

Lundbeck A/S
Q1 2013 Financial Results
Wed, 1st May 2013
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Chaired by Ulf Wiinberg

Ulf Wiinberg

Welcome to the Q1 earnings conference for Lundbeck and thank you all for your great interest in following our company. With me today I have CFO, Anders Götzsche, and our Head of R&D, Anders Gersel Pedersen.

The next slide is the company disclaimer, which I believe you are all well-familiar with and therefore I will not read it out loud. So let's go to slide 3. Q1 has been a great quarter for Lundbeck in every sense, from a financial point of view, from a product development point of view and from a strategic point of view. If we look at the results, we are up 33%, excluding Lexapro, we are up 13% from continuous operations and the new products are up by 36%. So clearly very good results, if you exclude the deal with Otsuka which is included in the results and the one-time gain.

Growth is impacted by significant one-offs from selling of the US business to Recordati for \$100 million, which we have recognised \$80 million in the quarter and the co-commercialisation dealing with Otsuka with an upfront payment of \$50 million is also recognised in the quarter. I believe the EBIT of DKK 1.5 billion, even more than DKK 700 million excluding before-mentioned one-offs, is a highly satisfactory result and the company is on good track for the year, especially considering the substantial investments we are making in both R&D and in product launches. We are therefore very pleased after the quarter to be able to reiterate the guidance we gave for 2013 in March.

When it comes to the new product launches, we see a continuation of the solid momentum. We are very pleased with both Onfi and Lexapro in Japan and we are also very excited about Treanda, which seems to be off to a very good start in Canada although we are only a few months into the launch. When it comes to the development pipeline, I am really pleased with the traction as important projects have come to the final stages. Abilify Maintena and Selincro have been approved in the US and Europe respectively, actually on the same day, and both products have been launched and we have a lot of excitement both in our US sales organisation and in our European sales organisation.

Next slide please. So when we look at our geographic expansion, it is very much on track. We have very strong revenue growth outside Europe, both in local currencies and close to 50% of our revenue comes from revenue outside of our home market in Europe. Going forward, we expect this trend to continue, driven by all the product launches already mentioned. Lexapro in Japan is delivering on our high expectation and it continues solid momentum, albeit facing tough currency headwind this month with the weakening of the yen. The US is also doing great. We are pleased with Xenazine and Onfi. We have

previously spoken a lot about Canada and this market continues to do extremely well for us.

I believe all of you heard about the challenging European environment for innovative companies and all the uncertainties related to the financial crisis in Europe. Therefore, I think there are reasons for us to be very pleased with 3% growth in the quarter. As you know, in 2012 we made a significant restructuring of our European commercial operation and implemented a more flexible operating model in order to adapt to the new business environment. We feel that with the 3% increase we had in the quarter, we can now say that we have been able to create this new organisation without losing momentum in the business.

I think we can go to slide 5. For several years we have now been trying to build and reshape the business for the era after Lexapro in the US. Although Lexapro is now behind us, this work will continue in the US, likely with an even more strong emphasis on product launches in many parts of the world. In this context, I am really pleased with the progress of our new products. We are now approaching annualised sales of DKK 2.5 billion and growing very significantly. Of course, we have many new products that are being launched this year and we are also seeing great growth from new geographic markets, especially in Asia.

So revenue from new products grew more than 35% in this quarter. This is in line with our expectations and with this development we are very much on track to reach our target of more than 50% new product sales in 2015. Just to give you some examples, a product like Onfi is now generating revenue close to DKK 100 million on a quarterly basis. Lexapro Japan is facing some destocking plus tough currency headwind but it is on track to deliver on expectations. During the autumn of last year Treanda was added to this portfolio of products and obviously we have already launched Abilify Maintena and Selincro and we hope to launch Brintellix towards the end of the year in the US.

