Lundbeck Teleconference

2020 Q1 Results
12 May 2020 at 13:00

Operator
Ladies and gentlemen, welcome to the H. Lundbeck Q1 2020 conference call. For the first part of this call, all participants will be in a listen-only mode and afterwards there will be a question and answer session. Today I am pleased to present Deborah Dunsire, President & CEO. Please begin your meeting.

Deborah Dunsire
Thank you very much operator. Thank you all for your interest in Lundbeck. We welcome you to this Lundbeck teleconference covering our financial report for the first quarter of 2020. Together with me are our CFO Anders Götzsche, Johan Luthman, head of R&D, Jacob Tolstrup, head of Commercial Operations and calling in from Chicago, Peter Anastasiou head of North America. On slide 2, you can see your disclaimer which I know you have read many times so let us move on to slide 3.

Firstly, I want to say how proud I am of the way Lundbeck employees responded to the immense challenges of the COVID-19 pandemic. They continue to put patients first while embracing and delivering on our Expand and Invest to Grow Strategy. Our strategic brands continue to show remarkably strong growth both in volume and value across all regions of the world. In total, our strategic brands grew 35% and now constitute 59% of revenue. In the quarter, Vyepti was approved on the PDUFA date by the US FDA, a phased launch commenced in April. Of course, these are not normal times but we are encouraged by the interest from patients, health care professionals and payers. The first patients received infusions of Vyepti the day after the product was made available in the supply chain. We have also accomplished the first submissions for regulatory approval in other parts of the world.

We are acutely aware that 2020 is a year with more than usual uncertainty but as of Q1, we see strong performance with good underlying demand growth. Anders will elaborate on the financials in detail so here I will just state that we are reaffirming our guidance. With that turn to the next slide, please.

Before we move on, I think it is reasonable to elaborate a little more on how the COVID-19 pandemic has posed challenges for us during the first quarter. Lundbeck's top priorities during the pandemic are and will remain preserving the health and safety of our employees and ensuring that we can continue to safely supply all of our medicines to the millions of patients who depend on them around the world. Working from home became the norm for all our employees across the globe except for our production and lab employees in Denmark, France, Italy and the US who continued to operate with streamlined teams throughout the lockdowns. We are proud to say that the global supply chain for our medicines has remained fully intact. We know that some of the strong growth in demand for our products in the quarter was partly driven by prescription lengthening in many countries. We also saw increases in inventory across the distribution channel. We anticipate such stocking will unwind during the second quarter. We now see a growing number of countries in which employees are returning to the office in line with government guidelines as the pandemic has peaked and receded in this first critical phase. China and Korea are getting back towards normal and in Denmark, we will have 50% of our office workers back on site as of tomorrow. This is very encouraging, but it is far from being normal.

Our ability to interact with healthcare professionals is still predominantly through virtual channels. We significantly expanded our use of digital solutions and increased the use of compliant remote platforms for educational and promotional interaction with healthcare professionals. It is important to note that the COVID-19 pandemic also impacts the clinical and regulatory activities as many healthcare systems have had to reprioritise, limit or cease activities in clinical trials to ensure patient safety and allow physicians and other healthcare professionals to turn their attention to combating the pandemic. We still expect to be able to start new studies later in the year and Johan will comment on this in more detail.

Next slide please. The graph to the right of the page illustrates that Lundbeck is returning to growth. If one excludes the loss of exclusivity-based declines in Onfi, Sabril and Xenazine in the US, revenue is up 22% driven by the significant growth momentum of our strategic brands.

The other mature brands are relatively flat as a whole with declines being balanced by growth in several markets like Japan and China. The momentum of the major strategic brands as well as the growth of our new arrival Vyepti will drive Lundbeck's growth going forward.

Please turn to the next slide. Our full major strategic brands generated substantial growth, up 35% in aggregate adding DKK 700 million in sales compared to the same period last year. There is healthy volume growth for all our strategic brands but we also recognise a certain benefit from inventory increases. These growth products constitute close to 60% of Lundbeck's sales. Rexulti is the majority US franchise. The brand achieved more than DKK 700 million in sales in the quarter which represents impressive growth of 48%. Very impressive in its 5th year on the market. Revenue from Brintellix/Trintellix reached DKK 817 billion in the first quarter 2020, growth of 36%. In the US, Trintellix continues to increase its market share. We have seen continued strong demand growth driven by an increase in new patients as well as improved persistence on therapies.

Abilify Maintena was launched in 2013 and still grew 33% to more than DKK 600 million. In many markets, Abilify Maintena is now the second most prescribed long-acting injectable treatment for patients with schizophrenia. Northera grew 24% finishing the quarter above DKK 530 million. We continue to expect good volume and value growth for this product in 2020. We continue to expect the strategic brands will continue double-digit growth in the rest of 2020, a testament to the value these products provide as well as to the excellence in execution by our commercial organisations around the world.

Next slide please. As you know, the FDA approved Vyepti on the PDUFA action date of 21 February and we managed the importation of the product in spite of the COVID-19 situation and we were therefore able to fill the first orders at the beginning of April as expected. The first patients already received infusions the following day from the supply chain being filled.

Following the requirement for our employees to work from home, the launch strategy has obviously been adapted into what we term a phased launch. During this period, we have conducted a lot of virtual training sessions, educational events and some promotional activities. Upon removal of our work from home policy, the sales team will begin to see healthcare professionals again. But we do anticipate this will be a slow ramp rather than a single flip of the switch returning 100% of the planned activities. We see strong interest from healthcare professionals and several payers have also issued coverage policies. It is an encouraging beginning given the times we are living in.

Next slide please. The fact that we have been able to continue to enrol patients in the RELIEF study with Vyepti is another demonstration of patients' interest in this product. We also have an

aggressive plan for maximising the value of Vyepti which we see as a pipeline in a product. The first new indication we plan to pursue is episodic cluster headache where we see strong potential.

