to the closure of the TRS programme which amounts to around DKK 100 million. We expect the SG&A to stay around the same nominal level in 2019. Based on these cost ratios, the EBIT margin has improved significantly from last year. The margin improved from 25.6% to 29.3%. The effective tax rate has declined following the US tax reform early last year and consequently we see very strong growth in our net profit and subsequently our earnings per share which have grown by 38%.

Next slide, please. Lundbeck continues to generate a very strong cash flow. Cash flow from operations has increased by 48% to DKK 6 billion. The net cash flow from 2018 also improved significantly. Investments include acquisition of Prexton in March 2018 of EUR 100 million and the EU approval milestone on Rexulti of \$ 50 million. For 2019, our cash flow will be impacted by the expected lower EBITDA and higher dividend pay-out in March 2019 for the financial year 2018. Please also note that the cash flow impact from the US Justice Department settlement announced in June last year will happen in 2019

Next slide, please. Net cash increased to DKK 6.6 billion by the end of 2018 up 80% and we expect the net cash to be around DKK 7.5 billion by the end of 2019. This provides Lundbeck with a lot of flexibility when it comes to pursuing external business opportunities. We have proposed to pay a dividend of 61% of net profit for 2018 in line with our current pay-out policy of 60-80%. This corresponds to DKK 12 per share or some DKK 2.4 billion. The dividend pay-out is subject to approval at the AGM on March 26 2019. Lundbeck will, however, see increased capital needs related to our strategy for growth and as a result, we have revised the dividend policy to a range of 30 to 60% of net profit from 2019 onwards.

Next slide, please. We expect continued growth for our strategic brands Abilify Maintena, Brintellix, Trintellix, Northera and Rexulti which only partly mitigate the negative effect from generic erosion on our mature portfolio. We will likely also see a slight tailwind from currencies. Therefore, the outlook for 2019 indicates revenue in the range of DKK 16.1-16.7 billion. We will continue to be disciplined in our cost spending in 2019 but margins will be impacted by the erosion of Onfi sales. EBIT is expected to reach between DKK 4.2 and 4.6 billion for the year, which indicates a margin of at least 25%. 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 2019, which will also be the range in the foreseeable future. It is important to note that the cash tax rate is somewhat lower and we expect it to be around 20%. With that I will now hand back to Deborah.

0.19.12

Deborah Dunsire

Thank you, Anders. Please turn to slide 20. In February 2016, Lundbeck announced three long-term targets to measure the progress and success of the company's journey towards increased profitability and enhanced cash flow generation. Coming in from the outside, I am impressed by the way the company has executed on that strategy. Revenue increased with the global roll-out and growth of our key brands. EBIT improved even more as the cost structure was significantly streamlined. In 2018, we delivered the best ever financial result in Lundbeck's history and the goal set in 2016 to restore profitability has been surpassed. Lundbeck now operates a highly profitable business. Lundbeck's strong financial position provides flexibility and opportunities for the next strategic phase as we prepare Lundbeck to deliver sustainable growth into the future. The key challenge we have is to ensure our pipeline has the right assets across all phases to deliver new medicines to patients globally.

Next slide, please. As we look forward, the dynamic growth of our strategic brands will be mitigated by headwinds from loss of exclusivity. Our pipeline contains some very interesting assets in the early and mid-stage. However, to deliver on our aspiration for sustainable growth in the years and decades ahead, we must continually seek to make our pipeline more robust supplementing with external innovation across all phases. Thus, we introduced our strategy Expand and Invest to Grow. Our purpose is unchanged. We are piously dedicated to restoring brain health so that every person can be their best. As we deliver on that, we can create a robust and sustainable future for Lundbeck delivering value for all our stakeholders. Our strategy going forward will focus on five strategic imperatives to drive growth. We will first and foremost maximise our current brand portfolio. We will not limit our focus only to four disease categories within the brand but expand to address brain diseases more broadly, capitalising on areas where we have competitive know how. We will maintain a tight focus on investing and operating efficiently and profitably. We will not rely only on our internal discoveries to build the pipeline but will actively seek external innovation across all phases of the pipeline. In short, we will expand and invest to grow.

