H. Lundbeck

Transcript: Q2 results 2019

Date & time: 14 August 2019 at 13.00

Operator

Hello ladies and gentlemen and welcome to H. Lundbeck's second quarter 2019 results. Throughout this, all participants will be listen-only mode and afterwards, there will be a question and answer session so today I am pleased to present Deborah Dunsire, President and CEO, Anders Götzsche, EVP and CFO, and Johan Luthman, EVP, R&D. Please begin.

0.00.25

Deborah Dunsire

Thank you very much, operator and thank you all for your interest in Lundbeck. We welcome you to our teleconference covering the first six months of 2019. As you know, we have Anders Götzsche, our CFO, and Johan Luthman our head of R&D here and also joined by Jacob Tolstrup, head of Commercial Operations and Peter Anastasiou, head of North America

On slide 2 you can see the company's disclaimer which I know you have read many times before so I am not going to read it aloud I am sure you will be glad to hear.

Turning to slide 3. In the first half of 2019, Lundbeck has delivered a solid set of numbers and we are on track to deliver on our financial guidance for the year. Anders Götzsche will discuss the financial performance in detail later in our call.

Importantly, our strategic brands continue to show strong volume and value growth in all regions. I am also pleased that our international markets and Europe regions continue to show solid growth driven by strong demand. The overall performance is as expected negatively impacted by the Onfi erosion in the US. Excluding Onfi we realised healthy revenue growth at 4%. Lundbeck's financial position is impacted by major payments, for example, the Abide Therapeutics transaction but even so, it is robust and continues to provide us the flexibility to implement our Expand and Invest to Grow strategy which we announced in February.

We continue to invest behind our strategic brands and have decided to initiate new trials for Brexpiprazole in post-traumatic stress disorder and a Proof of Concept in borderline personality disorder.

With that, please turn to slide 4. We have a marketed portfolio of four strategic brands which are generating substantial growth, up 27% in aggregate adding DKK 0.9 billion in sales compared to the first half last year. Each of the brands has achieved double-digit growth and is growing in all regions and they now constitute over half our sales. The continued growth in these strategic brands is a testament to the value these products provide as well as the excellence in execution by our organisation, both in development and in sales and marketing around the world.

Next slide please. Revenue from Brintellix/Trintellix reached DKK 1.3 billion in the period, growth of 30%. 54% of the revenue was generated in North America. In the US, Trintellix continues as in all other markets to increase its market share. We saw strong demand growth in the first half driven by an increase in new patients as well as improving persistence on therapy.

We started launching Brintellix/Trintellix in November of 2013 and the products' continued strong growth close to six years post approval reflects the market's appreciation of the value it provides in addressing the unmet needs for patients with depression. In value, the US leads with more than 24% share for Trintellix making it the biggest branded anti-depressant in the market. In the major European countries, Brintellix is approaching a 10% share. In China, we are encouraged by the progress but it is still early days given that we launched last year and we still await public listing for reimbursement. In Japan, the regulatory review appears to be on track and we continue to expect an approval in Q3 of this year so we see sources of growth for this brand well into the future.

Please turn to slide 6. Rexulti is still mainly a US franchise. In Europe, the product has recently been launched in Denmark, The Netherlands, Norway and Switzerland. Additionally, outside of Europe, it is launched in Australia, Mexico and Saudi Arabia. More countries will launch in the coming year. As you can see from the graph, the significant uptake continues. Rexulti achieved more than DKK 1 billion in sales for the period representing growth of 37%. The product also continues the very strong demand growth with 26% in the second quarter. We launched Rexulti in August 2015 in the US and Rexulti's value share has increased from 13.1% to 14% since November last year. We continue to have high expectations for this product as Rexulti has a very attractive profile and it is highly valued by the medical community for what it can do for patients. Johan will elaborate on the life-cycle management programmes in a minute.

Turning to slide 7. Abilify Maintena grew 23%, approaching DKK 1 billion for the period with strong double-digit growth in all regions. Abilify Maintena was launched in 2013 and volume share now approaches or exceeds 30% in markets such as the UK, Italy, Canada and Switzerland and we continue to gain market share. In many markets, Abilify Maintena is now the second most prescribed long-acting injectable treatment for patients with schizophrenia.

Turning to slide 8. Northera grew 19%, finishing the period above DKK 1 billion. There have been quite a few moving parts for this product in the last 12-18 months. In this quarter, we see good volume growth of 24% and continue to expect good volume and value growth for the product in 2019 and beyond.

Next slide please. Our North American region is obviously very impacted by the generic erosion of major brands such as Onfi and Sabril. However, we see very strong growth of our strategic brands which now constitute two thirds of the regional value. Additionally, if one takes Onfi out of the equation, then the growth in North America is actually 12% for the second quarter.

