

Lundbeck A/S**Transcript: Interim Report, 1st Quarter of 2019****Date & time: 08 May 2019 at 13.00**

Operator:

Ladies and gentlemen. Welcome to the H. Lundbeck Q1 Results Call. For the first part of this call, all participants will be in listen-only mode and afterwards, there will be a question and answer session. Today, I am pleased to present Deborah Dunsire, President and CEO, Anders Götzsche, Executive Vice President and CFO, and Johan Luthman, Executive Vice President of Research & Development. Speakers please begin.

0.00.28

Deborah Dunsire

Hello everyone. You see on slide 2 the company's disclaimer which I know you have read many times so I won't read it out. I also want to alert you to, in addition to Anders and Johan, I also have with me Jacob Tolstrup, our EVP of Commercial Operations, and over the phone, Peter Anastasiou, the EVP of North America.

So turning to slide 3. In Q1, Lundbeck has delivered a robust 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 the call. Our strategic brands continue to show strong growth in all regions. I am also pleased that our international markets and European regions show solid growth, predominantly driven by strong demand but also to some extent benefiting from timing of shipments and/or stocking, for example in preparation for Brexit. The overall performance is negatively impacted by the anticipated Onfi erosion. Excluding Onfi, we realised healthy growth of 6%. Lundbeck's financial position is very strong and continues to provide us flexibility to implement our Expand and Invest to Grow strategy announced in February. We took the first step in executing upon the external innovation components of that strategy with the acquisition of Abide Therapeutics announced this week. Abide represents a very interesting discovery platform which we expect has capability to deliver first-in-class compounds against multiple targets within a broad range of indications in both psychiatry and neurology in the years to come. We also expand our clinical pipeline with the lead compound ABX-1431. This is a first-in-class inhibitor of the Monoacylglycerol lipase or MGLL lipase and it is a modulator of the endocannabinoid system. 1431 is currently in an exploratory phase 2a study in Tourette's and the Phase 1b study in neuropathic pain.

With that, turn to slide 4. We have a marketed portfolio of four strategic brands which are generating substantial growth, up 24% in aggregate adding DKK 0.4 billion in sales compared to Q1 of 2018. Each of the brands has achieved double-digit growth and is growing in all regions. The growth of these strategic brands is testament to the excellence in execution by the organisation in development and certainly in sales and marketing around the world.

Next slide please. The revenue from Brintellix/Trintellix reached DKK 601 million in the period. 52% 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 Q1. Revenue growth was somewhat dampened by a number of factors, among them buyers' inventory planning and the so-called doughnut hole reset in the US. I would like to note here, that it impacts other products in the US also. Brintellix/Trintellix' continued strong growth 5 years post approval reflects the market's strong appreciation of the value it provides in addressing unmet needs for patients with depression. Many of our markets exceed 2% and some even 3% volume share in this very, very busy market. In the US, Trintellix' value share has increased from 21.9% to 23.8% since October of 2018. In China, we are encouraged by the progress but it is still early days given that we just launched last year and are still awaiting hospital listing. In Japan, the regulatory review appears to be on a good track and we expect approval in Q4 of this year. We foresee this brand continuing to grow well into the future.

Please turn to slide 6. Rexulti is still mainly a US franchise and outside North America, it is only launched in Australia, Mexico, Saudi Arabia and Switzerland and most recently Denmark in April. 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, the significant uptake continues. Rexulti achieved close to DKK 0.5 billion in sales for the period which represents growth of 30 % 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 12.8% to 13.2% in the last 6 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 7. Abilify Maintena grew 27% to close to DKK 0.5 billion in the quarter with strong growth in all regions. Abilify Maintena's volume share now approaches or exceeds 30% in markets such as UK, Italy, Canada and Switzerland and it's continuing to gain market share. In a few smaller markets, Abilify Maintena is very close to becoming the leading product in the category. 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 10% finishing the quarter at DKK 435 million. There have been quite a few moving parts for this product in the past 12-18 months. In this quarter, we do see a negative impact from fluctuation in specialty pharmacy buying patterns. The underlying demand, as seen in the graph on the right, is very strong and we continue to expect good growth for this product in 2019 and beyond.

Next slide, please. Europe is delivering strong growth with revenue increasing 10% to DKK 819 million. The European growth is an important part of our overall performance and is driven by our strategic brands which constitute 49% of sales in the region.

Rexulti has been formally approved for schizophrenia in Europe, including Switzerland, where it was launched recently. And we added Denmark as a launch country in April.

International markets increased 13% reaching DKK 1.1 billion for the year or 26% of our revenue. This region is still in the early part of the roll-out of our strategic products which grew by 25%. We expect to see significant long-term growth for these products in the region. The large markets in our International Markets region are Australia, Brazil, China, Japan and South Korea. These constitute some 56% of regional sales. Japan is an investment area for Lundbeck as we are establishing our own commercial organisation here for the expected launch of Trintellix pending approval towards the end of the year.

In China, which is our second largest market overall, we recently launched Azilect and Brintellix. It is still early days for both products as it takes time to obtain national reimbursement in China. We have completed the transfer of Lexapro back to our organisation from our partner and that transition has gone very smoothly. Our North American region declined 17% to DKK 2.2 billion given the expected generic erosion of Onfi. Adjusted for Onfi, our North American region grew 9%. Our strategic brands constitute around 65% of sales and grew 22%.

Next slide please. As I noted in my introduction, we have taken the first step in executing on the strategic imperative to rebuild our pipeline included in our Expand and Invest to Grow strategy which we announced in connection with the full-year 2018 results in February.