Next slide please. So just to comment specifically on Abilify Maintena launched in the US, we had a very successful launch meeting in Nashville last week and we have very excited sales forces in both companies going out this week. So to comment on this, schizophrenia is a debilitating mental illness that affects approximately 2.4 million adults in the US. It is a chronic condition, characterised by distortion in the process of thinking and of emotional responsiveness that often requires life-long treatment to mitigate symptoms. Abilify Maintena provides efficacy and safety of oral Abilify in a once monthly formulation and thereby it offers a new and effective maintenance treatment option that can help protect against relapse, an important consideration in the treatment of schizophrenia patients. We will watch with excitement here in Q2 to see how well this launch will do in the US.

Slide 7 please. Now I am turning to Selincro and we have just introduced Selincro in the first six markets in Europe. This is a great occasion. It is the first treatment for alcohol dependence to be made available for patients in Europe for more than a decade and you can say is this the first really new concept in alcohol treatment ever where we introduced a reduction concept for patients with alcohol dependence. Just to remind you, in the clinical trials Selincro reduced alcohol consumption by approximately 60% after six months of treatment and it is very exciting that we can introduce an innovative treatment concept that

provides a new and different option for patients who may otherwise not seek treatment. We expect launches to continue in 2013 and 2014 in the rest of Europe.

With this, I now want to turn over the presentation to Anders Gersel Pedersen to go through our pipeline.

Anders Gersel Pedersen

On this first slide is the pipeline that many of you have seen before. You will also see that we are indicating the move of 58054 into Phase III. Following the deal and agreement we made with Otsuka and discussions we have had with regulators, we are in the process of initiating the first Phase III studies in Alzheimer's disease with 58054. Also on the top right side you will see the two products that are currently under regulatory review and I should say for both of these products that, with the interim feedback that we get during these processes, we are still on track with the expectation sets when we filed them in September and early October in the US and Europe for Brintellix and around the turn of the year for Abilify Maintena in Europe.

If we go to the next slide, I would just highlight actually the first publicly available data on the dosages of Brintellix used at doses above 10mg was recently disclosed at EPA and, as you can see, it is a head-to-head study against another antidepressant available in Europe, which clearly showed a significant superiority of vortioxetine of Brintellix compared to Agomelatine. This is also the first study in which we actually test the molecule in a patient population where there is no preselecting in favour of other drugs that we are comparing ourselves to. So it is just an important signal of the efficacy of the molecule in this population. It also indicates that the effects that we see here, if you link it to some of the larger American studies that have been done sequentially, we actually see good and significant effects in populations that have already been treated with SSRIs and SNRIs. Let me also highlight that we will at the APA later on this month have ten posters on Brintellix available.

On the next slide, I will just briefly address the 58054. We were pleased with entering into a co-development and co-commercialisation agreement with Otsuka on this molecule. We have now been together in our collaboration with them for little over a year and have very successfully driven the other projects forward that we have together, so we are looking very much forward to also doing that with 58054. This is a molecule that, with the right momentum behind the study, could have the potential of being the first new treatment for Alzheimer patients when we have completed the pivotal program, which is expected to include about 2,500 patients. The clinical phase II studies, which have been completed a while ago and formed the basis of our decision to move forward, will be disclosed at the AIC in Boston in July 13-18 later on this year.

With that, I will hand over to Anders Götzsche.

Anders Götzsche

Thank you, Anders. Please turn to slide 11. This will actually be the last quarter where we need to compare previous quarters including Lexapro because that will be washed out in Q2. In general, we see that the continuing operation is doing very well. We can see that income from new products has grown with 36% in local currencies, so the significant

growth we saw in previous quarters is continuing. Also, as Ulf alluded, if we adjust for the one-offs, the total revenue, excluding Lexapro and these one-offs, is a total increase of 11% for the quarter and we are very pleased with that development.

Of course, it is important to say that the European environment continues to be challenging but, despite that, we saw a growth of 3% and this is, of course, an improvement compared to the recent quarters. That is actually reflecting the fact that some of these governmental price cuts which we saw in 2011 and 2012, they have now been analysed. Nevertheless, we expect also in the coming years to see a tough environment in Europe. So we need to be cautious but we are actually really happy, both with the growth we saw in Q4 and also in this quarter.