One additional comment I would like to make is that even though the volume decline for Onfi and Sabril is more or less as we expected, we do see a more unfavourable payer mix which impacts the average unit price negatively and creates uncertainty for the development of those two products in the coming quarters.

Next slide please. International markets increased 4%, reaching DKK 2 billion for the period or 24% of our revenue. The region is still in the early part of the roll-out of our strategic brands which now constitute 18% and had growth of 35%. We expect to see significant long-term growth for these products in the region. The largest markets in our international markets region are Brazil, China, Japan and South Korea and they constitute about 56% of the regional sales.

Japan is an investment area for Lundbeck and we have now established our own commercial organisation for the expected launch of Trintellix pending approval towards the end of the third quarter.

In China, which is our second largest market overall, we have launched Azilect and Brintellix. It is still early days for both products as it takes time to obtain national reimbursement in China, as we previously mentioned.

We have successfully completed the transfer of Lexapro back to our organisation from our partner and that transition has gone very smoothly.

Next slide please. Europe is delivering solid growth with revenue increasing 7% to DKK 1.6 billion. The European region is an important part of our overall performance and it is driven by the strategic brands which grew 28% and now constitute 50% of the sales in the region.

The launch of Rexulti in the larger countries in Europe will likely not take place before next year. I will now hand over the microphone over to Anders Götzsche to expand on the corporate financial picture.

0.10.21

Anders Götzsche

Thanks Deborah. Please turn to slide 12. I will turn to our financial numbers. Deborah has already elaborated on our performance for the strategic brands so no need for me to do that as well.

In the first half of 2019, we saw a decline in our overall sales from Onfi in line with our expectation. Both for Onfi and Sabril, we saw a negative development driven by the payer mix which for Onfi has been offset in the second quarter by positive impact from revaluation of return provision. Onfi will continue to decline and we have previously guided a decline of 60-70% versus last year. Our best guess right now is that the decline will be in the high end of that range and that the uncertainty is higher than in the beginning of the year due to the increased gross-to-net.

Revenue declined 9% reported or 8% in local currencies reaching DKK 8.5 billion. This is driven by all four strategic products. Please also note that the effect from hedging has moved from a gain of DKK 277 million to a loss of DKK 93 million.

Cost of sales declined 4% to DKK 1.6 billion in the half year. Thus, our gross margin therefore declined from 81.6% to 80.7%. This is fully in line with our expectation and we still expect the gross margin for the full year to be in a range of 80 to 82% of revenue.

We still have good control of our operational costs. The generic costs only increased DKK 100 million or 3.5% while investing in our commercial organisation. The main reason for

the increase is due to FX and mainly appreciation of US dollars. The SG&A ratio was 35.8% compared to 31.6% the year before. The increase in the ratio is a consequence of the decline in revenue compared to last year.

R&D costs increased by 2% to DKK 1.5 billion, representing 17.7% of revenue. Considering the sales performance, I think we have managed our costs effectively, thus a reported EBIT decrease by 23%, reaching DKK 2.3 billion and core EBIT declining 24% to DKK 2.7 billion.

Core EBIT margin thereby reached 32%. We see this as a very solid result for the first half of 2019. It might also be worth mentioning again that we still see room for margin improvements. Our gross margin is expected to improve by 4-5 percentage points in the next five years and amortisation will contribute around half of the improvement and reduced royalty cost and production efficiencies the other half.

We will need to invest in our business but we still expect that our EBIT margin, both reported and core, will show healthy improvement as well. The effective tax rate is unchanged and consequently, we see a decline in earnings per share of 23%.

Please turn to slide 13. Lundbeck continues to generate a strong cash flow. Also the first half has been impacted by some major payments. Cash flow from operations has declined from DKK 3.4 billion to DKK 850 million, first and foremost as a result of the lower profit. The net cash flow reached DKK 1.9 billion compared to a cash inflow of DKK 416 million last year.

We expect the net cash position by the end of the year to be at a range of DKK 5-5.5 billion and with our solid cash flow and limited debt, I believe we still have significant flexibility to pursue additional growth initiatives and execute on the Invest and Grow strategy.

Please turn to the next slide. 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 have had a good start to the year and maintain our expected revenue range of DKK 16.3 to 16.7 billion. We will continue to be disciplined in our cost spend in 2019 but margins will be impacted by the erosion of Onfi sales. EBIT is still expected to reach between DKK 4.2 and 4.6 billion for the year, which indicates a margin of at least 25%.

Please note that the operational costs related to the Abide acquisition are included in the guidance. For the financial items, you should expect a net amount +/- DKK 50 million depending on the currency development. The reported tax is expected to be around 26 to 28% in 2019 which also will be the range in the next couple of years. It is important to highlight that the cash tax rate is somewhat lower and we expect it to be around 20% for the next 3-4 years and around 22-23% in the following years.