As announced on Monday, we have agreed to acquire the La Jolla-based company Abide Therapeutics. Abide is a biopharmaceutical company focused on harnessing the therapeutic potential of one of the largest and most diverse enzyme classes, the Serine Hydrolases. The platform has the capability to deliver first-in-class compounds against multiple targets across a broad range of indications in both psychiatry and neurology. I

would like to hand over to doctor Johan Luthman, our new EVP R&D, to talk through this in a bit more detail. As you will remember, Johan joined us in February this year, bringing an extraordinary set of career experiences in the neurosciences across multiple companies in Europe and the US. Johan.

0.11.33

Johan Luthman

Thank you, Deborah. Please turn to slide 11. Since this is the first time I am joining this call, I will give you a little bit brief of synopsis of my background. I received my clinical training and a ph.d. in neuroscience at the Karolinska Institutet. Following that, I have been working with pharmaceutical R&D for some 28 years in companies such as Eisai, Merck and AstraZeneca developing and getting approval for both small molecules and biologic neuroscience, metabolic diseases, immunology and inflammation. I am delighted to be here at Lundbeck. Now back to the presentation.

The financial details of the deal you have already seen so no reason to repeat that. Abide Therapeutics has been working to become the world leader in realising the therapeutic value of modulating the activity of Serine Hydrolases. The first target they have addressed is the endocannabinoid modulator Monoacylglycerol Lipase or MGLLipase for short.

0.12.42

Abide has to this date identified both centrally acting and peripherally restricted inhibitors on MGLL opening up the possibility to selectively modulate the endocannabinoid system and to optimise indication choice. Abide's lead product, candidate ABX 1431, is a first-in-class inhibitor on MGLL. The ABX 1431 is an early clinical development for Tourette's syndrome and neuropathic pain. Abide has two additional MGLLi compounds that are ready for clinical studies in 2020. We see potential for MGLL inhibition to be beneficial in multiple neurological and psychiatric indications and see possibility to use bio markers to guide us for the most responsive patient populations. Abide also brings a rich pre-clinical pipeline of potent and selective inhibitors targeting other members of the serine hydrolase enzyme superfamily.

Next slide please. Serine hydrolases are one of the largest and most diverse classes of enzymes in the human proteome with around 200 enzymes representing approximately 1% of all proteins. Serine hydrolases influence human physiology by controlling the levels of diverse signalling molecules including transmitters, proteins, peptides and lipids, thereby playing vital roles in a number of pathophysiological processes. Multiple successful drugs which have serine hydrolase inhibitors have been launched, for example SDRI inhibitors, DPP-4 inhibitors, thrombin inhibitors and factor Xa inhibitors.

The initial target, MGLLi, acts to the endocannabinoid system to down-regulate overactive neuronal circuits. MGLLi act more physiologically with potential for greater therapeutic index compared to exocannabinoids, the active compounds in cannabis, given MGLLi will only have activity where endogenous neuronal pathways are overactive.

Next slide please. The lead product, ABX 1431, is a potent, selective and brain penetrant MGLLi. In contrast to exocannabinoids, endocannabinoid modulation of 2AG, via MGLLi, supports and enhances normal physiological responses by acting in a spatially and temporary restrictive manner or in other words at the right place and right time only where and when 2AG is released.

ABX 1431 is in early clinical phase 2 development for Tourette's and in phase 1 for neuropathic pain, but it is also expected to have potential in a broad range of other neurological and psychiatric conditions.

In April last year at the American Academy of Neurology AAN Conference, Abide presented details on the completed exploratory phase 1 study in Tourette's with ABX 1431. In this randomised, double blind placebo controlled cross-over study in adults, patients receiving a single dose of ABX 1431 consistently showed a positive impact on key measures of Tourette's Syndrome.

More than 100 healthy individuals and patients have been dosed with ABX 1431 to date and the compound has so far been well tolerated.

Please turn to slide 14. This is our pipeline, early pipeline as it looks now. As you know, we announced in February that the studies for Brexpiprazole for the treatment of manic episodes associated with bipolar I disorder did not meet the primary end point of statistical separation from placebo as measured by the Young Mania Rating scale. The phase 3 programme for Rexulti in Alzheimer's associated agitation is on track. We will also likely start a phase 3 programme in PTSD in the second half of the year. The phase 2 data for Foliglurax will likely be slightly delayed as high selectivity for patients to be included in the study has increased the recruitment time.

In keeping with our commitment to move only the strongest potential development candidates forward, we have made decisions to stop two phase 1 programmes. We have stopped the product 2513 which was an active immune therapy product for Alzheimer's. We will evaluate the potential for more potent vaccine approaches pre-clinically.

Additionally, we have decided to close the phase 1 study with the PDE1 inhibitor 76432 as we believe we have more selective and potent back-up compounds which is in late pre-clinical development. I will now hand over the microphone to Anders Götzsche to expand on the corporate financial picture.

0.18.02

Anders Götzsche

Thanks, Johan. Please turn to slide 15. 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 it as well. In the first quarter of 2019, we saw a decline in our sales from Onfi fully in line with our expectations. Revenue declined 8% reported or 6% in local currency reaching DKK 4.2 billion. This is especially driven by Brintellix/Trintellix, Rexulti and Abilify Maintena. Please also note that the effect from hedging has moved from a gain of DKK 182 million to a loss of DKK 48 million.

Considering the sales performance, I think we have managed our costs effectively thus reported EBIT decreased by 28% reaching DKK 1.2 billion and core EBIT declined 22% to DKK 1.4 billion. The core EBIT margin thereby reached 33.3%. I see this as a very strong result.