Next slide, please. Our strategic brands continue to grow strongly and we will seek to maximise the current portfolio revenue through new indications and formulation development as well as through selected expansion of our global footprint. For example, launching Trintellix in Japan alongside Takeda. We will continue to generate strong cash flows in the years to come. This strong foundation gives us the financial flexibility to pursue our growth agenda. We will also maintain a disciplined approach to profitability, aspiring to achieve an EBIT margin of at least 25% in the ordinary course of business. But of course, we may adjust this temporarily as we execute on specific actions to rebuild the growth platform.

Next slide, please. We will build on our unique strength to restore brain health. Our deep heritage and specialist knowledge in neuroscience across the value chain in our company gives us the capability to address these brain diseases more broadly. We can also capitalise on a highly efficient global organisation with uniquely strong relationships in the field of neurology and psychiatry to develop and launch improved medicines in these areas. We will move beyond the narrow focus on only four disease areas within brain health and we will take on diseases with a clear unmet medical need, attractive commercial potential and most importantly that have a clear fit with our unique strengths and capabilities in research, development or commercial. Our goal is to offer novel therapies that redefine the standard of care and address the functional outcomes that matter most to patients.

Next slide, please. In the years ahead, we will accelerate our innovation efforts and invest in both our internal and external opportunities. Our internal research will remain narrowly focused in the areas of brain biology where we have world class knowledge such as proteinopathies or brain signalling. We will allow the biological understanding to drive our medicine to the most appropriate disease states. In our development and commercial areas, we have capability to take on new medicines from outside our research pipeline in a broader range of brain diseases relying on our understanding of CNS drug development and building on our strong relationships with psychiatrists and neurologists. We will prioritise opportunities addressing the high unmet need where we can define a patient population most likely to benefit having a strong link to the underlying symptom biology or disease pathology. Combining our deep scientific understanding of brain disease with the newest technology, we will utilise those technologies to collect the fingerprint of defined patient populations and increase the use of bio markers to drive a higher success rate in the R&D pipeline. We will constantly refine and prune the early portfolio to ensure we are investing in the assets demonstrating the strongest proof of concept.

Next slide, please. Throughout Lundbeck's history, we have been successful developing and commercialising assets regardless of whether they are from internal research or from external acquisitions or licences. We have also demonstrated an ability to partner with other companies very effectively all the way from the early technology licences through to our very significant commercial partners as illustrated by this slide.

Going forward, we will continue to access external innovation through any of these pathways. Lundbeck has been and will continue to be a partner of choice in neuroscience.

Next slide, please. In 2019, we will drive our current business forward and begin to execute on our Expand and Invest to Grow strategy. We have already begun the roll-out of Rexulti in Europe and started the Phase II trial for negative symptoms in schizophrenia. In Q1, we will see the Phase III data for Rexulti in bipolar mania and we will achieve the proof of concept data for Forligrax in Q3. At year-end, we anticipate the approval of Trintellix

in Japan. We will also advance at least one new molecule from our internal discovery into the clinical pipeline.

Next slide. To summarise, leveraging our deep neuroscience expertise to restore brain health is the path to grow Lundbeck and create value for patients, for society, for our employees and for all our stakeholders. Through this, Lundbeck will be a robust and sustainable company in the years and decades ahead.

The outstanding operating results in 2018 give us the strong financial foundation to go forward and achieve our goals. With that, I would like to thank you for all your interest in Lundbeck and open the Q&A session.

0.27.42

Operator

Thank you. Ladies and gentlemen. If you have a question for the speakers, please press 01 on your telephone keypad. There will be a pause while questions are being registered. And our first question comes from the line of Trung Huynh from Credit Suisse. Please go ahead, your line is now open.