Now I will hand over to Johan to provide an update on our R&D pipeline.

0.16.25

Johan Luthman

Thank you Anders. Please turn to slide 15. I will start with an update on our Abide Therapeutics integration which is happening very smoothly following the final approval by the end of May. The transition into what is now called Lundbeck La Jolla Research Centre is completed. The products of which ABX-1431 in Tourette's Syndrome is the most advanced are progressing as planned and I expect to have the next project ready for the first human testing by early next year.

Next slide please. As you know, we had a very large life cycle management programme ongoing for Brexpiprazole. In November last year, Lundbeck and Otsuka announced the achievement of positive clinical Phase II results in post-traumatic stress disorder. Subsequently, we have had a positive and a Phase II meeting with the FDA where we agreed on the design of a pivotal programme in PTSD which we expect to initiate in the next couple of months. PTSD is a serious psychiatric condition as a response to traumatic events and with limited treatment options and therefore with a substantial unmet medical need. We are now going ahead with two pivotal studies in this condition, one study being a flexible dose and another study with fixed dose. In total, we expect to recruit some 1,250 patients in the programme. We expect to finalise the studies during 2022.

Next slide please. Borderline personality disorder is another serious psychiatric condition with substantial unmet medical needs. There is no drug approved for this challenging condition. Borderline personality disorder is a disorder that typically includes symptoms such as inappropriate or extreme emotional reactions, highly impulsive behaviour and a history of unstable relationships. Around 80% of people with borderline personality disorder display suicidal behaviour including suicide attempts and other self-destructive acts such as cutting or burning themselves. It is estimated that almost 10% of people with borderline personality disorder will die by suicide. We have reasons to believe that Brexpiprazole with its multi-modal activity might have the ability to address a range of the symptoms of this serious condition. We are thus now moving ahead to start a Proof of

Concept Phase II study during the fall period. The study will be two-arm flexible dose study and it is expected to enrol some 200 subjects with borderline personality disorder.

Please turn to slide 18. This is our current R&D pipeline. We continue to aggressively move early stage products forward and we have products that likely will end their human trials in the coming quarters. We will also continue pruning the pipeline. As a recent example, after a thorough revelation, we have decided to discontinue further development of 35700. With that back to Deborah.

0.19.48

Deborah Dunsire

Thank you, Johan. Please turn to slide 19. In 2019, we will continue driving our current business forward and execute on our Expand and Invest to Grow strategy. We will continue to invest in additional growth initiatives in general and in our strategic brands in particular. We anticipate the approval of Trintellix in Japan and will advance at least one new molecule from our internal discovery into the clinical pipeline.

Next slide please. To summarise, leveraging our deep neuroscience expertise to restore brain health is our path to grow Lundbeck and create value for patients, for our society, for our employees and for all our stakeholders. Through this, Lundbeck will continue to be a robust and sustainable company in the years and decades ahead. The outstanding operating results over the past years give us the strong financial foundation to go forward to achieve these goals. With that I would like to thank you all for your interest and open the Q&A.

0.21.04

Operator

Thank you. So ladies and gentlemen, if you haven't already and you want to ask a question just press 0 and then 1 on your phone keypad now in order to enter the queue and then after I announce you, just ask that question and if you find that question has been answered before it is your turn to speak, just press 0 and then 2 to cancel and there will be a brief pause while the questions are being registered. Okay, the first question for today is over the line Wimal Kapadia at Bernstein. Please go ahead, your line is now open.

0.21.39

Wimal Kapadia

Great thank you very much for taking my questions. I am Wimal Kapadia from Bernstein. So just a couple, please. First, I am just curious to know if there is actually any off-label use of Rexulti in PTSD today and if so how much? I am just trying to get a good sense of the off-side longer term from the new trial start and then I guess a similar question for BPD as well.

My second question, you clearly invested in headcount within China, Japan and of course the R&D personnel from Abide. When should we really start to see the fruits of this, so specifically within China, when do you expect to be on the NDRL and in Japan, what are your expectations for a Trintellix launch and then just one modelling question, could you just help quantify the inventory build-up impact for Cipralex in China in the quarter, please? Thank you.

0.22.36

Deborah Dunsire

Okay, thanks for your questions. I am going to ask Peter to address the first one and Jacob to address the others.

Peter Anastasiou

Yeah, hi Wimal. First I want to be very clear. We don't do anything to promote Rexulti inconsistent with the label. Having said that, doctors do have the ability to use products as they deem appropriate and we have heard and seen some reports of use in both borderline and in PTSD but it is not something I can quantify for you. The majority of the use is of course on label and mostly in MDD.

Deborah Dunsire

Thank you. Jacob?