We have also on previous occasions stressed the need for a market access study to support European pricing dialogue. This Phase IIIb study is planned to commence around the middle of the year but it is important to stress that the COVID-19 situation may hamper the process of starting new clinical activity.

Finally, I am glad to say that we have submitted for approval of Vyepti in Australia, Canada and Switzerland. It is still our plan to submit in Europe by the end of 2020. Johan will talk further about the pipeline in a minute, but I will now hand the microphone over to Anders Götzsche to comment on the financial picture.

0.10.23
Anders Götzsche
Thank you very much Deborah. Please turn to slide 9. Revenue increased by 8% reaching DKK 4.6 billion with limited impact from exchange rate. This is driven by the strong growth from all our four strategic brands. Cost of sales declined 2% to DKK 805 million for the quarter of which amortisation on product rights was DKK 197 million. Our gross margin reached 82.4%, up from 80.5% last year.

We maintain good control of our operational costs. The SG&A costs increased 18%, which is mainly linked to the Vyepti related costs and investments in China and Japan as well as other growth initiatives globally. The SG&A ratio was 37.7% compared to 34.5% the year before. R&D costs more than doubled but due to the impairment of product rights related to Foliglurax of approximately DKK 800 million, adjusted for this, the R&D costs increased by around 17% mainly related to Vyepti project costs.

Core EBIT reached DKK 1.357 billion and core EBIT margin only declined from 33.3% the year before to 29.7% this quarter. We see this as a very solid result. The effective tax rate for the quarter is heavily impacted by the Foliglurax impairment. Focusing on the core tax rate, it actually declined from 25 percentage points to 23%. Core earnings per share reached DKK 4.89 per share.

Please turn to slide 10. In the North American region, we are very pleased with the continued strong growth of our strategic brands which now constitutes more than 80% of the regional revenue. Actually, if adjusted for Onfi, Sabril and Xenazine, the growth is 32% for the quarter. International markets increased 16% reaching DKK 1.2 billion or 27% of our revenue. China has been negatively impacted by the COVID-19 situation in line with the expectations communicated in February. However, other markets in the region have had a positive impact from inventory increases in the distribution chain. This region is still in the early part of the roll-out of our strategic brands which had growth of 37% in the quarter.

We expect to see significant long-term growth for these products in the region. Japan is an investment area for Lundbeck as we have just launched Trintellix together with Takeda. Trintellix was launched in November so it is early in the launch phase but so far, the product has had a solid – very solid start. COVID-19 has had a slight negative impact on the uptake during the last two months.

Europe is delivering solid growth with revenue increasing 9% to almost DKK 900 million. The main driver is volume growth but we have also benefited from inventory building. The European region is also an important part of our overall performance as it is driven by our strategic brands which grew 28% and now constitute more than 57% of sales in the region.

Next slide please. Lundbeck continues to generate a solid cash flow although the level is being impacted by the major investments as part of the Expand and Invest to Grow Strategy. The cash flow for the quarter is impacted by the payout of dividend of DKK 850 million. We expect a net debt position by the end of the year to be around DKK 6 billion.

Next slide please. Based on the solid performance in the first quarter we have confirmed the guidance we provided in March following the Foliglurax data announcement. We expect continued growth for our strategic brands. Abilify Maintena, Brintellix/Trintellix, Northera, Rexulti and now also Vyepti which will more than offset the impact from the continued generic erosion on our mature product portfolio.

It is also important to point out that following the Corona virus outbreak, Lundbeck sees increased uncertainty for the remaining part of 2020. We still expect growth in the revenue to be around 2-6% and meaning a revenue range DKK 17.4 to 18 billion. We will continue to be disciplined in our spending in 2020 but as we have previously communicated, we will make considerable investments in launch and development activities related to Vyepti which will impact our EBIT for 2020. Core EBIT is expected to reach a range of DKK 3.5 to 4 billion which is a margin of at least 19%. Reported EBIT is expected to reach between DKK 1.4 and 1.9 billion for 2020.

For the financial items, you should expect a net expense of DKK 300-400 million depending on the currency development. Now I will hand over to Johan to provide an update on our R&D pipeline.

0.15.59
Johan Luthman
Thank you, Anders and first I would like to comment in general on the impact of the COVID-19 pandemic on our clinical development portfolio. We have implemented major mitigation activities with our partners and CROs including remote solutions as much as possible. We are making every effort to ensure that patients in affected areas who are enrolled in clinical trials can continue their treatment and receive their proper care and monitoring.

The situation is evolving by site and country, but as local conditions allow, we will enrol patients in ongoing studies and even start new trials when possible. It is, however, clear that enrolment in site activations are impacted. Furthermore, dropout rates in our ongoing trials have increased. The broad life cycle management programme on Brexpiprazole is heavily affected but currently it is too early to tell what effects on timelines this may have.

That said, we have also been able to maintain some critical activities such as the RELIEF study and the Japanese PK study on Vyepti. We also had some recent programme events. Initially, I would like to comment on the lead MAG-lipase inhibitor 06466. We are initiating a number of studies to fully explore its mechanism of action across a range of psychiatric and neurology indications. However, as announced earlier, the small Tourette's phase IIa study did not support continuation in that indication. This programme is one of several programmes we expect to see in the coming years after the serine hydrolase inhibition platform pursued at Lundbeck La Jolla Research site. We have high confidence in the research platform we acquired last year.

Foliglurax phase IIa study for Parkinson's disease add-on therapy up to standard care did not provide sufficient so-called off-time reduction and had no effect on dyskinesia. And with that, that the entire programme has been terminated. We also had some moments in the early-stage pipeline. Our lead Kv7 activator was stopped due to lack of desired PK and safety margin profile but we expect at least one more first in human entrant this year.

Importantly, I would like to highlight that we have substantially enlarged the programme around Eptinezumab. In the coming years it includes supported studies for registration and market access in various geographies as well as several indication expansion studies.