Please turn to slide 16. Cost of sales was unchanged at DKK 825 million. Thus our gross margin therefore declined from 82% in the same period last year to 80.5%. This is fully in line with our expectations and we expect cost of sales for the full year to be at the same level percentagewise as seen in the first quarter of the year.

For the next couple of years, we still expect the reported gross margin to reach a level of 80 to 82%. We still have good control over our operational costs. The SG&A costs only increased with DKK 22 million or 1.5% while investing in China and Japan. The SG&A ratio was 34.5% compared to 31.4% in the year before. The increase in the ratio is a consequence of the decline in revenue compared to last year. We expect the SG&A costs for the full year to stay around the same nominal level as last year. R&D costs increased by 5% to DKK 748 million representing 17.7% of revenue partially driven by additional costs moving the early-stage pipeline forward and including cost relating to the closure of the 2513 programme. The provision booked in the quarter is just around DKK 50 million. The effective tax rate is unchanged and consequently, we see a decline in earnings per share of 25%.

Please go to the next slide. Cash flow from operations has declined foremost as a result of the lower profits but also due to the lower gross to net accruals in the US following declining sales of especially Onfi and the quarterly fluctuations of these accruals. The net cash flow is additionally impacted by the increased dividend pay-out made in March. For 2019, our cash flow will be impacted by the expected lower EBITDA and higher dividend pay-out. Please also note that the cash flow will be impacted by the Abide transaction and the payment of the US Justice Department settlement announced in June last year. That will happen in the second quarter 2019. We expect the net cash position by the end of the year to be in a range of DKK 5 to 5.5 billion.

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 the generic erosion on our mature portfolio.

We have had a good start to the year which is why we narrow our expected revenue range to now 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 operations are included in the guidance range.

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 also will be the range in the next couple of years. It is, however, important to note 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.

With that, I will now hand back to Deborah.

0.23.20

Deborah Dunsire

Thanks, Anders. 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 have already begun the roll-out of Rexulti in Europe and started the Phase 2 trial for negative symptoms in schizophrenia. Provided that the Abide transaction is approved, the transition to becoming a Lundbeck US-based innovation engine is obviously very important. By the year-end, we expect 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, we will continue to leverage our deep neuroscience expertise to restore brain health and see this as 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 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 and achieve our goals. With that, I would like to thank you all for your interest and open the Q&A session. Operator?

0.24.44

Operator

Thank you. Ladies and gentlemen. If you wish to ask a question, please press 01 on your telephone keypad and if you wish to withdraw your question, you may do so by pressing 02 to cancel. There is going to be a brief pause while questions are being registered. And our first question comes from the line of Wimal Kapadia from Bernstein. Please go ahead. Your line is now open.

0.25.10

Wimal Kapadia

Great. Thanks for taking my questions. I am Wimal Kapadia from Bernstein. Just a few, please. If we start with Onfi, on my math, it looks like realised prices for Onfi in Q1 2019, you know, sort of a significant jump, if I look at the Y/Y number or even the Q/Q number so I guess the question is: Are Lundbeck maintaining the price of Onfi in the face of generics or is there some sort of stocking impact that skews the realised price on my math? Secondly, on M&A, post Abide. Should we continue to expect similar deals for early stage assets? Or should we now expect some development more mature in development and tied to that is licensing in assets or even licensing some regional rights of an asset an option that you are exploring rather than an outright acquisition? And then the final question is just on ABX 1431, the Phase 2a in Tourette's is relatively small. I just wanted to confirm that you would need to run a larger phase 2 study before moving on to a pivotal Phase 3 or is the Phase 2a enough for you to then move on to a larger Phase 3 study? Thanks very much.

0.26.22

Deborah Dunsire

Thanks, Wimal. Okay, we will start with Onfi. We did take a price increase on Onfi in the beginning of this year and so, you know, we continue to do that as we see fit going forward. Peter, do you have any comments to add?

Peter Anastasiou

Hopefully, you can hear me. No, nothing in particular to add other than of course to confirm what Deborah said and that we constantly monitor the marketplace and determine what is the value that our product brings and the marketplace dynamics as we consider pricing decisions but nothing in particular, Wimal, that stands out that would affect the calculations that you are referring to other than the price increase that Deborah mentioned.

0.27.15

Anders Götzsche

You should expect that what we said in the beginning of the year that you would see a decline in Onfi revenue in 2019 compared to 2018 of 60-70%. And are fully aligned with that in the first quarter.

0.27.30

Deborah Dunsire

Your second question, moving on to Abide, can you remind me of the question?

0.27.40

Wimal Kapadia

It was just, okay..

Deborah Dunsire

You know, this is a very exciting platform. And we certainly would look to do more deals of this type but what we said in our Expand and Invest to Grow strategy is that we look at deals across all stages of the pipeline. We are delighted to have an engine like Abide in the US being able to put compounds into our clinical pipeline today and into the future but linking to your third question on: Would we think about doing licensing deals or other types of deals? The answer is yes, we look at all types of deals structures across all phases of the pipeline and we also would have the potential to look at regional deals given that we have now a pretty robust global footprint and a commercial organisation that executes very effectively so it gives us freedom to look at a number of different ways of bringing profitable growth into Lundbeck. When we think about the 1431, I am going to hand over to Johan to answer the question about the current Phase 2 trial.