0.23.05

Jacob Tolstrup

So on China, absolutely correct, that is also what we stated in the opening remarks. NDRL in China is obviously important and we have a plan for that internally that we will not share externally but it is our plan of course to get reimbursement at one point in China and when that happens, that is also when we expect that we can see some more uptake of both Brintellix and Azilect in China.

To your inventory stocking, in China there are obviously some huge swings in China. You probably also remember last year, we had a lot of stocking on Lexapro in the first half, which is impacting our growth comparables for this year. But for this quarter, second quarter over the first quarter, we have a downside in China of something like 10-15-20% where most of that is driven by stocking so again, we do expect to see quite significant growth in China for the full year.

0.24.12

Deborah Dunsire

And then I think Wimal you had a question about Trintellix in Japan and when we expected..

0.24.18

Jacob Tolstrup

Right, Japan, so filing is going well. We do hope for and plan for an approval and that approval will include also a price that we will get, which is timed for November in Japan so towards the very end of the year is when we expect to have Trintellix on the market in Japan.

Deborah Dunsire

Great

Wimal Kapadia

Great, thanks very much

0.24.44

Operator

We are now over to the line of James Gordon at J.P. Morgan. Please go ahead sir, your line is open.

0.24.51

James Gordon

Hello, James Gordon from J.P. Morgan. Three questions, please. One pipeline and two financial. The pipeline question is on Rexulti for PTSD. Just wanted to clarify on the timeline because one of the slides, I think the slide on it says data in 2022. Then there is another slide, slide 18, that says filing would not be until 2024 or later. Is that because you need longer follow-up than the 12-week primary or you are allowing for the fact that you might need to do some further trials as well and if there is a filing that late, how does that pan in with the patent of the product because then the patent goes at the end of 2026 in the US so you would only have 1-3 years on the market or is there a patent extension end goal that you are pursuing as well as doing, sort of starting more Phase IIIs now? That is the pipeline question and then on the financial SG&A, the comment before was absolutely about flattish generic Q1 but you are up 5% in Q2 and some of that is FX and some of it is this Asian investment but for the full year, is SG&A not likely to be more like low to mid up or does it moderate later through the year or could SG&A actually be up materially this year and up more in 2020?

And then the bigger picture question on off-rate to margin. If I heard correctly, there was a comment on further healthy improvement in margins over the next few years I guess the margins could fall below the current level due to higher organic R&D spend and maybe even lower margins than the current level if you did pursue big-ticket M&A. So is that comment about healthy margin expansion here because bigger M&A now looks unlikely and there is not as much going in the pipeline for R&D, it is not going to ramp as much. Has something changed there or is it me mishearing you?

0.26.21

Deborah

Okay so let us start with the pipeline question and the PTSD timeline. Johan will take that.

0.26.30

Johan Luthman

Yeah, thank you for the question so we are, as you heard, we are going to plan to start up the study later this year and it is a 12-week treatment period in the study and that will constitute the main data for the filing. We are debating whether we will have an extension of the study but that will not affect the regulatory timelines we are working with. We are working right now with an estimate of time lines. As you heard, I mentioned completion in 2022, that is probably in the latter part of that year. We don't want to give any precise estimates because the study has not started yet and it is a pretty large Phase III programme. In terms of the time, the filing timelines and the approval timelines – we are working on fairly conservative estimates that this will be a regular review by the authority and it is possible of course that this may change but it is all dependent on the conclusion

of the study so I cannot be more precise how we can cut down that and quite frankly, it is a quite conservative estimate at this point in time.

0.27.37

Deborah Dunsire

And just a comment on the patent expiry, James. The patent for Rexulti expires in 2029 so I think you are thinking about the Trintellix patent in 2026. I am going to hand over to Anders to address your other two questions on SG&A and margins.

Anders Götzsche

So what you – the SG&A development for – overall, if we look at SG&A for the full year, we expect compared to 2018 that SG&A for the full year will increase between 2-4% and that is reported rates. If I make analysis of the SG&A for the first half, the major component to the increase is FX, it's mainly $, so we have taken on more FTEs but we have absorbed that in other parts of the organisation by declining cost. So what you should expect, the increase in SG&A will also be dependent on FX and mainly US currency but what we have said is it would be relatively stable over the next 2-3 years. And when we make that comment, it is based on the business that we have now and that also means if we – we really hope that we will execute on Expand and Invest to Grow strategy and the imperatives that are about acquisition and strengthening the pipeline so what we have said before is if we find very interesting projects that we can put into the pipeline and if we come to stage where we need to invest more on that, then we will of course be willing to do so but that means that we have prioritised the cost internally first and the same goes for if we make an M&A, then of course we need to revisit what is kind of the overall picture of Lundbeck so the comments we give are of course based on the business we know about today.