Next slide please. I have probably not been speaking much about Vortioxetine for a while but we are actually still performing quite a few studies on this very interesting drug. For instance, we have recently finalised the complete study which was an open label flexible dose study of Vortioxetine investigating emotional functioning in patients with major depressive disorder with partial response to SSRIs and SNRIs. Up to 75% of patients treated with those agents can suffer from so-called blunted emotions which have real functional consequences for patients' social, family lives and work lives. The outcome of the study has not yet been published so there are limits to how much I can describe at this stage. However, the data are very good with highly significant effects on emotional blunting observed already one week after initiation of treatment. This adds to the body of data supporting Vortioxetine's broad impact in major depressive disorder. With that I hand over to Deborah.

0.19.34
Deborah Dunsire
Thanks Johan. Next slide please. Through the hard work of our employees, we have adapted our ways of working to the changed conditions in the wake of COVID-19 keeping our employees safe and ensuring business continuity and including maintaining supply to ensure our medicines reach the many people suffering from brain diseases. As a company, we also do not forget that we have a role in the societies we live in. These unprecedented conditions have also led stakeholders to ask for our support. We have assessed each request carefully and responded with care and consideration to the specified needs. We are pleased that we have been able to provide financial and medical support to eligible recipients and patient groups in many countries, including China, Europe and the US. The pandemic has generally reduced the physical activity on our sites so that together with our other preventive actions has led to a reduced number of lost time accidents.

In spite of the pandemic our focus on progressing to carbon neutrality has not diminished and Lundbeck has contributed as part of the Danish climate partnership on business ambition 70%.

Next slide please. It has been a very busy quarter and I am sure the rest of 2020 will be just as eventful as we work to mitigate the effects of COVID-19, continue the phased launch of Vyepti in the US and drive our current business forward while we continue to execute on our Expand and Invest to Grow Strategy.

To summarise, leveraging our deep neuro-science 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 and achieve these goals. With that I would like to thank you all for your interest and open the Q&A session.

0.21.53
Operator
Thank you. Ladies and gentlemen, if you have a question for the speakers please press 01 on your telephone keypad. Our first question comes from the line of Wimal Kapadia from Bernstein. Please go ahead.

0.22.06
Wimal Kapadia
Great. Thank you very much for taking my questions. I am Wimal Kapadia from Bernstein. The first one is on the stocking benefit in Q1. Are you able to provide any impact in terms of DKK million amount which products were most impacted and particularly within which regions and then tied to this how should I think about the margin benefits from these additional revenues? Can you confirm these higher margin revenues which will then be rebated away later in the year? My second question is just on Vyepti coverage. You mention several payers so I am just curious how much access you actually have today and how do you expect that to evolve over the coming months and you know has COVID-19 really slowed down your ability to negotiate the coverage and then tied to this you know the DKK 2 billion spend in 2020 given COVID-19 should we expect less this year and some of the spend to roll into 2021? Thank you very much.

0.23.04
Deborah Dunsire
Okay, lots of questions there and I am going to hand over to Anders to start on the stocking benefit.

0.23.09
Anders Götzsche
So we have seen a lot of different movements in the quarter from stocking. We have seen a slowdown in China due to that reps are also not in the field. Now we see a rebound. You see stocking in some areas, you see destocking in other areas. It is extremely difficult to quantify and we have decided not to go into it because I think if we quantified it, it would only, the only thing we could be sure of it was a wrong number so we are not going into that but of course having 8% growth in the quarter and that is actually driven by 35% in the strategic brands and please remember that last year we had 28% growth in the strategic brands so what has happened in the first quarter is that we continue the growth momentum and then on top of that there was an impact from stocking so of course that also impacted the good margin in the quarter and for the full year we still anticipate growth of 2-6%. If the destocking will come in the second quarter, third quarter, fourth quarter is extremely difficult to predict.

0.24.19
Deborah Dunsire
Yeah, then you asked the question, Wimal, about will these sales as the inventory comes off will it be rebated later and I don't think that we can tell that now. Anders would you comment on that?

0.24.35
Anders Götzsche
No, we don't have a lot of insight into.. basically the business is ongoing, you have seen, we have taken the price increases as we have taken which is in line with last year. The only outstanding price increases are for Rexulti and Abilify that will probably be taken in mid-year but of course that call is Otsuka's call so that we are waiting for that. That is basically only outstanding. The underlying growth is continuing and with respect to the DKK 2 billion we anticipate that we will continue to invest in - as Johan alluded to – in R&D investments for expanding the indications we will continue to invest in the launch activities. There will be some, if this continues, then there will be some savings in travel and events and other things but we might want to use that for investing in digital platforms and other ways of working so for the time being, we stick to the numbers that we laid out when we started the year.

0.25.40
Deborah Dunsire

I think just one comment on the stocking benefit before I hand it over to Peter to talk about Vyepti coverage. It is hard to discern what is prescription lengthening so in other words the patients instead of getting a couple of weeks or a month get maybe a month or 90 days and therefore it is sales that have moved forward versus actual inventory build and so it is a complicated mix of things, Wimal, and we cannot really dissect it. With that I will hand it over to Peter and ask you to comment on Vyepti insurance coverage and whether it has been more difficult and how much of the market is now covered.

0.26.25
Peter Anastasiou
Yeah so thanks for the question, Wimal. Hopefully, you can hear me. As you know when you get a new product launched, access does not happen all at one time. It happens over a period of time and different payers have different policies. Some have a wait and see policy. They want to see what kind of demand is out there. Some have preliminary decisions have been made kind of automatically no matter what the product is and then of course others make decisions right away so I think it is important to highlight that pandemic or no pandemic, getting access for new therapies is always a process that can take many months. Having said that, I would characterise our situation with Vyepti as being on track, to our expectations from an access perspective or maybe even slightly ahead of schedule. We have had many plans that have made positive decisions. Most notably Anthem which is the second largest payer in the US, which is great but we have also had several regional plans and other plans that have made positive decisions and in terms of is it more difficult, I don't believe it is more difficult with the COVID-19 situation because many of the interactions we have had with payers, some are face to face but many of them are virtual already because the payers, the personnel that we deal with where we are working on the you know health economic story where we talk to them about the clinical story etc. often times are disbursed across different sites for the payer across the country and it is very rare that all of those people are at the same place at the same time. So we have been used to it in past working in this virtual world with payers and so working under the current circumstances haven't hampered our efforts at all. I would just close by characterising it as on track at the very least and maybe even slightly ahead of schedule.