0.28.55

Johan Luthman

Yeah, thanks, Deborah. Yeah, obviously, the question is if we would need a larger phase 2 programme before we are going to more larger phase 3 or pivotal studies. Obviously, it will be data driven. We have promising data already from a smaller Phase 1b study and the ongoing 1a study could tell us that it has a very strong potential. The data so far have been encouraging. But obviously, we are not going into a bigger programme until we have a robust validation that the drug works and clear understanding about the dose for moving into Phase 3, so it is unclear at this stage whether we will stay in phase 2 with another study or we can go directly into phase 3.

0.29.37

Wimal Kapadia

Great, thank you very much.

Operator

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

0.29.50

James Gordon

Hello, thanks for taking the questions, a couple of questions, please. One is about the Q1 US sequential slowdown for some of the new launches. They look quite a bit bigger than we have seen in previous years. My question is: Why is that? Is that doughnut hole related? I heard some comments about the doughnut hole. For Trintellix, it seems to be twice as big a sequential fall of last year. And Rexulti did not seem to have a sequential fall last year in Q1 but they have quite big fall this year. So what caused that Q1 phenomenon to be a lot bigger?

The second question is on the doughnut hole. I apologise if I missed it, but which products are most doughnut hole-impacted? How much was the impact? And would you see a bigger or expect to see a bigger impact once you move into Q2 if more patients are in the doughnut hole, then?

And then a third and final question, just on pipeline deals. I think at one point there was a comment about potentially looking to do something that was revenue accretive but is there much out there that is mature that you can buy in the sort of areas you are looking for? Could we see something big this year that is revenue accretive? Or is there just not much to buy at this late stage and that is why it is going to be assets that are much further out?

0.30.49

Deborah Dunsire

Okay, lots of questions. Thank you for your interest. And so the Q1 US result was impacted by a number of things. We had very strong demand growth across all our brands so the script growth has been very strong and revenue growth was dampened a little bit by some, we believe, inventory management at the wholesale level and I will pass on to Peter to amplify that and then Peter to take the questions around the doughnut hole in Q1 and Q2.

0.31.22

Peter Anastasiou

Yes just a couple of additional words to add colour so of course, as you know, Q1 is a challenge for the entire market. There is always factors that create headwinds whether it be the doughnut hole, whether it be high deductible re-setting, a number of different factors and we have consistently, as the whole industry has, seen a decline in Q1, but when you compare Y/Y to Q1, we saw, as Deborah mentioned, strong growth not only in sales but most importantly, in prescriptions and I think you guys have probably tracked the prescriptions and saw that we had strong double-digit growth for all of our strategic brands so there is nothing certainly underlying that is creating any kind of headwinds from a prescription perspective. If you see some of that in sales, it is absolutely what Deborah described in just normal quarter-to-quarter fluctuations and probably some wholesaler and specialty pharmacy management of their own inventory, but certainly, as you know, when the prescription trends are strong despite those quarter-to-quarter fluctuations, will sales typically follow.

And in terms of the doughnut hole and certainly the rest of the year, there is nothing in particular that we will comment on that you would expect throughout the year. Most of the effect of these things is observed in Q1. Sometimes, it lingers into Q2, but nothing in particular that we would expect that would be out of the ordinary from any past year. And the most important part I can emphasise is the strong prescription demand that we have seen regarding our strategic products.

Deborah Dunsire

Thanks, Peter. Turning to your question on what type of deals will you see. We continue to look across all stages of the pipeline and there is a lot going on in neuroscience, really, from the early science all the way through. What we have said and we will stick to is Lundbeck is in a very strong financial position given the growth of our strategic brands, the financial footing we stand on, so it gives us the opportunity to evaluate in a very thoughtful way and be very disciplined with respect to price so that if we find the right asset that has a great strategic fit with our capabilities and we find it at the right price, then you will see the deals coming in with later stage assets and if we don't find that, we will continue to work on strengthening our pipeline in the mid and early stage in any event, so that will always be ongoing so it is going to depend on seeing that strategic value at the right price in the later stage as to whether we act now or in the future.

0.34.10

James Gordon

Thank you.

Operator

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

Mark Goodman

Yes, I.. questions, first Trintellix opportunity in Japan. Can you help ... the opportunity, the size of that market and how big we think that opportunity can be for your second.. You mentioned the Foliglurax delay. Can you talk about what is happening there? Why the delay and when should we now expect to see the data? And third, on 11167, can you just remind us of how this product is differentiating and how it is going to have to have a hook in the market? Thanks.

0.34.55

Deborah Dunsire

Okay, I am going to ask Jacob Tolstrup to take the first question.

Jacob Tolstrup

Yeah, thank you very much, very happy to. So the filing is well underway in Japan for Trintellix, as you know, we expect hopefully to get an approval and that means price approval by the very end of this year. So that launch will officially take place very late November-December of this year. And we are building up a commercial infrastructure as we speak where we will copromote together with Takeda. I don't think we have ever communicated specific sales terms for specific countries. Japan is obviously important, it's the second biggest depression market in the world and together with Takeda, I am sure that we will make Trintellix, as it will be called in Japan, a very successful product. We are going to deliver 20% of the resources in Japan and get a royalty that is higher than that. Approximate one third.

0.35.55

Deborah Dunsire

Good. Moving onto the Foliglurax delay, that study has been a relatively small study but it is short and it doesn't have an open label extension and I think that has made it a bit more difficult to accrue the patients. So I think we would expect to see the outcome just towards the end of this year or may spill over into the early part of next year. To comment on our PDE 10 inhibitor, I am going to ask Johan for any comments there but just say there are really no products approved for negative symptoms in schizophrenia, so if we can crack that difficult issue that patients face, we believe there is going to be a big market. Johan, any comments on Foliglurax or the PDE...