0.29.40

James Gordon

Thank you.

Operator

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

Trung Huynh

Hi guys, three questions from me please. Firstly, your comments on the increasing gross-to-net for Onfi and Sabril, are you also seeing this with your strategic brands? Secondly on Wimal's Cipralex China question, can you tell us what percentage of your Cipralex sales are in China specifically? And I think Lundbeck lost the 4+7 tender this year, how many potential certified Cipralex generics could win these 4+7 tenders? And then finally if I can push you on China specifically, can you share your thinking on the 4+7 expansion for next year? Thank you very much.

0.30.30

Deborah Dunsire

Okay, Trung. I will hand the first question over on Onfi gross-to-net which really speaks to payer mix on the gross-to-net to Peter and then I will ask Jacob to give you the commentary on China.

0.30.42

Peter Anastasiou

Yeah, first on your question with strategic brands. No, there is no change in gross-to-net with our strategic brands. The reason that we are observing a gross-to-net change with Sabril and Onfi is because they are post-LOE and as Deborah said, the mix change is post-LOE and what we are seeing is that the commercial and Medicare channels are eroding more rapidly than Medicaid and that mix shift is what accounts for the gross-to-net increase. We don't know if that will continue or if that was just isolated for now but that is why we have called it out as a potential uncertainty.

0.31.20

Jacob Tolstrup

Yes, and on China. So, first, I think your question was to break out the Lexapro sales on China specifically. I don't think we have done that externally so I will refrain from doing that here. Looking at Lexapro in China, there are different factors you should consider, also when we talk about 4+7, so firstly, we have taken back Lexapro from our partner and we are handling that ourselves. That will give us a longer term upside on Lexapro in China. Then I think it is also important to remember that you are absolutely right that Lexapro was on the 4+7 list and we did not choose to go in with bidding for a lower price, so we have seen generic coming in and taking a bigger volume share in those 4+7 cities that were included in the first round. And obviously you are right that if the 4+7 gets expanded, we will see further volume loss on Lexapro going to these generic quality equivalents in China. But status today is also before 4+7 is that more than 70% of all Lexapro sold in China is already ungeneric so of course, this will have an impact but it is important to

remember that Lexapro is already quite heavily genericised in China but we can continue to grow the brand because of the underlying growth of the Chinese market.

0.32.56

Trung Huynh

Thank you.

Operator

We are now over to the line of Emily Field of Barclays. Please go ahead, your line is now open.

Emily Field

Hi, thank you. I had another question on Rexulti and BPD, I was just wondering if you could elaborate a bit more on what gives you confidence that Rexulti could show efficacy there and are there any therapeutic treatments to the best of your knowledge that are used off-label or are generally those patients left untreated therapeutically? Secondly, just any updates on your approach to M&A, I believe you reiterated that you have approximately USD 4-5 billion in firepower. You know, are you noticing still a disconnection in the evaluations of the targets you want and what could potentially generate value to an acquirer such as Lundbeck or just any updates there? And then also just within your US business, how much of your business is in Medicare Part D and then also Medicaid? And just whether you see the recently proposed overhauls to each of those programmes as having a significant impact on your business if they were to go through? Thank you.

0.34.00

Deborah Dunsire

Okay, lots of questions, Emily, thank you. The first one on borderline personality disorder, maybe you can elaborate a little bit about what gives us the thought that Rexulti could be helpful? And then Peter, you could talk about what is happening in the marketplace.

0.34.19

Johan Luthman

Yeah, hi Emily, Johan here. You may recall that we have done a Phase II Proof of Concept study that we reported out, so that is of course one of the main support for progressing with this programme.

0.34.33

Deborah Dunsire

But she asked about borderline personality disorder

Johan Luthman

Sorry, I didn't hear that. So, borderline is a different case. We have first of all, the mechanics action is promising for this indication. There are some ideas about the proper physiology of course of the disease but it includes dopaminergic and serotonergic changes and we believe the profile of the drug fits well with that understanding of the part of physiology. The second bit is of course that we have data from other studies in our clinical use that indicate that we may dip into some of the symptoms of borderline which includes acting out and also aggressive behaviour. So we have indirect evidence from other studies so that lands the support. But as you heard, we are doing a Proof of Concept study here so sorry for the confusion about PTSD. We are actually going to go in more carefully and evaluate this if it truly works in the indication. So we are running the Proof of Concept study and then we will decide further development.

0.35.37

Peter Anastasiou

Then I can describe a little bit what happens. Patients are of course treated but there is no approved treatment. Only about 25% get pharmacotherapy and it's experimental, they try to basically work on the symptoms so if they have aggression or agitation, they might use a benzodiazepine or an antipsychotic so there is a lot of experimentation but there is not real evidence base of effective treatments in borderline and that is what we are seeking to fill, that unmet need.