0.28.15
Deborah Dunsire
Lastly, Anders do you want to add anything on this question?

0.28.19
Anders Götzsche
Yeah maybe to your question around cost, it goes without saying, the situation right now is that it seems as a lot of countries are starting to reopen. What it also means is that some of the clinical trials will start to regain momentum. If it continues, you know, if you have a long lockdown in countries then and the clinical trials are not restarting, then of course we will have some saving from a project point of view but already we have seen for example in Denmark there have been trials not for our company but other companies are restarting so you slowly see things are regaining momentum and if it is only a couple of months, we don't anticipate to see a lot of cost saving so in general you should anticipate that the level that we have indicated before is more or less that level but of course not more than the DKK 2 billion. It could be slightly less.

0.29.17
Wimal Kapadia
Good thank you very much

0.29.21

Operator
And the next question comes from the line of Marc Goodman from Leerink Partners LLC. Please go ahead.

0.29.29
Marc Goodman
Yes, hi, a couple of questions. One: Rexulti in Europe, can you just give us a sense of what countries it has been rolled out in and where we should expect that to go so we can get a sense of the ramp there? It still seems it has not got going yet. And then can you give us a sense of Vyepti in I guess in the month and a half that you have had it on the market how it has done and how you expect that impact you know you talk about a phased ramp. Maybe you can explain what you mean by that and how we should expect that product to do in this environment and the last question, well it is just the gross margin, the core gross margin was obviously very strong in the quarter. I was wondering if that you know 86-87% type range was sustainable for the year? Thanks.

0.30.20
Deborah Dunsire
Great. Jacob is going to start on Europe

0.30.23
Jacob Tolstrup
Thanks very much for the question so on Rexulti for Europe, true it is still in a relatively limited number of countries. Switzerland and Northern European countries where we have launched Rexulti at this time and I think we also commented on this earlier. Rexulti for us in Europe is focused on schizophrenia, will be a great addition to our product portfolio but it is also a product where we do not anticipate it to grow strongly compared to the other key brands in Europe like Brintellix and Abilify Maintena. The next bigger launch that we are looking at in Europe would be Spain right after summer.

0.31.11
Anders Götzsche
Yes, and please remember that 90+ of the potential of Rexulti is in the US from a peak sales point of view.

0.31.17
Deborah Dunsire
While you are talking do you want to finish up on the gross margin and then we'll get Peter on the Vyepti question.

0.31.22
Anders Götzsche
Thanks Deborah. Yes for the COGS you should – it is high in the quarter, you should not expect that to stay as high. What you also see is we have launched Vyepti and we will start to make amortisation of product rights so you should anticipate that cost of sales will increase north of 20%, 21-22% for the full year, which brings the gross margin below 80%. So that is what you should expect.

0.31.52
Deborah Dunsire
Thanks. Peter over to you for the Vyepti.

0.31.56

Peter Anastasiou
Yeah, so I won't be able to provide you quantitative comments because of course we don't provide numbers for the quarter that we are in, but I will be happy to provide qualitative comments and that is that the stocking went well. The facts that Deborah pointed out that we were able to get the products in the market and the supply chain fully filled so it was a great achievement. We have had many patients who have been treated. You may say to yourself and you know in this environment there are patients coming out for infused therapy and there have been many patients who are dissatisfied with other therapies who have been waiting for Vyepti and many clinicians who have been preparing patients and had patients ready for treatment and so we are definitely seeing numerous clinics and numerous patients utilising the product which is all great. The things that we intended to have ready to support the product, things like our Vyepti Connect programme which is a kind of reimbursement support programme which is pretty common for these types of infused products is up and running. We also have a patient support programme called Vyepti Go which is up and running. We have been able – as Deborah, I think alluded to earlier – to do numerous activities online. Speaker training programmes, actually been able to do speaker events virtually and of course a number of details, through phone and then also to through Viva and other online tools that we have and that is really what we mean by the phased approach. You asked the other question. What do we mean by phased ramp so by phased we mean first phase is now of course virtual, the second phase will of course be full face-to-face launch but even when we get to face-to-face, these tools that we have already created and this ability to work in a virtual environment will continue to be there as a supplement, not just for our launch efforts for Vyepti but on the rest of our portfolio because everything I have just said about Vyepti is also true for the rest of our portfolio that we are able to do the same type of promotional activities virtually while we are in the stay at home mode so hopefully that gives you a qualitative sense of how things are going.

0.34.15
Deborah Dunsire
Thanks Peter and I think just the last thing to say is: It is definitely not the same as it would have been with a full, normal launch but it is very encouraging and we don't think that that has bearing on the ultimate potential for this brand. Next question.

0.34.34
Operator
The next question comes from the line of James Gordon from JP Morgan. Please go ahead.

0.34.40
James Gordon
Hello, thanks for taking the questions. James Gordon, JP Morgan. Three questions please. First one was about stocking and extended prescriptions. I noted the comments about it being difficult to quantify but can you just talk qualitatively about where the most benefit was observed? Would it be fair to assume it was Trintellix and Rexulti that got the prescription length and the stocking benefit because Maintena could be stocking but wouldn’t be prescription length. And Northera, are you actually seeing any less use because people are housebound and so if they are socially isolated, they don’t want to take the products and pay the co-pay? And on stocking, I noted the comment about destocking in H2. Most of the companies are talking about the Q2 destocks, I am just wondering if there is any reason why they might be that different?

Second question was China. I know that you said that international markets have seen stocking benefitting the health but can you talk about how much China did actually slow so what does COVID actually do in the region which would be most impacted?