If we go into Cipralex, we can see that we saw a very tough, negative trend for Spain but that has now been washed out and at this point of time at least it appears that the negative pressure in general is easing up but please bear in mind the comments I made about Europe. So in Q1 the European Cipralex sales were actually up 1% and that is actually in line with what we see in Q4 and the most important Cipralex countries in Europe are France, Italy, UK and Germany and that will also be very important going into 2014.

Outside Europe, revenue from Cipralex in Canada continues to grow with a high margin and is now having an annualised sale of DKK 1 billion and Canada is our second largest Cipralex market. China and Japan are continuing to show nice growth and Japan is actually fast approaching Brazil as the second largest Cipralex market outside Europe. So all in all, Cipralex in international markets is growing around 9% for the quarter, which is an excellent performance.

Of course, we are very pleased with the development for Ebixa also in Europe in the quarter, where we saw a 3% increase in Ebixa sales. You should expect that – during the latter part of 2012 we saw the first generic versions of Ebixa were approved and launched in Europe. So you should also expect that we in the remaining part of 2013 will see a generic erosion for Ebixa and our best guess is that we will have a reduction of 30-40% in Ebixa sales compared to 2012 but still the growth in the quarter has primarily been driven by Italy, UK and Finland. We have () markets here but you should not change your expectations for the full year.

Then we are also very pleased to see that Azilect in total was up 30% in the quarter and 24% in Europe. It is a broad-based growth. Of course, we will not be able to keep that kind of growth pace in the remainder of the year but it was an excellent quarter.

Xenazine continues with an increase of 18% up to DKK 308 million for the quarter and that is just a continuation of the previous quarters and we are on track. So we are meeting our expectations, peak sales price.

Revenue from international markets back on track, 15% growth and, as I said before, our Canadian business continues to be very impressive. Lexapro in Japan, we now have an annualised sale around DKK 250 million, also making a positive contribution. Significant growth in China but we also know that in China there will be swings between the quarters when we look into the sales for that country.

A couple of other factors: Turkey is still heavily impacted by price decreases and we see generic competition in Brazil on CipraleX which also impacted the quarter. Despite that, we have very satisfactory sales in CipraleX.

So all in all, we are extremely pleased with the top-line growth. We believe that the geographical diversification we are making, the product diversification we are trying to do is on track and that is spreading really well out. We also need to emphasise that it is, of course, a difficult business environment in some countries but we think we have had a very good start for the year.

Please turn to slide 12. As I said before, revenue looks really good and I think that we also can see from the quarter that the cost development is under control, even though we realised our financial plans in December and, as we are going through a period of the next three quarters with heavy investments in R&D and in the launch of the new products. Cost of sales is up for the quarter but that is due to the mix of revenue and the share of in-licensed products and that, of course, is impacting our cost line because we have booked the royalties under the cost line. So that is fully in line with our expectations, no surprises in R&D. In line with what we have said previously, you should still expect that we will have R&D costs around 20% of our revenue base for the full year and when we combine all these things, our EBIT for the quarter around DKK 1.5 billion is also we think a very strong result. Our cash flow generation looks good and you should expect that we now – or you can see in the account that we have a net cash position of DKK 2 billion. You should also expect that by the end of the year.

Please turn to slide 13. Most of you know that we revised our guidance in connection with the expansion of our Otsuka cooperation in March. This guidance has been kept and that is, of course, due to the fact that I mentioned before, the decline in Ebixa sales in the coming quarters and the heavy investments in R&D and product launches. We have three product launches this year. We have Abilify Maintena in the US which is ongoing, as Ulf said, we are launching Selincro in 20 countries this year and we are building up or adding more people to our psychiatric franchise in the US, starting to prepare for the launch of Brintellix by the end of 2013. Just that you are aware of, we have restated the amortisation of product rights and that is due to have a more – we have made a benchmark in the pharma business and this should be best practice. So we have amortisation on product rights and royalty payments in the same accounting line under the costs but please pay attention to the restatement that is included in the Q1 release.