0.36.10

Deborah Dunsire

And to your question on our approach to M&A. First, let me say, in Expand and Invest to Grow we said we would look at all flavours of bringing in external innovation to the company from acquisition, liaisons, partnership and across all stages of the pipeline. And so that continues to be the evaluation that we do pretty broadly in diseases of the brain. By proportion, of course, there are more early stage than later stage, unfortunately we are

in an area where there is attrition so there are more things progressing in the early phases. So, just by share proportions, it is more likely to do early deals than later but we evaluate across all stages of the pipeline. And I think it connects a little bit to the next part of your question about valuations. I think there is still in the market the haves and the have nots in a way, there are some companies, whose valuation, who received a lot of love and whose valuations have run up very high and certainly, with our focus at Lundbeck being a discipline about returning to our shareholders, we would certainly not proceed to go after an asset that we think is over-valued where we can't make an appropriate return. There are some companies, the hidden gems, where they haven't received as much love and where valuations would still allow us to give a good return to those shareholders and a return to our shareholders and those are the deals that we would like to pursue. So I will stop there and then Peter, there was a question on Medicare Part D and Medicaid.

0.38.03

Peter Anastasiou

Yeah, first, we are not overly reliant on one channel so there is a good mix across commercial but there is of course some Medicare and Medicaid. We won't speculate on the impact of any proposed actions. As we have seen many times, there have been proposals for actions that haven't materialised or have changed significantly in the process so we certainly won't speculate about what impact those things could have.

0.38.30

Deborah Dunsire

I realised I didn't answer your question about the firepower so I am handing over to Anders to do that.

Anders Götzsche

So depending on the target and the cash flow of the target that we are looking into, what they are coming with, we anticipate that our firepower is around or it is around USD 4-5 billion.

Emily Field

Okay great, thank you very much.

0.38.57

Operator

Our next question is over to the line of Michael Leuchten at UBS. Please go ahead, Michael, your line is now open.

0.39.02

Thanks very much, just one question from me. Could you talk about the full-time employees you have taken on in China? I understand that you have added about 200. Just wondering, what does that get you in terms of penetration into the Chinese market? Where are you now in the buildout and how do you think about the phasing as the rest of the portfolio comes through both in terms of timing and maybe also the extent of the investment?

0.39.30

Deborah Dunsire

Okay. Jacob, would you take that question please?

Jacob Tolstrup

Yeah, totally, and just to correct you a little bit here on the numbers, it is not 200 that we are taking on in China, it is a little less than 100 that we are taking on in China and we did that as part of the project to take back Lexapro from our previous partner which was Xian Jansen so not only has that given us full access and control of our own product but it also allowed us to come out and see about 1,000 hospitals in China. That gives benefit for us as an organisation but it also benefits Brintellix as we can grow the number of target hospitals that we visit with both products.

0.40.18

Michael

Thank you.

Operator

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

Michael Novod

Thank you very much. Just a few sort of housekeeping questions. In terms of Onfi and also Sabril, maybe if you can just give a feeling for how we should model this going into 2020, is there also a lower sort of formulary positioning I know that you lose most of the commercial first but there is not always exclusion so more getting to where should we be at a steady state from 2020 and onwards? And then for Northera, it has been extremely volatile as you also mention, is the quarter as such giving you optimism for coming in above expectations on Northera internal expectations or should we just expect that there is going to be continued volatility in Q3 and Q4 for the product and seasonality as we have seen historically? That was it. Thanks a lot.

0.41.21

Deborah Dunsire

Okay, I will ask Anders to start on thinking about modelling that is going forward with the gross-to-net.

Anders Götzsche

I think, Michael, it's extremely difficult to predict 2020 but what we can say, my best guess is for Onfi that it will be a decline this year around 70% and maybe even more and Sabril we have seen a decline if I remember the numbers right, 29% for the first half and that might, for the totality of the year, it might even be higher due to the channel mix. But you know then we are also down to pretty low numbers and is it 150 million for Onfi a quarter, is it 200 million, you know, it will be between 100 and 200, I would assume, but no one knows because it will definitely depend on the change into generics. So it is really difficult to predict. So what we can predict is more or less what we know about this year and we anticipate accelerated decline for Sabril for the remaining part of the year and we also see a higher decline for Onfi.

0.42.34

Deborah Dunsire

Then Peter would you comment on the formulary question for Onfi and then on the growth of Northera?