And then third and finally, just pipeline. So unfortunately you did have some setbacks in the earlier pipeline. Does that mean that plans change at all in terms of the extent of which you might be looking to license more assets in for the rest of the year? Could we see some more deals or does that not change anything and it's much more just a focus on what you've already got in house? Thanks.

0.35.53
Deborah Dunsire
Okay, thanks James. I think the first thing to say is that the stocking affects basically all the products at the distributed level. The extended prescription, you are right, will affect the oral brands more, Abilify Maintena certainly not. Where we think Abilify Maintena has benefitted is people may be looking to a longer-acting formulation than an oral formulation so we may have seen more utilisation of the long-acting injectable in this environment so there is definitely demand going up on all the products and there is the prescription lengthening on the oral products. For Northera, we know that there is always a reset at the beginning of the year as prescription plans change so it looks as years like 2018 does, we don't know how much of that could be people not taking medicine because they are homebound, that is certainly a consideration but we don't have a clear view. With respect to unwinding, I think I said the second quarter. If it came out as the second half, then I apologise but we had also indicated, we should have indicated second quarter. China, Jacob?

0.37.21
Jacob Tolstrup
And absolutely right, we have seen a negative impact in China compared to last year, we have growth in China but compared to our expectations, we do see a negative impact in China. Remember for international markets, I also expected China to be the worst hit market, it is where the vast majority of sales are going through hospitals in China and hospitals in China have obviously been very impacted by the COVID-19 situation and trying to combat that epidemic in China. What we see now is that 60% of patients are now back into the hospitals in China and we see growth again coming back into our business in China. So the negative impact we have seen in the beginning of the year, we expect to sort of even out not completely but even out as we go through the remainder of the year.

0.38.19
Deborah Dunsire
And then on our pipeline setbacks and business development, I think we have had the Expand and Invest to Grow Strategy in place that continues unabated. We said we would look for deals across all phases of the pipeline, that continues to happen. I think what is great about the position that Lundbeck is in with strong momentum in our brands and a good solid financial foundation means that we are not, we don't have to rush to do any particular deal, that we will only do deals if we find the right assets for our company at the right price. So we continue to look in the way that we have said we would look before. We would like to strengthen that mid-stage pipeline but we will continue to be disciplined. Johan?

0.39.10
Johan Luthman
Maybe I can answer that that obviously we have our Brexpiprazole phase II activities, one study and of course Eptinezumab we are going to look at the indication expansion as you heard so there are more phase II-III trials that will come out of that programme, quite a bit. And obviously on top of that, we are trying to progress our internal pipeline as quickly as possible. We are replenishing of course phase I continuously with new hopefully promising molecules and when they deliver in early

stage, we will force them more quickly to the pipeline but obviously, we are also looking continuously at the value of the outside world and what they can add to our pipeline.

0.39.47
Deborah Dunsire
Thank you. Next question.

Operator
The next question comes from the line of Trung Huynh from Credit Suisse. Please go ahead.

0.39.59
Trung Huynh
Hi, thanks for taking my questions, Trung Huynh from Credit Suisse. Three if I can. Following on from Wimal's Vyepti question on market access, can you just talk about how prescribers have reacted to the reimbursement process, given that it is different to the sub Q CGRPs and you mentioned there was a bolus of patients waiting for Vyepti. Should we expect the first quarter of sales to be unusually higher than the later quarters because of this bolus or should we expect a more sort of normal sales development earlier on? And then just on your Tourette's failure, what have you seen that gives you encouragement in the other indications? And which indication do you think holds the most promise? And finally very quickly on James' question on M&A, what do you think about the valuations in the current environment today and what leverage ratio could you go to? Thanks very much.

0.40.55
Deborah Dunsire
Okay, starting with Vyepti reimbursement – Peter, the process and how physicians….

Peter Anastasiou
Yeah, as we have mentioned on previous calls, in our targeting, we are mostly focused on customers who in the headache clinics already have the capability to do infusions and they have experience doing in-office procedures, either having done infusions for other products for migraine or having done in-office procedures like Botox, so the initial customers, as we had planned, are quite experienced with this approach. They are used to dealing with medical benefit, either buying and billing the product or working with a specialty pharmacy that does then what is known as white-bagging where the vial is then sent from the specialty pharmacy to the office to do the infusion. So they have reacted quite normally because they had that experience so there is nothing that really stands out. As I also mentioned, we try to provide strong levels of reimbursement support, all within compliance of course through the Vyepti Connect programme and so those things also of course help the commissions and practitioners. On your point about bolus, I just want to be clear, I didn't mention that there was a bolus nor do I expect that this would have any kind of front-end loaded uptake. I think you will see probably something that is pretty traditional in its uptake. What I was trying to highlight is despite the fact that there is the pandemic, this disease, migraine, is quite debilitating for patients and it causes not just pain but also it exacerbates other things functionally for patients. So for many patients, because they were dissatisfied with previous treatments, the risk benefit of going out and getting an infusion weighs in favour of going out and getting the infusion. That is what I was trying to highlight but I don't necessarily believe that there will be some lumpy uptake as you had mentioned.

0.43.13
Deborah Dunsire
Johan, would you like to comment on the Tourette's?

Johan Luthman
Yeah, thanks for the question. I mean obviously you may recall that the Tourette's study was started by Abide, the company we acquired in May-June last year and was a small study but was a very clear signal that it didn't work in that indication. However, what we learned from that one was obviously a lot on the molecule's safety and tolerability and doses that we can use. We have still very, very strong confidence in the biology here. This is a very broad biology and what we can do now in a much more comprehensive way is to really cover the areas where we have expertise where the previous company could not really cover and we have done a very thorough analysis of the biology's potential together with different external opinion leaders and experts in the field so we have the possibility now to position it maybe a little bit better to explore the full potential of the biology.

Deborah Dunsire
What indications?