0.36.43

Johan Luthman

Yeah, for Foliglurax, it is very much, as you well know, the problem of not have a robust proof of concept so that's the tricky balance you have to make in a phase 2 study, so shorter-term treatment always causes a little bit of problem to engage patients. This study was initiated by the company Prexton that we acquired some years back so it's a study that we have rolled in under our development organisation and we are doing all our efforts to speed up. In terms of PDE 10 inhibitor, first of all the MoA action is very exciting, it is dealing with the balance of different dopamine signalling systems in the brain and that lends the possibility to have an effect maybe on negative symptoms and even cognition. The study programme has started up quite recently and it will take a while to complete our study, we are in the earlier phase of the phase 2 to reach proof of concept.

0.37.40

Deborah Dunsire

Thank you

Operator

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

Trung Huynh

Hi guys, thanks for taking my questions, I have three if I can. Just a first question on the one-offs in the quarter, so there are quite a few. Are you able to outline for us the impacts of the bigger inventory movements, the Brexit stocking in the EU and the China tender stocking? And then overall, can you just tell us if these were positive, negative or awash on the impact on the net profit. Secondly, of the revenue doubled for the quarter from increased contract work, how should we view this line going forward? Is this a new level we should be modelling? And then finally a question for Johan. You have been with the company since March so I know you haven't been there too long, but can you give us any comments on your initial thoughts of Lundbeck's R&D organisation, the internal portfolio and if there has been anything that has surprised you? Thanks very much.

0.38.46

Deborah Dunsire

Anders is going to start.

Anders Götzsche

Yeah. The one-offs in the quarter, it is important from a – we had around from a cost perspective, more or less we had DKK 70 million including the provision for 2513 so it's around DKK 70 million in additional cost. And then we had of course some of these de-stocking in the US but then we had, you know, the Brexit. We have a small, you know, our revenue in the UK is not very big, so it's a small issue, but of course, it impacts the growth. So I would say more or less maybe at levels – it doesn't level out, it is more to the negative side, the de-stocking in the US impacting growth than even out. So of course, the US, it is much bigger numbers and it is difficult to kind of isolate what is just normal fluctuations, what is actually optimisation at the wholesaler level. But definitely, it has been negative to the growth you see for the full Group, for Lundbeck as a whole. Did it answer your question?

0.40.12

Trung Huynh

That's great, thanks very much. And the other revenues doubled in the quarter, how should we view this?

Anders Götzsche

So we should expect it – no, it's difficult because it is a tender business, so more or less, if you expect it to be around the same level as last year, then you are good with your numbers.

Deborah Dunsire

Then we will go to Johan, comment on the 75 days?

0.40.35

Johan Luthman

Thank you. Yes, so actually I started in February so it adds up to 75 days today. So, first of all, I would like to say that it is a great pleasure to be in this company. I have been working in a few companies as you have heard and I always over the years looked at Lundbeck as a fix star up there in the neuroscience sky and it is a good team. We have very strong people here. The R&D organisation is really robust, very experienced, have shown before that they can deliver compounds to the market for very large unmet medical needs that also have been commercially successful. So we have a very, very strong platform to build on. Obviously, we need to strengthen our pipeline further and you saw the Abide deal which is just one element of this. But for the moment, we are gradually, together with our business development and research colleagues, doing our utmost to refill the pipeline as much as possible. We are doing some changes to simplify the way we work. We need to be global, impactful and simplify the organisation in terms of how we operate across the globe. So, I often say we like to create the positive problem of choice and that is really what we are trying to create now with our portfolio.

0.41.54

Deborah Dunsire

Thanks, Johan.

Operator

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

Michael Novod

Thank you very much. Just a few questions. Going back to the other revenue line, maybe Anders you can explain how much of in relative terms is actually the contract manufacturing and what do you kind of expect for the full year where the contract manufacturing is going and do you expect that to be growing? And then other parts of revenue perhaps more, say, flattish or declining? That is one thing. The other thing is also just for housekeeping. So Abide, how much is it adding to R&D cost in general on a full year basis just for us to model it better going into 2020? And then lastly on the gross margin, you say 80-82% in the next couple of years. I recall it has been a bit more aggressive commentary earlier, at least I have my gross margin going up a bit more. Has there been any change to this or is it just as expected or an unchanged communication?

0.43.12

Deborah Dunsire

Okay, So Anders will take the other revenue.

Anders Götzsche

Yeah. You know, the other revenue, it's two components. It is of course some of the mature products and it is our contract work. And more or less, you know, it's around 40% or something like that is contract work just off the top of my head, something like that. You should expect – the mechanics in other revenue is we expect contract work to be pretty stable compared to last year and then what you will see in some of the more mature products is of course that we will expect 5-10% decline for the products because you will see a slow erosion but of course, they are in a very later phase of the product life, so, and some of them are also keeping up the pace so it's a bit difficult to say. But if you anticipate it more or less to be at the same level, then I think it would be fine.

0.44.16

Deborah Dunsire

Yeah, then taking your question on the Abide running costs, I think we have been saying ongoing, after we get through to the stable organisation, would be about USD 8-12 million a year. We have also been very clear that they will be absorbed within our guidance this year. Gross margin, Anders?

0.44.39

Anders Götzsche

Gross margin, it will be – you know, the 80-82%, I said also in the beginning, is what we expect for the next couple of years. Of course, Onfi was very profitable and that is of course also what you see when we have a bit of decline but we expect it to be at this level that we have in the first quarter, that is what we expect for the full year. And then, it will be depending on how the product mix is developing. But the 80-82% is what you should put into your model for the next couple of years.