0.42.40

Peter Anastasiou

Yeah, there aren't any particular major formulary changes since that it really is the post-LOE phenomenon that is more pronounced than what we expected where there is – all the channels don't erode at the same pace and so there is a faster erosion in certain channels than others and as a result of that payer mix, that is where the gross-to-net impact comes from. And in terms of Northera, Northera had a very strong quarter as you saw which is great and there has been, as you pointed out, seasonality effects and this is, Q2 is certainly part of the season where we have had good results in the past as you have seen but we do expect that there will continue to be seasonal patterns. Part of it is the disease where there is of course more activity that the patients engage in in the better weather months and oftentimes become dehydrated and it worsens their bodies' ability to control their blood pressure and so therefore, you see the nOH symptoms more acute in some of those months and less so in winter months so there is some disease seasonality and then there is of course some seasonality as it relates to various payer dynamics, as you know, in the industry with deductibles resetting in the beginning of the year. So we do think that those seasonal patterns still have pertinence here.

0.44.05

Michael Novod

Okay, super. Thanks a lot.

Operator

We now go to the line of Carsten Lønborg Madsen of SEB. Please go ahead, your line is open.

0.44.16

Carsten Lønborg Madsen

Thanks a lot. Just one question from me here. One of the bear cases on Lundbeck is that you have some catching up to do in the R&D and therefore in the future, you will have to significantly increase your R&D to sales ratio in order to catch up. And this quarter, you print just about 18% R&D cost to sales. Could you maybe take a view just a couple of years down the road with the pipeline you have now, with Abide closed and everything, how do you feel about the level you are at right now and what could move it materially in either one of the directions?

0.45.00

Deborah Dunsire

Thanks, Carsten. I will start and then I will ask Anders to comment as well. I think that the first thing to do with the pipeline is be very disciplined in only taking forward the best molecules and you have seen us be active in pruning the pipeline where we think things don't have the success and that creates headroom within the rate of spend in R&D that we have said that we would project around 18% of sales. So you can always count on us to do that. If we find the right assets, we have an acceleration opportunity that we think is very strong. Once we have been disciplined about all our cost, we wouldn't hesitate to invest more if it is going to give us the best possibility for growth in the future. Anders?

0.45.52

Anders Götzsche

I think, yeah, it is just to add to that, of course Johan is working with the guys in La Jolla and they are now coming in with new molecules, we are looking to progress them and they are doing well, and then of course, then you immediately start to say what is it, is there anything you want to prioritise within your organisation or the projects within your organisation, what is it actually that is most attractive? So it is not that they just have a playing field where they can go all over the places so of course, the kind of threshold or what we are torturing them against is the 18% and then if they come up with good brands where we can show to ourselves and the outside world that it gives a lot, that it's meaningful and it will support our Expand and Invest to Growth strategy then of course, we could go above the 18%. But I would assume for the next couple of years we will manage to be within the 18%, could it be 19? We cannot exclude that. But we need to make strategic investments in some other assets to go beyond that.

0.47.03

Johan Luthman

If I may add one element to this as well, obviously we are working vigorously with portfolio management and strong prioritisational programmes but as you well know, the big cost in R&D is primarily in the late stage of the pipeline and we are going to very carefully look at bringing the high value assets into phase III, meaning that we bring those that have a higher success rate and maybe also burn less in that stage and mainly try to shift our R&D attrition earlier and thereby also hopefully keep the finances under control.

0.47.43

Carsten Lønborg Madsen

Okay, thanks a lot.

Operator

Right. We now go to the line of Marc Goodman from SVB Leerink. Please go ahead, your line is now open.

0.47.52

Marc Goodman

Yeah hi, two questions. One, Peter, if you could just talk about if there are any major inventory changes in the key products in the US, just you know from the first quarter to the second quarter that may have helped or hit any of the numbers there? And then the second question is in R&D, can you specifically just talk about the Parkinson's programmes that you have and just give us an update, just update us on the programme and timelines there if anything has changed and you know a couple of earlier programmes in alpha synuclein, the D1/D2, how are those moving forward and when are we going to see some data there? Thanks.

0.48.29

Deborah Dunsire

Okay, thanks Marc. Peter, you will start.

Peter Anastasiou

Yeah, on inventory changes, from that perspective, it wasn't a remarkable quarter. There was – and there is always, of course, inventory fluctuations but it was normal from that perspective unlike what we saw in maybe other quarters so nothing really remarkable there.

0.48.50

Deborah Dunsire

R&D, Parkinson's programme, Johan

Johan Luthman

Yeah, as you see, we have a number of programmes in Parkinson's Disease. They are all mid to early stage programmes so Foliglurax you asked about and that of course is symptomatic treatment, that is now, we are trying to wrap up the Proof of Concept Phase II trial and we have had some delays in the timelines with enrolment but we are doing our utmost now to speed up and we hope to have the results by Q1 next year. We have another symptomatic programme at play, a dopamine modulator agonist programme,

which we think is a good mix of balance for add-on to standard therapy, quite similar in thinking like the Foliglurax so it is symptomatic, there are no other possibilities and then obviously we have our disease modifying approaches. We have something going on of course in research but what you see from our pipeline, we have the alpha-synuclein antibody which is approaching end of phase I and we look forward to thinking about how we will bring that Proof of Concept study in the coming year.