Looking at the different ratios, you should expect that the cost ratio will be slightly higher than last year. You should expect SG&A after restatement to be around 40% due to the heavy investments and you should, as I said before, expect that the R&D ratio will be around 20%. The tax ratio we have guided 30% but it will be a little depending on the earnings mix. If US continues to deliver so well, there is a risk that the tax rate will be slightly higher and we will be more informed about that in Q2.

With this, I have finalised the financial presentation and I will now hand over to Ulf for the concluding remarks.

Ulf Wiinberg

As you know, 2013 is a year of transition for Lundbeck as we are going from old products to new products. In that context, I am very pleased with Q1, both with financials, strategic and new product points of view. When one looks at the balance of the year, we have a lot of things going on that we hope will help us drive new product sales, which is the key success factor for us, and also drive the new product development, which is very important for future new product sales. So continue to follow us. We are excited about the start we have had and we think we are going to have a very good 2013 even if it is a transition year.

Thank you. We are now open for questions.

Questions and Answers

Tim Race – Deutsche Bank

Hi there. It is Tim Race here from Deutsche Bank. A few questions if I may – first upon Brintellix. You have now – with the new PDUFA V rules you have better communication with the FDA earlier. Can you just talk what has been discussed so far and whether we should expect an outcome or whether you are at that point where they should have let you know by now?

Then just on Brintellix trials we will be seeing later this month, obviously you have got a couple of active referenced studies with Cymbalta. For the layperson, lots of people will look at those active references and try and compare the efficacy. Could you just explain the recruitment criteria and whether those patients will have actually been previously exposed to Cymbalta and been responders whereas with Brintellix they may not have been and what that introduces into the study and how we should deal with that when we look at it?

Then perhaps just a last question: you have just made 70% of the mid-point of your guidance in Q1 already. Are you being overly conservative or should we just expect you to – can you put a more explicit point in the range that you are giving? It is a very wide range. Should we expect you now to be at the top end of your guidance range, if you will answer that?

Ulf Wiinberg

Tim, I will try to answer the last question. We have just launched Maintena in the US, so we will be accelerating spend behind that. After summer, we will start preparing for the launch of Brintellix in the US and we will expand our investment in sales force there, which will be a significant investment too I should add. Then in Europe we have so far only launched Selincro in a few smallish countries but the big markets are coming here in the quarters that are coming up. So we are going into a very heavy investment period. We are also seeing with our development pipeline that we have full speed ahead on Brintellix and cognition studies, we have full speed ahead on Desmo, we have some additional work to do on Selincro and we are starting up on 58054 after summer. So you should expect us to continue to invest in R&D the way we have done and you should also anticipate that we have the Ebixa generics that will play out during Q2. So those are the moving parts. That

said, we are very happy with Q1 and, should the development continue in this way, then we have to look at what we do with guidance in Q2. Now I hand over to Anders to answer the other questions.

Anders Gersel Pedersen

Thank you, Tim. First and foremost, with respect to the PDUFA V, it is correct that we have had the initial interactions with the FDA and they have clearly signalled that they do not intend to have an AdCom Committee for the review of Brintellix, so we don't expect that.

With respect to the status that will be shown, it is quite correct there are some nuances with respect to these types of studies they want to be aware of because, in contrast to the study that has just been released, these studies all require patients to be, when they are being randomised and they have the risk of getting a comparator and in this case it was Duloxetine, they cannot have demonstrated any lack of efficacy to this molecule before. So actually a very significant group of the patients have already been treated with this drug before and have had to show efficacy on that drug.