0.28.05

Trung Huynh

Hi guys, thanks for taking my questions. I have three if I may. First, in light of your updated strategy, how should we think about your absolute R&D spend going forward given the need to accelerate your pipeline? Two, in the past you have spoken about smaller deals, retaining more economics but given the lack of late-stage products in your pipeline, has this view changed? And how much debt could you take on? And then finally a pipeline question on 11167. It has been in early development since 2011. Why is this drug taking so long to get into Phase II and what gives you encouragement now? Thanks very much.

0.28.47

Deborah Dunsire

Okay, so first of all, I will start with the R&D spend and then Anders will take on the deal economics and I will come back to 11167. So when we think about our R&D spend, the first thing that we need to do is ensure that we have a pipeline that can deliver growth for the future. We also need to be sure we are only focusing our resources on the assets that have the strongest proof of concept that we can take forward to patients. And so you can

look to us: While we bring in new assets to always be looking to prioritise and be selective in the assets we take forward. Having said that it may be that temporarily our R&D spend increases above the previous margins of around 18% so that we can take forward those developments, but always with a disciplined eye to maintaining profitability and targeting growth. Anders would you like to comment on..

0.29.53

Anders Götzsche

On the M&A, you know, if you ask what is our fire power then I would say \$ 4-5 billion is what I would assume but of course you also know that it is very much target-driven if it comes with earnings or not.

0.30.16

Deborah Dunsire

11167. I don't know all the details of where it started in the pipeline but what I can tell you is we now have a path forward in negative symptoms understanding the biology of PDE10 and the need to give this molecule alone to address both the negative symptoms and profit from the biology to keep the positive symptoms under control. So given that we now have a feasible development plan, we are moving it forward in monotherapy and negative symptoms.

0.30.53

Trung Huynh

Thank you.

Operator

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

0.31.06

Michael Novod

Yes, hello, it is Michael Novod from Nordea Markets in Copenhagen. Excuse me for being a bit frank but I don't think you have really answered the question from Trung before on the R&D cost because of course we are struggling when you mention you have an aspiration

at least just to keep 25% EBIT margin so it would be super helpful for us also to get, say, a sense of where you would see R&D costs going also with reference to the earlier question with or without deals because you know getting down to a reported EBIT margin of 25% is say quite a step down from where consensus estimates are currently so it would be nice to get perhaps a bit more concrete answer. Of course, we know you are going to be disciplined, we know that you are going to be selective but just to get a feeling of the absolute R&D costs. Where are they, say, going with or without deals, especially without so if you don't do anything then where are they going? And then, secondly, maybe you could give an update to pricing in the US. We saw that you took high single-digit hikes but we also saw that Takeda only took say around a 1%-1.5% hike on Trintellix. How much of say growth going into 2019 should we expect in terms of US pricing and would you expect the Trintellix price to take another step up during the year?

0.32.36

Anders Götzsche

If I can start with the R&D costs. Michael, you are totally right. If you look at the consensus longer term then the margin is above 30%, 34 or 35% - I don't remember exactly. So you know we don't have a dedicated aim to use 9% more for R&D to bring it down to 25%. What we are saying is there might be years where we see loss of exclusivity where if the right opportunities arise, then we could come down to 25% or if we see even more opportunities, then we would of course go for it. But what we also want to signal is, and we believe we have sent a very strong signal for 2019 with an implied EBIT margin of 25-29%. In a year where we have big headwind from generisation of Onfi but what we also signal is that we believe we have delivered a very strong fourth quarter with good growth for our strategic products and we expect that to continue so I think this is kind of creating a foundation so you can understand that we are not going back to the old days where we are not earning any money at all, and as Deborah alluded to, we will definitely also prioritise our own projects. We will before expanding beyond the DKK 3 billion in average or 18%, we will of course, you know, it is not just that we feel okay, it doesn't matter if we go out using more, if we can see a value for Lundbeck and the shareholders, then we will invest.

0.34.14

Deborah Dunsire

I think the other answer to your question, with or without deals, is that we will do deals across the pipeline to strengthen near, mid and long term and it depends on the shape of the deal as to whether it fits as a tuck-in within our current operating parameters or whether it's in a larger case needs to change the operating parameters, so there is not a single answer to that question. In pricing in the US, I am going to hand over to Peter Anastasiou to comment.