Johan Luthman
And the indications we are looking at in particular are across psychiatry and neurology but we are looking at things like MS spasticity and epilepsy and you are well aware that those are areas where exocannabinoids have delivered also in the past so obviously that is part of our considerations. But overall, we are looking at potentially four indications that we will initially explore in, smaller phase I b type of studies.

0.44.39
Deborah Dunsire
Thank you. Valuations, Anders?

Anders Götzsche
I think our interest in strengthening the pipeline is not driven by valuation, it is driven by the scientific rationale in the compounds and you have seen companies developing all over the place, of course when crises are facing global environments, then some companies are declining and some have actually appreciations in the share price due to good results so we are more looking into what is the scientific rationale and then of course it needs to be combined with an attractive valuation and then we of course will look to strengthen our own portfolio with that.

0.45.19
Deborah Dunsire
And the question of firepower?

Anders Götzsche
And the firepower is still what we have said, USD 1-2 billion, but it is very much depending on the target that we are going for, if it's a target with earnings, then it would of course go towards 2 billion but if it is dilutive target where we need investments, then it is more in the ballpark number of USD 1 billion that we could use. But for the time being, we want to go through with the next couple of months, see how the pandemic actually is – we hope that it will kind of ease out and then the countries will reopen and then we have more visibility into the future and then we will continue but of course we are very active as we have been doing for the last 3-4 years or last couple of years, we will be looking into executing on the Expand and Invest to Grow Strategy so that is unchanged.

0.46.17
Trung Huynh
Thanks very much

Operator
And the next question comes from the line of Martin Parkhøi from Danske Bank. Please go ahead.

Martin Parkhøi
Hello, Martin Parkhøi, Danske Bank. I have two questions, I think they are both for Johan. Firstly, I'm just a little bit curious, maybe it's not relevant for the long-term perspective but you announced the termination of Kv7 and as I recall it, you started phase I in December and announced it in the full-year result and now you terminate it based on pre-clinical data so just walk me through how that can be. Is it pre-clinical data you have made after the phase I decision or what has happened actually?

And then secondly, also to Johan, now you have been in Lundbeck for a year or so, are you satisfied with the development that you have seen, in particular on the internal development of projects. Do you think that you are responsible for a pipeline which can live up to Deborah's aspiration of creating a sustainable growth company?

0.47.24
Johan Luthman
Okay, thanks for those questions. I have to say, the first one is pretty easy to address because you know when you progress a molecule into man, there are a lot of uncertainties how they behave because we have only animal data and cell data and you get surprises in either way because biology is not that predictable across species. The other thing that is happening when you develop a molecule, you continue with your pre-clinical safety work etc., you are building up further, so this is continuing of generating data. This molecule, basically we needed to go very quickly into man and we realised the pharmacokinetics did not deliver the required margin for the calculated pre-clinical safety data so it was really not a massive change in the pre-clinical safety data but basically, the pharmacokinetic data did not deliver. It had a peak exposure that was too high. So that is a very simple thing and those things happen all the time in phase I, that is kind of regular business.

But to your more important question, one year at Lundbeck. We are working vigorously to try to build our pipeline and progress our pipeline. Am I confident that this is good enough? No. We continuously have to improve this by working more efficiently, deliver our drugs as fast as we can from our discovery machine with high value and all the toolboxes we need and obviously, we should explore the full potential of the molecules we have at hand. And I mentioned Epti. So there are a lot of things we need to do and we need to de-risk late development further and that is why we are investing so much in early development, that is where the molecules should fail if they fail, not in late development. Generally we are of course, we commented on BD and other activities to fill the pipeline. The pipeline is weak in the middle admittedly and we have to do something about it.

0.49.18
Deborah Dunsire
Just clarifying that the Kv7 stop was in man, so we were actually in people.

Johan Luthman
Yeah, sorry, that wasn't clear. It was first in man dosing that you know it has delivered the data we didn't want to see.

Martin Parkhøi
Thank you.

0.49.33

Operator
And the next question comes from the line of Michael Novod from Nordea Markets. Please go ahead.

Michael Novod
Thanks a lot, it's Michael from Nordea. So a couple of questions, maybe one to sort of the effect of COVID-19 and social distancing and also economic crisis on depression rates. We saw some quite concerning stats out of an express scripts back in March, dealing with the February data. So already there, you could see this major increase in scripts. So maybe you could just talk about whether we have seen anything driving additional prescriptions for depression drugs, anxiety drugs etc. in past crises? And then secondly, maybe Jacob could talk about the Brintellix/Trintellix launch in Japan and what you are seeing there, whether the uptake is satisfying or not? And then lastly on Vyepti on the 3 months. Is there a formulation advantage? We have heard Teva talk about it, I know they are the only ones with a subQ 3 months talking about this in terms of COVID-19, less frequent visits to the physicians, etc. Is that something that can be done more about in this area of social distancing?

0.50.52
Deborah Dunsire
Okay, lots of great questions, thanks Michael. First on the COVID-19 and its impact on mental illness. You know, this is a global infectious disease pandemic but what is following behind it is an acute rise in mental illness. People are faced with an existential threat to their safety and their life in the infectious disease. They are also faced with the economic dislocation of job loss and change and then on top of that, there is the isolation of the social distancing, so unprecedented numbers of people are seeking mental health counselling for the first time or coming back after having been well for a while and we are seeing a rather profoundly disturbing trend for an increased volume of calls to suicide hotlines so we know that this global crisis will be followed by a huge tsunami of mental illness and that is beginning to manifest. And so there is a demand, yes, there is increased demand for drugs to help patients with depression, with anxiety particularly and we may even see, we have seen some indications of rise in posttraumatic stress disorder in some of the healthcare professionals who have been dealing with pretty apocalyptic settings in places like Northern Italy, Wuhan and even in New York City. So no doubt, there is a huge need for the medicines that Lundbeck produces. I am going to hand over to Jacob for comments on Trintellix in Japan.