0.45.20

Michael Novod

Thank you

Operator

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

0.45.32

Jacob Lademann

Thank you. Just a few questions. Could you talk a little bit about your decision to terminate your Alzheimer's vaccines phase I project? Does this have any implications to your – presumably - your broader strategy in Alzheimer's Disease and have you had to cancel other projects that were sort of in the vicinity of entering clinical development? And then a question on the Australian patent case that is still outstanding. Could you talk about what is your base case at the moment? Because you have added the sentence in your report that the patent office has issued a license to export your patent and thus, you might not be liable or you might not be able to claim any compensation here. Would that have – so, first question is, could you say what is your current base case and second question is would there be any sort of reasonable grounds to open up any of the other already concluded cases on this basis and potentially reverse some of the claims that you have had? Thanks.

0.46.41

Deborah Dunsire

Okay, Anders is going to start with the patent case and then Johan will take the questions on ACI-24 and the other compounds.

Anders Götzsche

So the 3 court cases that have been settled, there is no way back for them. They are closed so the revenue or the income we took in 2018, that is a done deal. We have one to go and it can take 12-18 months before that is closed. There are two appeal court cases ongoing and the outcome of that is – we believe we have a very, very strong case, but of course, we need to go through the court process and then we need to wait to see the outcome. So, you know, there is not anything more to say about that. But we will keep the guidance independently of if we win the case or not.

0.47.45

Deborah Dunsire

Moving on to Johan

Johan Luthman

Yeah, thanks. So, first let me express that we are actually still extremely committed to Alzheimer's Disease. That stays firm. It is our past core strategy and it remains part of our strategy moving forward. Specifically for ACI-24, the active immunisation approach for Alzheimer's which was against A beta peptide as the immunogen. There were several technical reasons why we did not progress that compound including some issues with getting the titres up with the vaccine and also the design of studies moving forward with some uncertainties in how to execute those trials and also a little bit around the regulatory landscape. There is also, as you may know, some hesitation out in the field in terms of the amyloid hypothesis and when to address it timewise during the development of the disease, so those were the main reasons for terminating that programme specifically. We have other programmes in Alzheimer's Disease that we hope to progress in the clinic in the future. In terms of other terminations, I mentioned the PD1 Inhibitor but that was a very clear case when we had a bet to back up, that is solid strategy and I often call those follow-ups, you like to have better molecules to choose between so again, the problem of choice. We are maybe delaying some of the entrance into clinical development because we like to be sure that we have the proper platform to mould us forward and what I mean by that is that we would like to have the needed biomarker for target engagement and pharmaconomic relation of the molecules for patient stratification etc. So again, moving forward with a much more robust portfolio. We are not particularly looking at for the moment at terminating any pre-clinical programmes. I think we have a very rich and very strong pre-clinical programme right now.

0.49.45

Anders Götzsche

One clarification if I may on Michael's question around other pharmaceuticals and other revenue. You can see it explicitly in the release, just to clarify, both other revenue and other pharmaceuticals, I expect it to be at the same level as in 2018 and the ratio between these two numbers, if that was the question, is around 20% and not 40% as I said. So just to get that clear.

0.50.12

Deborah Dunsire

Thanks Anders.

Operator

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

Peter Welford

Hi, thanks. A few follow-ups, please. Firstly just on Rexulti, commercially have you seen any impact either with conversations with physicians or any sort of impact in terms of I guess your prescription data that you can say were.. post the failure in the bipolar disorder? I guess I am just wondering whether or not that has had any impact on discussions that you have had with doctors in particular in the US market. Secondly then just on the Alzheimer's vaccine, I think if I remember right you saying, you said you are evaluating more proton vaccine approaches pre-clinically. I guess I am just wondering, given your comments you just made as well and I appreciate the titre issue and regulatory but.. the A beta hypothesis? I guess does this suggest you are still investing at the moment behind the A beta hypothesis and you still think there is a rationale in your opinion there but you just need the vaccine to be further optimised? And thirdly then just on Brex depot, has that also been discontinued? I think there was a long-acting Brexpiprazole depot that used to be in the pipeline. And then just a query to Anders on gross margin. Just so I am clear, I believe there were some amortisation charges in gross margin that come out or go down over the next few years. So given your comment on 80-82% over the next few years, I wish to understand .. that was the given mix, essentially the product mix offsets the benefit you likely would get from these amortisation charges decreasing over the course of the next few years? Thank you.

0.51.53

Anders Götzsche

I can start with the gross margin. So what is in the gross margin, the reported gross margin has around DKK 450 million is amortisations of Northera and that will be declining after

2021 where the exclusivity is running out. So you should expect that more or less, you would have an improvement of 2-3% in the gross margin. So if you look at the cash gross margin, then it is of course higher than the reported one. So I hope that answers your question.

0.52.35

Deborah Dunsire

Yeah, so just turning to Rexulti, the impact of bipolar mania studies. First, let me say, we don't discuss these at all with physicians because they are not in our label so I am going to ask Peter to amplify a little bit more on that, whether we have seen any impacts in the market.

0.52.55

Peter Anastasiou

Yeah, the short answer is no, we have not seen any impact and of course, the event happened, learning about the data in the middle of the first quarter and despite that we had a very strong quarter in terms of prescription demand which was very strong double digits. In terms of qualitatively or anecdotally, we don't hear much from physicians, certainly nothing that has propped up to be of any kind of concern. Rexulti is a very effective therapy in MDD and schizophrenia that is delivering great clinical results and our physicians are very happy and patients are happy with the outcomes so nothing of particular note to comment on.