0.34.52

Peter Anastasiou

Yeah, of course, as you know, pricing is very complex and when we take pricing decisions, we factor in a lot of different factors, certainly the marketplace environment, the value that our products bring, competitor actions, the continued investments we need to make in assets and so when we make decisions on price, as we recently did, we take all those factors into consideration. We won't speculate on any future pricing actions, we constantly re-evaluate all of those factors that I just mentioned so don't expect us to be prepared to describe any additional of any pricing actions on any of our products and in terms of price volume, we do expect continued growth for our key brands of Rexulti, Abilify Maintena, Trintellix and Northera and most of that is demand and volume driven that we expect for the future.

0.35.42

Deborah Dunsire

And just to add to that, when we think about the pricing environment in the US, you know as well as we do that that is an ongoing conversation and there is thoughts of changing the entire pricing structure and how pricing is done in the US, you saw the secretary come out with a comment about changing the safe harbour for rebates in the future and of course, the conversation is ongoing, nothing has been decided, but we are part of that conversation and following it. What is very important to us is to ensure that patients can have access to the right medication that addresses their particular disease state and that is what we will continue to argue for within the US and around the world.

0.36.36

Michael Novod

Okay, thank you very much.

Operator

Thank you. Our next question comes from the line of Carsten Madsen from SEB. Please go ahead, your line is now open.

0.36.44

Carsten Madsen

Thank you very much, Carsten from SEB. Two questions. Anders, in relation to this new pay-out ratio of 30-60%, there is of course quite a gap from 30 to 60% but in a situation where you don't do any deals, for example 2019, where should we actually be in our model? Should we expect you to retain a lot and stay at 30% or the other way around go to 60% So just some thoughts about what should we actually put into our models when not assuming any M&A, you are just saving for M&A? And then to the US market, especially a question to Trintellix. When we look at the very recent prescription data, it seems there is actually an acceleration in growth from an already very high level. Maybe Peter could give some comments on what your expectations are for 2019 for Trintellix and maybe also Rexulti? Thanks.

0.37.49

Anders Götzsche

The pay-out ratio, of course we have received a lot of questions for why did we change the pay-out ratio and I think it's a logical consequence of the strategy, so there are two ways to of course return or make returns to the shareholders, that's by dividend or it's by increasing the share price and we believe that the 30-60% is on par with the European benchmark and of course we will go through 2019 and hope that we will find investment opportunities to fuel the growth but of course, if we are going through 2019 not finding anything, then we need to make a decision, what is the appropriate level. We have made a big range and that leaves headroom for making decisions when we are at the end of 2019 and it hasn't been decided what level to have. But it goes without saying, you know, if we are not successful with finding opportunities, then we will not continue to pile up cash for two or three years more, it goes without saying. We have USD 1 billion in cash and we hope definitely we can find good opportunities for that.

0.39.05

Deborah Dunsire

Peter, would you like to comment on Trintellix?

Peter Anastasiou

Yes, with Trintellix, certainly from the beginning of the year, we were seeing good performance and growth, really establishing the product as the best, having the best combination of safety and tolerability, there were some good data early in the year that was published and the Lancet that supported that with a Cipriani med analysis but then on top of that good momentum, we got two label expansions, one for speed of processing, which is an important part of cognition, which happened in the spring, and then after that, label language inclusion around sexual dysfunction and the nice profile that we have with Trintellix, especially relative to something like Lexapro and all of that data has been well received by the customers so there has been, we finished the year with a very strong

quarter in the fourth quarter, as you saw, and it is because the clinical profile on that data is being met with very positive reception and doctors certainly are expanding their use, those who are already using it, and then there are new prescribers that are coming on board all the time with that and we expect, I won't speculate on a particular growth rate but we expect the good growth to continue.