0.52.49
Jacob Tolstrup
Sure. Thanks for the question, Michael. So very briefly, we launched at the end of last year as you know, we had actually a really good launch, great start, market shares did better than expected in the beginning, we have a great partnership with Takeda in Japan. And then of course the lockdown came and for a brand that is new to market in Japan, you have a two week prescription ban for the first year and that means that there is no possibilities to have extended prescriptions for instance like you see in other markets. So we are being impacted by that in Japan. So since the lockdown, Trintellix has been growing but slowly and up until very recently, we now start to see a pickup again for Trintellix. So overall, I am very satisfied because we managed to change as much as we could into virtual detailing for the brand and looking at the share of voice in Japan, Trintellix is the brand that is having by far the highest share of voice in the market, also including virtual and remote detailing. So I am very hopeful that we will be able to pick up again and come back to the trajectory that we were on in Japan.

0.54.16
Deborah Dunsire
Great, and then with respect to Vyepti 3 months, Peter, would you like to comment?

Peter Anastasiou
Yes, before I do that, I also just wanted to mention to add onto what Deborah said about mental health. I would also point out that there is a high comorbidity of migraine and mental health conditions like depression and anxiety and we have heard from key opinion leaders and customers that those two things often travel together so I think everything that Deborah said is absolutely true but could also have some impact on the migraine market. Specifically on Vyepti 3 months we believe it is an advantage with or without the pandemic. We have talked about it in the past on these calls that we believe that the benefits of the product are that it's fast, that it's powerful and that it's sustained and that sustained piece really references the fact that one 30 minute infusion can last patients for 3 months. And we think that is a benefit in both the COVID-19 situation certainly but even outside of that circumstance.

0.55.23
Michael Novod
Okay, thanks a lot.

Operator
And the next question comes from the line of Emily Fields from Barclays. Please go ahead.

Emily Fields
Hi, thank you. I was just wondering if you could comment on your current mix in the US between commercial and Medicare and Medicaid? And with obviously the massive jump in unemployment, how do you see that trending over the course of this year and then also impacting reimbursement? Whether that will be a 2020 issue, more of a 2021 issue, any colour there? And then also, I know there was an earlier question on Northera. I just wanted to dig into that a little bit more because I know you cited this as one of your brands that could be more impacted by COVID-19 given the need, I believe, to titrate patients but actually it looks like based on the IQVIA data that your growth was accelerating through March and April from a volume perspective, so I was just wondering if you could give us a little bit more colour on how we should think about that product, both in terms of COVID-19 impact and also seasonality. Thanks.

0.56.34
Deborah Dunsire
Okay, since a lot of that pertains to the US, I am going to ask Peter to take those questions on the Medicare/Medicaid mix, unemployment and Northera.

Peter Anastasiou
Yeah, no problem, thanks Emily for the questions. First of all about mix. Every product is different so in the case of depression and migraine, those are more heavily influenced by the biggest payers, our commercial payers, and Medicaid and Medicare are smaller. And in the case of something like Northera, because it is an older population, it tends to be more Medicare and commercial but then also Medicaid and of course with Abilify Maintena, that is mostly a Medicaid and Medicare population and less commercial. So every product has a different payer mix. It's tough to speculate what will happen, nobody knows of course but as people lose their job and potentially lose insurance, then hopefully as we all hope that some of the interventions that are happening, stimulates relief for patients that are happening will help us have a quicker recovery, that is certainly something we all hope for but it's very difficult for us or anybody really to speculate about what mix shifts may happen because of the pandemic and the economic fallout. With regard to Northera, you are right that we haven't seen any impact from COVID-19 in the first quarter. That's not to say we have seen it in the second quarter but we don't really make comments on the quarter that we are in

but in the first quarter, we didn't see any impact from COVID-19 but I think when Deborah made that point, it is just highlighting that the patient population is different for Northera than it is for most of our other drugs, where most of the other medicines are for younger patients that are generally in kind of like the 18-60 year old range and Northera obviously skews more towards the elderly. But we have not observed yet any impact from the COVID-19 situation.

0.58.44
Emily Fields
Thank you.

Operator
And the next question comes from the line of Jannick Denholt from ABG. Please go ahead.

Jannick Denholt
Hi, thanks. Just a quick follow-up to Johan's comments on the clinical trials. So you mentioned higher drop-out rates in some of the trials and obviously delays. Could you just give a little flavour to how you see those and also in particular are there specific trials where you are more concerned in those regards and vice versa?

0.59.16
Johan Luthman
Yeah, thanks for that question. Obviously, it is really very hard to predict this with some certainty because it is very unclear how countries open up etc. but we do have some – we start to get better and better ideas about this and generally, we talk about 6 month-ish delays across the board but that varies tremendously and some trials are still ongoing and going quite well, surprisingly well, and some have come to a grinding halt so we are mapping this out per trial and per molecule. I think the biggest problem is not the ongoing trials because those we can sort of manoeuvre around have various ideas of how to manage. The ones that are more uncertain are the ones to start up. We can technically prepare everything, we can regulatory-wise be prepared and we may even get one or two sites up and running. But really to get – you know, the big element in clinical trial fast execution is to get as many sites up as fast as possible and that is the big, big element that is the unknown that we struggle with.

1.00.23
Deborah Dunsire
I think just to say, you had asked where we are seeing impacts. We know for instance that Rexulti agitation and Alzheimer's disease trial includes elderly patients and we have got patients who are with Alzheimer's disease in nursing homes for some of the sites for that trial so that makes it a particularly difficult trial to maintain accrual for so we definitely would anticipate, right now it's very difficult to enrol patients into that trial so we would anticipate some delays in that but I don't think we can fully quantify them at this time.

1.01.06
Johan Luthman
Yeah, maybe one more comment. What we see so far is that our migraine activities have been less impacted by this and that really speaks to Deborah's comment about the type of patients. I mean obviously Alzheimer's, dementia, institutionalised patients, that is the biggest threat right now, so it's going to be very difficult to predict but generally, it will be very uneven.