0.53.37

Deborah Dunsire

And Johan, would you like to comment on working on vaccines?

Johan Luthman

Yeah, so there are sort of two things we mean by this, working on more potent vaccines. One is obviously that, I think you alluded to that, the amyloid hypothesis, it is a little bit, the theory is out there that it works but I think most people today would say if you believe in it, you should go very early and obviously, we would like to see whether we can achieve vaccines that give us the titres that we are after if that possibility would open up in the future and the amyloid hypothesis is strengthened. So that is one aspect, that would of course be a pre-clinical programme, so it would take some years until we will reach that point and at that time point, we will have much more understanding about the amyloid hypothesis. We would also of course like to learn from this programme. We think the

approach is very attractive with vaccines. It could work for other targets so we would like to harvest the understanding how we can get more potent vaccines across other protein or peptide targets that may be of interest for other neurodegenerative diseases. I am thinking about primarily about Parkinson's Disease in this case.

0.54.46

Deborah Dunsire

Great. Talking about the Brex depot, that is something that we continue with our partner to examine, is there a feasible path forward and we didn't have one in development, we have been trying to find the right formulation to create the depot formulation for Rexulti and that work continues.

0.55.13

Peter Welford

That's great, thank you

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

Yes, good afternoon, it's Peter from Handelsbanken. I have three questions if I may. The first relates to the decision to take core EBIT back into guidance. You know, in a pharmaceutical industry context, core EBIT typically means that we will see some increased levels in amortisations, write-downs, etc., etc. In your annual report, you detail the amounts related to, I believe it's Northera and also the Prexton acquisition. Clearly, Northera shouldn't be an issue here, but are there any other larger chunks that you would like to highlight at this point in time that should not come as a surprise to us if anything happens there? Second question, Anders, could you just specify the amount of Chelsea related amortisation that you expect in cost of goods sold in 2021? And the third question to Deborah, a follow-up on the discussion that we had at the last call, i.e. this postulated need to add or not add, let's say, revenue accretive acquisitions. Essentially, a part from, let's say, the fixing the Northera patent gap or expiry gap, do you see any other strategic reason to add more revenues to your top line through M&A? Thank you very much.

0.57.05

Deborah Dunsire

We will start out with Anders taking the questions on core EBIT and the amount of Chelsea.

Anders Götzsche

Yeah, so, reporting on core EBIT and EBIT, that is not new. We have been doing that for the last many years. So there is nothing hidden in that. We have around 800 million in amortisations a year, so that, you could say, is the difference. We do not expect any kind of changes in that line. The only thing that can change is if for some reason we get a very negative outcome for Foliglurax before year end or in the beginning of next year where we have to take it into 2019 and we conclude that this programme doesn't work at all. We have no indications. But then you know that we have EUR 100 million on the balance sheet and if we say that platform is gone, if we get negative results, then we have to make a write-off. Then it would hit amortisations and then that would be additional difference between EBIT and core EBIT. In 2021, I must admit, I can't off the top of my head, I don't have the number but it will decline significantly, the amortisation, I think over a couple of years more or less, it will be washed out because we all know that there will be a tail and we defined that tail when we made the acquisition so off the top of my head, I can't recall that number but it will be less than the 450, I can promise you that. So if you build in 100 or 200 million, then it might be appropriate.

0.58.48

Deborah Dunsire

Great. And then to your question on the need to add revenue that is accretive now, I think we are in a great position that we don't have to rush out and do that just to put revenue back on the top line. I don't think you will speak to any CEO who sees growing revenue on the top line to be a bad thing so it would always be nice but for us as Lundbeck, the most important thing we can do is be sure that the company can grow profitably into the short, mid and long term. So it makes us very valuation sensitive as we think about doing late-stage deals and making sure that we can return to our shareholders. So it's always good to be in a position where one can act in something that makes this right strategic sense for this company in the long term but we don't have to do anything in a rush.

0.59.50

Peter Sehested

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.

1.00.01

Michael Novod

Thanks. I just have a follow-up. Just going back to the gross margin, just trying to figure out, if we go back around, say, half a year, a year, then I think the communication was around maybe there is going to be an impact of course in 2019 from Onfi but then we should easily see in reported growth margin also due to amortisations going away, a reported increase of 6-700 basis points easily over the tune of 3-4-5 years. Is that still the case? It seems there is a different communication now, 80-82 in the next couple of years. So I can easily understand that about the amortisations but is there something in the mix that we should just be aware of? Just for ease of our modelling.

1.00.48

Anders Götzsche

Thanks for the question, Michael. I definitely believe that we will be able to improve our gross margin, also going forward. But we are in a transition, you can say, in kind of the next couple of years, we need to wash out Onfi which is very profitable and then the other products are taking over with the strong growth we see for the strategic brand, I think it is very important to remember that the strategic brands are growing. And then from 2021, 2022 and 2023, you should definitely see an improvement based on these 2-3 percentage points from Northera but also due to adjusting general improvements based on product mix and what we said back in time, that is still what we believe in. This was just to give you a bit of more mid-term guidance to what to put into the models and say within the next couple of years, we should expect 80-82% and then it will maybe, two years after, it will improve a couple of percentage points and hopefully, we can drive it a bit further up. But then, you should not expect more than that and that was why we said the ambition is, including Northera amortisation, to maybe 6 percentage points to improve that. That would be a nice target and I think that is realistic. And then from when we have reached that, then let's see what is actually the product mix because you also know it is very product mix dependent. But most of the strategic products we have now, they have more or less the same kind of gross margin so they come with a very high gross margin, all of them.