0.40.16

Carsten Madsen

Thanks

Operator

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

0.40.26

James Gordon

Hello, thanks for taking the questions. Two questions, please. First question about M&A. Is the plan to look for a big revenue accretive deal or are you more focused on pre-revenue partnering opportunities? And also, what time scale are you looking to make the most impact on the top line, how far out is your focus and is it correct that we could potentially see the bigger deal first and then you lay some tuck-ins on top when you know where you are going to be able to find more synergies? So that's the first question. And then the second question, I know you touched on it already but this idea that you might go below 25% operating margin, is that the case that would only go below it if you did a big deal and if it's a deal where you subsequently can find some big cost savings so you quickly go back up or is it that you are buying really big assets? Or could you actually go below 25% just because you are scaling up organic investments?

0.41.14

Deborah Dunsire

Boy, that is a lot of questions, James. Phew. So, let's start at the top with the M&A and what do we look for. First of all, we are looking not only at M&A but we are looking at also potential other opportunities to generate revenue in the near- and mid-term and that could include partnerships, it could include regional deals, so there is a lot of different shapes that could come in. When we think about sequencing, deals are not always available in a given sequence and so we know we need to strengthen our shots on goal across all phases of the pipeline, so I would say if we see the right early stage tuck-in that

fits with our ability to take forward and can give us a potential broadening of the pipeline in years to come, that is something you might see us do. Those will be smaller. But you know we won't limit ourselves to a specific sequence. Other questions, Anders, did you capture all of them?

0.42.30

Anders Götzsche

I think it is, you know, and if it's early stage, late stage or marketed product, I think it will depend on what kind of opportunities we see and I think we still have a pretty large headroom to invest more in R&D before we go to the 25% margin. I think it is a pretty big impact from the operations that we lost the exclusivity on Onfi last year and I think we demonstrate with the 2019 guidance that we are continuing, we expect SG&A to be flat in spite of the fact that we are investing in China and Japan so we are willing to secure that we find efficiencies to actually eliminate salary increases, investment in the growth geographies by reducing in other parts of the world so I think we have been pretty disciplined and I think being in a situation where we have this discipline embedded in the organisation, then we have a lot of opportunities to strengthen early stage, mid stage and late stage and we are not in a situation where we need to be in a panic. What we can do, we hope that we have over the last 10 years actually increased the revenue base more or less with 50% for Lundbeck. We definitely hope that we can take Lundbeck to the next stage by adding external opportunities, partnerships into Lundbeck and then drive it to the next stage. That is actually what we aim for but the 25% should not be seen as kind of that is what we are aiming for. We definitely aim for more and we also aim for improving our nominal EBIT level going forward and to do better than the projections in the market. That is definitely part of the strategy.

0.44.30

Deborah Dunsire

And just to address your question on the EBIT margin changes for organic versus inorganic. I think we would only with our organic pipeline, I don't foresee that we would be increasing sufficiently to drop the EBIT margin to 25% or below. That will happen when we bring in additional compounds from the outside across the various phases of the pipeline. I don't know whether we hit all of them, James?

0.45.04

James Gordon

That's great, thank you.

Operator

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

0.45.13

Rushee Jolly

Hi, Rushee Jolly from Bernstein. I know that you said that Onfi would decline significantly in the 2019 guidance but I was hoping you could provide a bit more colour on what levels of generic penetration you now expect for 2019 for Onfi? and secondly on Rexulti, do you have any updates to how the Alzheimer agitation trials are progressing? If there is anything you can share on the trial design that is different from the prior trials and when we can expect to see the next data. Thanks.

0.45.57

Anders Götzsche

I can start with the Onfi. What we have anticipated in our guidance for 2019 is that Onfi will be declining with 60-70% compared to the numbers we delivered in 2018. And then for, I couldn't hear most of the rest so some of you, I hope you heard it.

0.46.18

Deborah Dunsire

The Rexulti question on the Alzheimer's agitation trial, this trial is ongoing and will likely finalize towards the end of 2020. It's a single trial, it's continuing to accrue. We had two trials, as you may recall. One had a comparison of placebo and effects to dose of Rexulti and showed a significance in the achievement of the outcome. The second trial had a flexible dose regimen that covered the range of doses from 0.5 to 2 milligrams and we saw a trend to significance in the overall population. When we looked at the 2 milligram patients, they separated from placebo. So the third trial is again a fixed dose at 2 milligram and compared to placebo and it should be finished in the second half of 2020.