1.01.34
Jannick Denholt

Okay, thanks. So it's not possible to say that you see a drop-out rates that they have been increased by 5-10% or something…

Johan Luthman
No, you cannot put any metrics on it at this stage unfortunately.

Jannick Denholt
Okay, thanks.

Operator
And the next question comes from the line of Carsten Lønborg from SEB. Please go ahead.

1.01.55
Carsten Lønborg
Yes, thanks a lot. First a question to Jacob on Cipralex actually in IO, you report 24% growth this quarter and a lot of this is of course COVID-19 related but I guess a lot is also the changed collaboration with Xian-Janssen where you are not booked through sales, is it possible for you in any way to give us a little bit more colour on this process, of course a massive growth component in the quarter? And then Johan, following up on Jannick's question, one thing is of course the delay but another thing could also be that patients drop out differently in the two arms and thereby kill the randomisation. How do you monitor this during a trial and how concerned are you that you will end up with results that could be inconclusive or not particularly useful and therefore you don't normally have a delay to the trial but maybe would need to do a full new trial. Thanks.

1.02.55
Jacob Tolstrup
Thanks Carsten. So you are right, there is of course some timing associated both with China and also with Japan, as it is – in China, as you know, we took back Lexapro from our partner Xian-Janssen there and last time at this year we were in transition between one type of pack to a new pack so there is a timing effect that is benefiting us this year. And the same goes for Japan where we ship to our partner Mochida who is handling Lexapro in Japan and while we are a little behind on Trintellix in Japan, we are actually ahead on Lexapro here in the beginning of the year. So also there we see a benefit. But we don't break it down to countries so I am not going to give you numbers on how much that is but it is a part of the increase – a visible part of the increase for the quarter.

1.04.04
Johan Luthman
To your question, that is really a very great question, it is very operational too. So there is basically two amounts, two things that you asked, there is the amount of data and the quality of data and how that distributes into studies. There are a lot of elements that we use in clinical trials to try to mitigate for this. I will not go into details but we are monitoring data and the randomisation algorithms, we can correct for these things without jeopardising the integrity of the studies and unblinding so the studies' teams are following this. I have to say, in terms of challenges, it is more can we really get the amount of data we want to have? And when will we get it? And there are various ways we can play with this, having interim analysis of data etc. we are looking at all those possibilities to really try to engineer the details of the studies. I cannot give you more of that but I am not worried about imbalance between placebo and treated groups, that we can handle.

1.05.05
Deborah Dunsire

I think the other thing to say about this is – health care authorities or the regulatory agencies have already been indicating to companies that they understand that some of the data is not going to look as pristine as it would have in normal circumstances so they are thinking creatively about how to manage things like missing data so we are cautiously optimistic that we will be able to potentially restart and get the data we need even if it may come with a delay and then be able to work with the authorities on things like missing data as well as all the mitigation that Johan has spoken about.

1.05.47
Johan Luthman
And the regulators are definitely living up to that, we have fresh interactions with them, they are really very forgiving as long as it relates to the pandemic. So missing visits etc. we can deal with.

Deborah Dunsire
Next question.

Carsten Lønborg
Okay, thank you very much.

Operator
The last question comes from the line of Peter Welford from Jefferies. Please go ahead.

1.06.12
Peter Welford
Hi, just got three quick follow-ups, firstly just with regards to the Alzheimer's agitation study, just wanted to know there with regards to have you actually or have you considered actually putting that study on hold I guess for new patient enrolment, it just seems as though, given what is going on in nursing homes, it is a pretty challenging sort of study I guess to enrol anyway and I appreciate your comments on the imputing data but given the challenges we have already had with those sort of studies in the past, it does seem like a particularly high risk strategy. And secondly then just with regards to the RELIEF study of Epti, is that still enrolling patients or is it fully enrolled? So I guess how confident can we be to basically get those data this year? And then just finally, I wonder if you can comment at all on compliance/adherence rates, understand the longer prescriptions and obviously the volumes it got but can you talk at all whether or not you have any data on whether or not actually compliance rates and how they may actually be changing for the orals over the last month or so? Thank you.

Deborah Dunsire
Okay, Johan

1.07.14
Johan Luthman
Yeah, maybe I can talk a little bit about the agitation in Alzheimer's. Obviously, this is a partnership with Otsuka and we have had very intense work together with them how we are going to manage this. I think Otsuka and we have been pretty public about this and Otsuka recently went out and said that the study is on hold, basically. We are not enrolling any more subjects. So that is a severely trial, one of the most in our portfolio. We have, as I alluded to before, various instruments how we can look at the data but obviously, this is the third trial in a set of studies that should deliver the indications, so we are carefully manoeuvring around the ability to restart as quickly as possible and also analyse data in various ways earlier so that is part of the package there, I cannot say more than that because we are in the process of looking into that.

The RELIEF study. It has gone very well as I alluded to. We actually don't expect much delays in really getting the data out of that study and it's – to just remind you, this is the study that looks at the before 20 hour period, before the first day period so we are looking at the early resolution of the data, the effect on migraine, so very critical data. One of the key points is 2 hours after start of infusion there. We expect to get the data almost as planned from that study.

1.08.39
Deborah Dunsire
And then with respect to compliance with our oral therapies, as patients have received their scripts. Jacob, do you want to comment on that? Any hints from the market as to were the patients actually taking the medication they had been given?

1.08.56
Jacob Tolstrup
Okay, yes. I think in general, the answer is yes. I think the issue has more been whether patients are coming in for consultation and whether they are able to come in, whether it is a hospital or to see the treating physician. I think on the compliance, we don't see any changed behaviour at this point in time.

1.09.18
Johan Luthman
No, and you should know that we monitor this quite closely and there were some concerns really initially and even some signals that that would happen, but it doesn't look like it.

1.09.30
Deborah Dunsire
Great. With that, I would like to thank you all for your interest in Lundbeck and we look forward to talking to you at the end of the second quarter. Thank you.