1.02.47

Operator

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

Marietta Miemietz

Yes, good afternoon, thanks for taking my questions. Actually I some follow-up questions on the Abide compound keys and I apologize, the line was not very good when Johan was speaking so apologies if any of this was addressed. Just wondering on the phase 2a study in Tourette's, can you please give us a recruitment update? The list of exclusion criteria looks fairly long so it would be good to know if you actually do get on-screen failures in practice and what do you think the timelines listed on clinical trials are more or less correct? And somewhat related to that, why do you not expect a finding before 2025? I mean, I would have assumed that the pivotal trials are fairly modest in terms of both enrolment and treatment duration and even with another phase 2 study potentially, 2025 sounds quite long so I am just trying to understand the major bottlenecks there or are you just being conservative? And any sort of detail on why the dyspepsia study was terminated would also be very helpful. And then just a quick commercial question on Rexulti in Europe, please. Can you just give us some detail on the status of the reimbursement negotiations in the major countries just to help us with modelling the sales trajectory, should we expect material sales busier or is that more like 2020 or even beyond, given that the reimbursement can take a very long time in Europe? Thank you very much.

1.04.24

Deborah Dunsire

Okay. To start with Abide, the 1431 study in Tourette's and the long list of exclusion criteria. I am going to hand it over to Johan to comment on that.

1.04.36

Johan Luthman

Yeah, obviously, we are just starting to learn about the study and how it has been run but it is actually, I have to say, it has been running quite well. They had enrolments just when I was there a couple of days ago to patients in the morning, so enrolment is going quite okay, actually. I don't foresee that we should see any major delays in the planning of that study. But it is a complex patient category, we are working with adult subjects at this stage, so there are limitations also in terms of which patients one can enrol, we are not going into adolescents or paediatric patients right now, so it is sort of a more narrow group of people we are enrolling. In terms of the filing, obviously, this is a matter for regulatory discussions that are upcoming. Without giving any specific details, the discussion of course will centre around robust efficacy and the safety package you need to have. So I think, in terms of the pathway for convincing efficacy, as I said, we have convincing initial data so probably it wouldn't require too big of a package from that aspect but we have to discuss with our regulatory colleagues in terms of how many patients they would like to see dosed and how many years they would like to see dosed so

at this timepoint, 20-25 is, I will have to say, a placeholder until we understand a little better those requirements from regulators.

1.06.01

Deborah Dunsire

Yeah, and I think, you know, it is a first-in-class in a new class of agents so, you know, the scale of the package, we just don't know yet so there is a lot still to learn and this phase 2a trial will give us the parameters that allow us to predict better what we are going to have to do for the next steps. With respect to the dyspepsia study, I can't say that I have any information – first of all, did I hear you correctly, a dyspepsia study? That sounds odd. Well, we don't have any specific information that we can comment on today. With respect to your question on Rexulti and the status of reimbursement, I am going to hand over to Jacob.

1.06.51

Jacob Tolstrup

Sure. Marietta, remember that Rexulti is obviously an important launch for us in Europe but it is a targeted launch where we specifically go for a market where we believe we can get an acceptable price. So where we have launched today is where we have gotten what we believe is an acceptable price where we also have reimbursement in place. But that said, it will still take some time in Europe as it usually does, so you will get well into 2020 before you can say some of the bigger markets are coming online. So, a slow roll-out in that sense and remember, it is targeted markets, important for Europe but numbers will not be huge when it comes or significant when it comes to group level for Lundbeck. But of course, an important launch and a perfect product for us to detail in Europe.

1.07.48

Deborah Dunsire

And I think it's important to add that we are not adding additional people resources, it is being absorbed into the current infrastructure so it makes it a very nice addition to the portfolio.

1.08.05

Marietta Miemietz

Thank you.

Operator

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

1.08.15

Peter Sehested

Yeah hi, it's Peter from Handelsbanken with a follow-up question. Just touching upon development strategies in Alzheimer's. With the increasing emerging understanding, you know, that the biological changes that occur in the brain, you know, they occur up to 20 years before you actually see any symptoms. Does this knowledge in any way affect or will it affect guidelines for how to develop these drugs and does this imply that developing drugs based on the amyloid hypothesis is dead as we speak and are we actually going back to the fact that the only approved drugs are based on the old signal transduction hypothesis, are we going back in that direction now, is that what you see? Just some flavour high-level on this topic. Thank you.

1.09.15

Johan Luthman

Yeah, this is obviously a very, very big topic so we can, yes, briefly touch upon it. But the identification of subjects is a matter of big investigations right now. How we genetically or through various biomarkers could identify people way before they show symptoms. This is the conundrum of the disease. Obviously, there are dominant mutations, those are small groups but there are many risk factors including AP4 that people now start to realise that maybe we should have more screening earlier in people 45-50 years old. We are not there yet. But I think the technology will advance with the therapies. When it comes to the guidelines, I am sure you are aware about FDA's pretty recent draft guidelines where they actually open the door for approvals based on biomarker effects. Of course, that would require substantial validation of that biomarker, that it links to some clinical meaningfulness, but that is really probably a pathway to go in terms of future clinical trials. We have to figure out how this will be done but there are ongoing activities through many different consortia, academic groups and industry groups looking into this.

1.10.27

Peter Sehested

Okay, thank you.

Operator

Thank you. And that is the last question in the queue so I will hand the call back to you, speakers, for your closing comments.

Deborah Dunsire

We would like to thank everybody for dialling in today. We are very pleased with a strong start to 2019 and the first step in our external innovation agenda, Abide Therapeutics being announced and we look forward to talking to you at the end of the second quarter. Thank you.