0.47.13

Rushee Jolly

Thank you. Can I just follow on from that, is there any interim read-out we can expect from that trial?

Deborah Dunsire

We are not anticipating an interim read-out.

Rushee Jolly

Thank you very much.

Operator

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

0.47.32

Peter Sehested

Yeah hi, it's Peter from Handelsbanken, thank you for taking my questions. I have actually three. The first one relating to your fire power. My numbers at least assume that you have a DKK 10 billion drop in revenues between 27 and 30, let's just stay around the numbers say that the price of sales right now is 4.5, basically meaning that you to finance 10 billion, you need DKK 45 million in fire power, that is a bit higher than the USD 4-5 billion that you are sort of implying right now. So that was the first questions or at least comments to that question. Deborah, you touched upon areas of high unmet need in commercial potential within CNS. That looks like Alzheimer's but also.. so just I mean what areas do you actually see as a high unmet need and whether it is a high commercial potential and also a comment on where in these unmet need areas you actually have the competencies yourself? Final question relates to your investments or build-up of infrastructure in Japan. How will they impact SG&A costs over the next two years? Thank you.

0.48.53

Anders Götzsche

With the fire power, you of course need to look into the target so if you aim for a target with zero earnings, then of course, the fire power or the M&A capacity will be different if you acquire a target with earnings. So if you assume that we buy a phase I product for USD 3-4 billion then you are right, then our firepower would be maybe more limited compared to what a...

Deborah Dunsire

We won't be doing that

Anders Götzsche

Yeah, it was just to illustrate that of course, the target is very important compared to what kind of debt level you can undertake. And I have been asked this also by journalists and what we have said is that this is maybe 4-5 billion dollars, that is the possibility but again, it's not a fixed number because it will be depending on the earnings from the target.

0.49.52

Deborah Dunsire

And then coming to your second question on areas of high unmet need and strong commercial potential, of course you are right, Alzheimer's is the unsolved area to date but it's not the only area in brain diseases. On the neurology side, there are certainly other types of dementias, movement disorders, areas like epilepsy where we have been incredibly successful in the US where there are still unmet needs areas we could go into. As we understand the biology and the genetics of diseases, new areas open up where we could have a particularly targeted therapy that will advance potentially very quickly so over time, those areas will change on the psychiatry side. When I think about unmet needs, even within our current focus areas, negative symptoms, we are going after addressing that. The growing needs in PTSD. There are a number of different psychiatric diseases that are still high unmet needs and what would be terrific is if we are able to start to group patients where a particular type of therapy could be most successful in psychiatry as well and I am hopeful that as we use machine learning and artificial intelligence to look at very big patient data sets, we will be able to uncover those linkages and those patient subgroups and so the unmet needs will become even better defined. To comment on Japan I am going to ask Jacob to step in.

0.51.40

Jacob Tolstrup

Yeah, thanks Peter, this is Jacob. So for Japan, we hope to get an approval for Trintellix by the very end of 2019 and that means that sales will not be visible from Japan before we get into the final month basically of 2019. So the organisation of build-up will begin during the spring and especially around summer where we add about 50 medical reps to the Lundbeck organisation in Japan, so on the cost side it is something like 50 million that we are spending in Japan in additional costs for 2019.

0.52.18

Peter Sehested

Thanks, Jacob.

Operator

Thank you. Our next question comes from the line of Marc Goodman from SVB Leerink. Please go ahead, your line is now open.