So in our terms, the way these studies are, we include Duloxetine mainly as a reference drug. It is not a comparator. It is done to secure that the studies have assay sensitivity as we painfully show to the world some studies are not successful in depression and for these studies it is very important to have an active reference in there to show whether it is the way the studies are conducted or whether it is the drugs that don't work and that is the reason why we had the actual reference drug in there. That is also what will be shown at the upcoming meeting in San Francisco later this month. So this is not a head-to-head comparison but a reference study with a placebo obviously, which is the comparator, and then an actual reference drug that has been – well, many patients have been preselected for their sensitivity to that molecule.

Perfect, thanks for clearing that up.

Kerry Holford – Credit Suisse

Kerry Holford, Credit Suisse – a few questions if I can please. Firstly, on SG&A and R&D, both were relatively low in Q1, even adjusting for that reallocation of amortisation in SG&A. This is in part I guess due to your recent restructuring but how should we think about ramping those costs through the remaining three-quarters of the year? Will it be heavily back-end loaded?

Secondly, on Abilify Maintena in the US, clearly it is early days and early prescriptions and perhaps not a good sight to the full future potential of the drug but I wonder if you could provide a little more detail on your () targets with the roll-out, perhaps talk about () access targets, proportion of covered lives and so on. Are you aiming for something similar to Invega's Sustenna or will your relative size versus J&J suggest the expansion access might be slower to achieve?

Then, lastly, just quickly on the slowdown that we have seen in prescriptions and sales for Forest hybrids(?), if you are willing to make any comments on what this might mean for your strategy with Brintellix. Does it signify that we should expect a quick initial ramp for

these products, patients and physicians that are willing to try new drugs but then significantly slower growth thereafter? Many thanks.

I think I will start with the last question first with respect to Forest. We have tremendous respect for Forest as a marketing company and a strong force in the depression field and obviously they have been our partners on Lexapro for years. We have very deep respect for them. We think, however, that our drug is a different drug and it is a better drug and hence we are not so focused on Forest in that context. So we are busy working with our partner, Takeda, preparing our launch plans and obviously, if there are learnings we have from the market, we will consider that but we are not obsessively following what is happening with Forest in that context.

I think with Abilify Maintena, not willing to give you any of the details that you are asking for. We think it is a superior product for maintenance with respect to the profile and the milder side effect profile and clearly we are very excited about launching it but I don't want to give you covered lives or data. It is just too early. We will, however, update on sales next quarter and comment on these things then when we have had some results there.

Then I hand over to our CFO to comment on SG&A and R&D.

Anders Götzsche

I think you should not make any conclusion on the level of SG&A and R&D in this quarter. Of course, it is nice that we had lower SG&A and R&D in the quarter. That is better than higher but you should expect that the guidance I gave that we would have a total SG&A margin of 40% for the full year, that is what you should stick to. There will be swings between the quarters also due to there can be a holiday in Southern Europe impacting the different launch activities or whatever. So there will be swings between the quarters and the same goes for the R&D. You should expect R&D to be around 20% but we also know it can be 19 or 21%. It really depends on how we progress during the year but it will be around 20%.

Many thanks.

Michael () – DM Markets

Hello. This is Michael () from DM Markets in Copenhagen – just two questions. One is could you try to enlighten us on some of your ambitions for Selincro in terms of sales because I have seen different flashes in the media today saying that you don't expect the bigger countries to be online until one to two years from now? So maybe if you could just take us through some of your both near term but also mid-term sales expectations for Selincro.

Secondly, is it correctly understood that there will only be posters at APA? I am just a bit puzzled about if there are no oral presentations, given the fact that this should be the first material new drug in depression for a very long time. So is that correctly understood and, if there are no orals, why is that? Do you mind to speculate on that?

I think we can start with Selincro. What I have said, Michael – just to clarify, what I have said earlier today to the media is that you know it is nothing new with Selincro or other

products. It is exactly the same. When you launch in Europe, you will not have one big bang with launches in all countries at the same day. It will take some time. We expect roughly 20 countries to launch this year but you also know that getting rights and brands(?) and so forth will take some time. The launch sequence and the launch timing for Selincro, you should expect it will take one to two years before we have launched in all countries.