0.50.08

Deborah Dunsire

Those are such early programmes, I think to your question on when will we see data, as Johan said, Foliglurax hopefully in the first quarter of next year, other programmes in Parkinson's Disease the asymab the D1/D2 they will be much .. the phase I isn't going to tell us a whole lot. It will be have to be through the phase II Proof of Concept that will take another couple of years.

0.50.35

Marc Goodman

Thanks.

Operator

Okay. We are now over to the line of Peter Welford at Jefferies. Please go ahead, your line is open.

Peter Welford

Hi, thank you so much for taking my questions. Three, please. Firstly just on the BPD indication for Rexulti, I am curious why not wait for the read-out from the investigative responsive study in April, it seems it is a relatively short time away so why initiate your own Proof of Concept if there is already a study ongoing which seems to have similar end points albeit underpowered? Have you already seen any initial data from that study? Secondly then just on China. I understand you said you are targeting 1,000 hospitals at the moment. I have no idea how many hospitals there are in China but I am guessing 35-40,000 or something. Can you give us some sort of idea, if that is sufficient, if you do get on the drop list for Trintellix, or is this just a start and much more significant expansion will be needed if you are going to promote a product of that sort of value? And finally then just on Abilify Maintena, your largest product at the moment in Europe. I wonder if you could comment, do you still envision this being the case by the time we get to 2025 pattern expiry of that product in Europe or do you think there will be another brand that could surpass Abilify by the time we get to that point in five years' time? Thank you.

0.52.00

Deborah Dunsire

Okay, thanks Peter. Johan, would you like to comment on the borderline personality disorder?

Johan Luthman

Yeah, thanks for that question. Obviously, as you know, there are two elements here. One is the robustness of the data to move forward and the other one is timing. And when it comes to robustness, of course, we are better in control of a study that we are running ourselves and we are not going into details of the investigative study, we think we have designed a study where we will have much clearer stop/go-criteria so it wouldn't help us so much to wait for that investigational study really to make that decision which of course will be a phase III decision. We also of course have had conversations with the authorities about the end point. So we think we have a good understanding of what it will take to bring it forward so that is of course in the balance when we decide to go into phase III.

0.52.54

Deborah Dunsire

Okay and then Jacob, would you comment on the hospitals in China and Abilify Maintena in Europe?

Jacob Tolstrup

Yes, absolutely, so the 1,000 hospitals that we are targeting right now in China is primarily for Lexapro which is a fully reimbursed product in China, so to give a shorter answer to your question, 1,000 hospitals is sufficient and having that sales force also allows us to take Brintellix out to more hospitals in China than we did before. On Abilify Maintena in Europe with the portfolio that we have today then I continue to expect that Abilify Maintena will be our biggest product also in 2024, closely followed by Brintellix.

0.53.40

Deborah Dunsire

I think it's fair to say that we are very selective in China and we are not trying to reach out to all the hospitals but really looking as the principle for Lundbeck at where can we grow profitably, so being selective.

Peter Welford

Thank you.

Operator

Okay, our final question for today is from Peter Sehested from Handelsbanken. Please go ahead, your line is now open.

Peter Sehested

Thank you, it's Peter from Handelsbanken, thanks for taking my question. I have only one and that is for Anders. Anders, could you – just for housekeeping purposes – just give us an indication of the gross margin impact due to the channel mix? Thank you.

0.54.33

Anders Götzsche

The gross margin. I think we are not willing to disclose the impact from the gross-to-net – was that the question?

Peter Sehested

No, it's just for my modelling, when we model these numbers on our line item basis, we should be able to… plug in a gross margin.

Anders Götzsche

Peter, could you repeat your question?

0.54.53

Peter Sehested

Yeah, it was just if you could guide us on the gross margin change if there is a delta to the gross margin for these two products due to the channel mix, it's just for modelling purposes. Thank you.

0.55.08

Anders Götzsche

No, sorry for not being able to do so. We do not want to go into the details for each specific product but what I can repeat is that what we anticipate is what we have said during the year, that we expect to have a gross margin of 80-82% for the year, that is unchanged including the change in gross-to-net or not the change in gross-to-net but the changed channel mix for Onfi and Sabril.

0.55.40

Peter Sehested

Okay, thank you.

Operator

Okay, I will pass it back to you now for any closing comments.

Deborah Dunsire

I would like to thank you again for your interest in Lundbeck. We are very happy to report the very strong growth of our strategic brands and we look forward to a strong performance in the second half. Thank you.