Marc Goodman

Yeah hi, a couple of questions. First of all, I just want to make sure I understand what would be the strategy so we should not be surprised if you buy a product that is commercialised right now? I am just trying to understand how important that is relative to looking into the pipeline and thinking about phase III, I know historically it has been more earlier stage stuff, so you are willing to move into later stages but I am really curious about how you are looking at assets that are already commercialised and how important that may be. Second question is the key products had very strong growth in the US in the quarter and I was just curious if there was any inventory changes that helped in the quarter, if there was any unusual benefits from growth and there was just anything out of the ordinary that may have helped in the fourth quarter and then just third question, can you just talk about China specifically? You know, just the size of your business there, key products that will be launching, how we should expect that business to grow over the next three years? Thanks.

0.53.37

Deborah Dunsire

So let's start on the business development side of things. I think that we have said pretty clearly we are going to act across all phases of the pipeline and we are opening to do deals that will bring growth into Lundbeck. So when I think about the specific question of commercialised assets, the keyword is growth. We would have to, to do such a deal for a commercialised asset, believe that we could drive superior growth by bringing that asset into our commercial footprint and there may be assets where we could make that argument. So, would we automatically default for doing a commercial deal? No. Commercial deal has to fit our strategic capabilities and be able to deliver significant growth. Perhaps I will ask Peter to comment on US inventory changes?

0.54.39

Peter Anastasiou

Yes, of course there is always quarter-to-quarter fluctuations but to your question, there is nothing notable in particular in terms of inventory or GTN, it was strong performance, mostly driven by demand.

0.54.53

Deborah Dunsire

I think the other thing to say about the fourth quarter is the resolution of the Northera backlog, made the quarter much stronger for Northera.

Peter Anastasiou

Yeah, I think the quarter was strong and we resolved those issues in Q3 as we said we would and we believe that is behind us and Northera is back on track.

Deborah Dunsire

And Jacob, how about China?

0.55.13

Jacob Tolstrup

Yeah, China, so briefly on the China setup we are about 400 employees in China today. We have revenues of around 800 million in China and it's a relatively broad portfolio of many promoted products that we have in China. So what drives development going forward would be the ongoing launch of Brintellix and Azilect, the further expansion into more hospital listings in China and then in 2019, we are taking back Lexapro from our partner Xian-Janssen and that means that we will be hiring an additional 100 employees in China to take over Lexapro. So, outlook is strong, even considering the ongoing reforms in China, and I think we all expect double digit growth rates going forward for China.

0.56.29

Operator

Okay, so it looks like Marc's line is on silent mode but I will move on to the next question so our next question comes from the line of Emily Fields from Barclays. Please go ahead, your line is now open.

Emily Fields

Hi, thanks, just some quick ones. In terms of the delta in the revenue guidance range between the 16.1 and the 16.7, is the biggest variable there going to be the rate of Onfi and Xabril generic erosion or is there anything else that could have a wider scenario to it? And then in SG&A, I know we have talked about absolute level of spend being flat Y/Y, as

the key brands grow, is that an area of potential leverage in 2020 and beyond? And then just quickly on Cipralelex, what was the sort of rate of demand growth ex the inventory stocking in the international segment and is it right to assume that that will now return to double digit growth for 2018?

0.57.32

Anders Götzsche

...the guidance. So, we have anticipated this 60-70% decline for Onfi and it goes without saying that if we surpass that, then we will be in the higher end and Xabril, we expect the continued trend and what could kind of be the low range, high end is of course if we see faster generisation for Onfi, faster, if the tablets for Xabril will suddenly take a high or create a dip to our revenue for Xabril, we don't foresee that as the generics have launched that price with a 20% discount which is more or less in line with what we saw with the Xenazine also, so we anticipate, that is kind of the outcome and then of course, we expect double digit growth for our key products, also our strategic products, for our strategic products in 2019 and it will also depend on how high is that double digit growth and that will kind of be the boundaries and then for SG&A, yeah, we expect it to be flat next year. Our aim is for the next 3-4 years to keep it at a stable level but of course, it will depend on if we can see more investment opportunities to create even stronger growth, then we will not be shy of investing in that growth but then it comes with the earnings also. And the Cipralelex, the stocking?