Let me just add on that, that's just the nature when you launch products. Normally, you have a US launch involved and then we only talk about the US but the timelines we have for our launches in the big countries in Europe on Selincro is just anything better than what you would see with any other drug.

Okay but the quote in the media was it will take one to two years before we are ready in the big markets. That was the quote.

It is probably a bad quote. I will blame my CFO for that but, to be serious, I think from a sales expectation point of view, it probably will take a bit of time before we see how that is working. I think what is important for us to see this year is obviously the number of patients in the small markets starting on treatment and the numbers coming back to fill their prescriptions a second time. That for me is a more important guide than the actual sales we achieve in this year. So I think when we get towards the end of the year, when you add all the information, we should have a pretty good feel for whether we will be highly successful with Selincro or mildly or moderately successful with Selincro.

And just before going for the APA, it is also important to mention that in some of the countries we are launching without reimbursement and it will take a year or two to get reimbursement. So it is not that all the launches will be with reimbursed products. We will, of course, get a good uptake but, of course, in the long run it is important that we for the major markets negotiate reimbursements for Selincro.

With respect to the APA, it is correct that it is exclusively posters that are going to be presented over there. I don't know of any particular policy with respect to how APA judge this but one thing that I know that they are concerned about in general is that when you have a drug that is under regulatory review and you don't know exactly where it is ending up, there is also some limitation to what they want to give a platform for in terms of having an audience and somebody to speak freely within or without label, even knowing it or not. So I think that that is probably some of the considerations that may be in place here.

Okay, super, thanks a lot.

Martin Parker – Danskebank

This is Martin Parker from Danskebank. I only have one question left. Could you elaborate a bit on how we should see the quarterly situations for the next three quarters now? We saw a very strong quarter and maybe will Q2 also hold up, which means that we actually will see red figures in H2 if we adjust for the one-off income that you probably also will see in Q4? So can you elaborate a bit on the quarterly situation until the end of the year?

Martin, you are fully right that Q2 will also be a quarter impacted heavily by the investments in the new product launches. So Q2 and Q3 will, of course, be the weakest quarters this year if we, as expected, receive the milestones from Takeda for the launch of Brintellix in the US in Q4. I will not go down to the detailed numbers but you are right that they will definitely be the weakest quarters and there will be fluctuations.

Carlson Madison – Carnegie

Thank you very much. Carlson Madison, Carnegie. Anders, did you mention the cost to sales ratio when you mentioned all your ratios? Then also I don't think you have changed anything in your communication after you made the deal with Otsuka about I will not call it () guidance but the rewrite 2014 guidance? Wasn't there supposed to be some sort of R&D sharing or something like that that could impact your longer term guidance?

Finally, when it comes to Lexapro in Japan, I know Q4 was an unusual quarter but still there's quite a slowdown also not only in reported sales due to currencies but also from a market share perspective here in Q1. Has anything changed at all? Thanks.

Carlson, thanks but I think on Lexapro we had a very high market share in Q4 and when we presented that to you, I think we were extremely candid saying it is an exaggerated share which we sort of did not understand. I think the share we have now, which I believe is 8.4%, is sort of in line with our expectations and still gives us a chance to become market leaders in Japan but, of course, we will work with our partners to see that we continue to accelerate growth for Lexapro in Japan.

But nothing has changed in the set-up?

Nothing has changed other than the currency and that-

-that is also a big change.

Yes, that is a big change but there I can't take responsibility. With respect to guidance for 2014, there are many things impacting guidance for 2014 and we will come back and guide 2014 in the beginning of 2014. The most important factor for 2014 is obviously new product sales performance.

Okay, thank you.

Peter Sehested – Handelsbanken

Hi, it's Peter from Handelsbanken. Thanks for taking my questions. With respect to the reporting of potential Selincro and Abilify Maintena sales, do you expect that to be reported on a separate line this year or will that be chucked under other pharmaceuticals?