0.59.11

Jacob Tolstrup

Emily, on an overall level, we do not expect Cipralelex to grow on a group level. We have markets where we are able to grow Cipralelex like in China, markets where we can keep it relatively flat end then there are a lot other markets where we have decline for Cipralelex. So, the deviation you see in the fourth quarter here is primarily driven by China so since the middle of 2018, we haven't had any shipments going to China in anticipation of the take-back happening also in 2019, so where we are switching out inventories.

0.59.47

Emily Fields

Okay, thank you very much

Operator

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

Martin Parkhøi

Thank you very much, just a couple of questions. Just a first to Anders with respect to the Onfi decline of 60-70%, do you then model in that we should see a further significant erosion to this going into 2020 or do you expect Onfi to reach a stable level for 2019 and then onwards? And then second question, could you just comment on the other revenues line which increased significantly in 2018 due to contract manufacturing? How should we maybe model that going forward? And then finally, if we look at 2018, there was a lot of one-off items, you have all these settlements in Australia and sale of buildings and stuff like that, anything that you have included or that could occur going into 2019?

1.00.58

Anders Götzsche

Thank you for the questions, Martin. Onfi, I will not speculate to 2020, I think there is a lot of uncertainty around 2019, so I think we have been pretty specific in our guidance for that and then we need to see how that plays out. And for the manufacturing part, it will be, you know we had 30% growth this year so we hope to continue with that, it varies a lot with what kind of contracts do we get into our sites so it could be a slight decline but we anticipate it will be more or less flat. And then for the one-offs, what we have anticipated is that we have this fourth trial in Australia and of course, that has just been appealed by Sandoz so we don't know when that will conclude. It could drag into 2020 and therefore, it could be, that is why we also have a range from an EBIT perspective so if that is a win in 2019, then we are of course heading for the upper end, not that that is the difference in that range but of course that will then be a positive deviation and then the same goes with the other strategic projects or products so the growth will also be impacting what end of the guidance we will land. Did I answer all of your questions?

Martin Parkhøi

Clearly. Thank you.

1.02.28

Operator

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

Peter Sehested

Yeah hi, it's Peter again, I have a follow-up question to this BD strategy question that was asked a couple of minutes ago and I mean just looking at your top line development, would you say you are in no hurry, there is no panic, there is a minor dip in 2021 with the Northera patent expiry, you can fix that with, let's say minor M&A but apart from that, the big thing is of course the patent cliff we talked about earlier, I mean, making a large revenue generating acquisition right now where the patent life is, you know, probably limited, you could add it to the top line but perhaps just push out the patent expiry cliff by one to two years which would then potentially be slightly bigger than that? So, from that way of thinking one could argue that what you should do is small acquisitions to fix the Northera dip but then go for something that is in late-mid stage clinical development with an extended patent life to extend the patent cliff going forward. Just your comments on this way of thinking. Thank you.

1.03.45

Deborah Dunsire

You are absolutely right. Buying revenue to try and solve a short-term problem that creates a bigger long-term problem is certainly not part of our strategic focus. There are certainly deals that could look like that and we will avoid them. I think that we won't take off the table all the various different paths to growth and so our pipeline will be shaped in the future as will our commercial portfolio by what are the things that will fit most neatly with our strategic capabilities and would address our needs for growth when we take into consideration the lifecycle of our current brands and the loss of exclusivity, Northera is the first step but then of course we have to consider Abilify Maintena and ultimately Rexulti so we are constantly in the phase of refreshing the pipeline and it will take, as you rightly point out, deals that address the middle and even the beginning of the pipeline so that we can have the appropriate shots on goal to make the right choices to secure growth in the long term. But you are thinking about it in the way we are thinking about it.

1.05.10

Peter Sehested

Thank you very much

Operator

Thank you. And just to remind you, ladies and gentlemen, if you wish to ask a question, please press 01 on your telephone keypad. There will be a further pause while questions are being registered. Okay, it looks like there are no questions registered at this time so I will hand the call back to you, speakers.

1.05.37

Deborah Dunsire

I would like to thank everybody for their interest in Lundbeck, we are very proud of a highly successful 2018 and we look forward to growing Lundbeck and serving patients in the future. Thank you.