The second question comes back to other pharmaceuticals in international markets: any one-offs for the quarter that we should be aware of going forward? Also just update us on the gross margin expectations for Abilify Maintena and Selincro please. Thank you.

I can start with Selincro and Abilify. This is Anders Götzsche. Peter, you should expect that we will include Selincro and Abilify in the other pharmaceuticals line and we need to

find out when it is material enough to separate it. What you should expect to see is what we have done with all our products, which is we start to make a more verbal guidance and maybe continue to include it just in a text base ... and then we will start to report it in a separate line when it is material enough, but we are not defined when to do that.

The cost percentage, just to clarify also the previous question, you should expect the costs to be in line with previous years. We have not guided the cost percentage. Your question – what product was that, Peter, sorry, for not guiding?

Just an update on Abilify and Selincro please.

Abilify and Selincro, you should expect that profitability and the gross margin for these products are pretty high, also due to the fact that Abilify is a revenue, cost and profit-sharing. So from a margin point of view, the only slight dilution is, of course, that we will have amortisation due to making amortisation of the upfront payments but basically it is as profitable as our own invented products and that is nearly the same with Selincro. We have some small royalty payments for Selincro but, all in all, it is a very profitable product from an EBIT margin point of view but also from a gross profit point of view. Have I answered all your questions?

There was one last question.

It was the international markets. There are no one-offs in international markets but we also know that sometimes we deliver some bulk deliveries for international markets and it can also change due to the wholesaler set-up. So it is not that you should try to forecast that we will continue to have the same kind of growth figures for other pharmaceuticals. It is swinging between the quarters. The pace for this quarter is excellent but it will continue with the same level.

One just one-follow up question: can you give a ballpark figure for the expected other pharmaceutical sales for this year?

For international markets?

No, for the whole line.

There is no doubt, based on the booking of – we will include new products in that line. You should expect to see – you should expect double digit growth in that line.

Compared to what base because that is something...

Last year.

To reported last year after Onfi has been taken out?

You should see it line by line compared to last year. It was without Onfi. With Onfi taken out, you should expect low double digit revenue growth in that line.

Okay, thank you.

Eleanor Fung – affiliation

Hi, good afternoon. Eleanor Fung from Goldman Sachs. Two questions, gentlemen, if I may. First of all, I notice Xenazine sales had significantly slowed versus previous quarters. I was just wondering if there's an element of price there. Have you not taken up prices or has patient uptake slowed and should we expect this sort of rate of growth to normalise going forward?

Secondly, on your other revenue line, besides the Otsuka milestone and US business divestment, I was wondering if there was any swing factor in the Q1 numbers that contributed to a higher than normal other revenue line? Thanks.

The other revenue line, there are some small swings in other revenue but you should not pay a lot of attention to that. In the full year's other revenue, you should expect it to be a little higher. We also make this Abilify Maintena deal, which is insignificant for the tablet deal and that impacts that line but it is immaterial from a profit point of view.

Xenazine sales, I think we are – normally when we start the year, there is a slower patient uptake related to changes of insurance and general bureaucracy and so on and we have seen that every year. This year it appears as if this period has been prolonged. So we are not sure we fully understand the dynamics behind that but this is something we are working on and we will give some more light to that when we report in Q2.

Thank you.

Peter Welford – Jefferies

Hi, it's Peter Welford from Jefferies – just a couple left. Firstly, I notice on the pipeline slide that Zicronapine is noted as being no longer an active clinical development. Presumably, that means therefore the initial trial you started in Phase III has been completed. Could you perhaps comment therefore on either what you or your conclusions or your thinking is at this stage, if there's data inhouse?

Then, secondly, just on the financials, can I just clarify the 30-40% Ebixa decline, is that Ebixa as a whole or is that Ebixa in Europe? Equally, for the amortisation number that you booked in Q1 in COGs(?), should we assume that that picks up markedly in the remainder of the year now that Maintena is launched in the US? Thank you.

I can start with the 30-40% decline in Ebixa. That is for the total group. It is not related to Europe. It is the total group.

Okay, thank you.

You should assume the total amortisation for the year to be around – it will be around this DKK 1 billion in total.

So that's possibly DKK 1 billion in total?

Yes.

Okay, thank you.

With respect to Zicronapine, we have a study ongoing which is also related to some pharmacology things that we are clarifying with the molecule at this stage. Right now we are not going to publish any data piecemeal as we go along. Normally, when we run these larger programs, we don't disclose the numbers until we have sufficient data to know where we are heading with the whole program. So you should not expect to see some data from this study coming out publicly.

Tim Race – Deutsche Bank

Hi guys. Sorry, it is me again – just a couple of questions on the pipeline and timelines. Brexpiprazole, you get various bits of phase III data throughout this year. Good comments on not publishing it piecemeal but could you help us understand what quarter this year or next year we should expect some sort of publication on the Brexpiprazole data? The same goes for Desmoteplase and also the cognition studies for Brintellix. Thanks.

I think with Brexpiprazole obviously we are working with our partner on that and we haven't finally agreed how we do this but historically they prefer to release data at conferences and that is the approach whilst we have been more keen on going earlier on it, but this is something we have to discuss and agree upon. Just to get an idea, we should have the full dataset early next year. So if it is a publication, it is probably a little bit into next year before you have that. What was your other question?

The same on the Desmoteplase phase III readout, when we should expect that, and also the cognition studies for Brintellix.

Desmoteplase, we would expect to be seeing the first set of data just by the turn of the year and we will then obviously submit them for publication as we normally do. The extent to which they are material to our understanding of where we are heading with the program, we will obviously disclose them if that is necessary, so that would be the time point of that. The cognition data, we will expect to see some data by the turn of the year also on these studies and have a good understanding of that. We will discuss with Takeda whether we will go for a limited disclosure of that or if we will only submit them to conferences before they will be disclosed. We haven't decided on that with them yet but nothing sooner than that.

Okay, thank you.

Peter Sehested – Handelsbanken

Hi, it is Peter Sehested again from Handelsbanken. Could you possibly give us a ballpark figure for Sycrest sales in the quarter? Second question relating to marketing costs for Brintellix in the US: Cymbalta is the most advertised drug in the US. I think Lilly spends probably 200 million just on DTC alone, of which two-thirds of that is for DTC on the pain medication, i.e. the differentiation of that drug. Could you elaborate how those marketing costs or DTC will be split between you and Takeda?

I think Sycrest sales, Sycrest is very much work in progress for us and is not so far a great success in terms of performance. With respect to your comments on Duloxetine, we cannot go into comparative spending plans when we have significant competitors out there watching what we will do and look to block us and that goes for sales force numbers, it goes for DTC spend and all other competitive aspects. Then, of course, for us ourselves, we will with our partner, Takeda, finalise our commercial plans when we have a good understanding of the label but even when we have finalised, we will not go out and advertise because we know all the other competitors are very interested in what we do and how they can block and tackle to set us back. So that is our thinking. I think we have a comment I want to say. DTC is not – it is the first year **text here**... It is not the year of DTC because you want to establish the drive in the medical community first. You don't normally start DTC immediately but again this is a decision we haven't made at this point.

But are you completely or do you completely disagree with the argument that the main reason for Cymbalta's success has been the huge amounts of DTC advertising put into the market?

I don't want to comment on that but I would completely disagree – I certainly disagree on it but 'completely' might be too strong. I would say it is partially a reason for their success but we are into splitting hairs in this semantic discussion, but that's where I am on that.

Alright, thank you.

Closing Comments

Thank you very much. I think that completes all the questions we have had and again thank you for following us and we look forward to keep you updated on the progress we are making with respect to pipeline and everything else we do and we hope to have a good update for you when we get to Q2.