

12. august 2014

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H. Lundbeck A/S

Transcript :: Lundbeck teleconference for Q2, 2014 ::

Ladies and gentlemen. Welcome to Lundbeck's Q2 2014 financial results. Today I am pleased to present Ulf Wiinberg, President and CEO. 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. Ulf Wiinberg, please begin.

0.00.16.7

Ulf Wiinberg

Thank you operator and welcome to the Lundbeck Q2 teleconference. I am joined by our CFO, Anders Götzsche and our head of R&D, Anders Gersel Pedersen. Before we go on to the presentation I just want to remind everyone about the company disclaimer. Please make sure you are familiar with that.

Now we go to slide 3. Let me say that from an operational point of view we are very pleased with where we are at the midpoint of the year. We have more than 125,000 Brintellix prescriptions and we are performing really well there and we have had great feedback on the product from the market. We are also extremely pleased that we have been able to close the transaction on Northera enabling us to launch this product in the fall over the year. Our neurology franchise in the US has performed extremely well and we have expectations that this will be the largest product we have launched in this franchise to date. Also with Abilify Maintena we see that we are getting market access and prices on time or ahead of our own time lines in Europe and I know many of you have waited for Selincro and this fall we expect to see the launches of this in the big markets in Europe – France and Spain, Germany and the UK. So overall we are on track. And we are also very pleased that we have filed a Brexpiprazole for depression and schizophrenia and things going well this will be a big launch in the second half next year. We were disappointed with Desmoleplase. The study was interesting in the sense that we showed efficacy in the target population but we did not meet the primary endpoint of the study so clearly we have to the results from the DIAS 4 and then we have to embark on talks with the regulators but it is not a clear path forward here and I will ask Anders Gersel Pedersen to comment on it a little bit more when we come to him. From a financial point of view I think it is a great quarter considering that we have with the new products almost completely offset the generic impact for Cipralex in June so we are very pleased with that and obviously we are confirming our financial guidance for the year, but all in all we are on track to deliver long-term growth for Lundbeck.

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Now, Northera is a big event for us and obviously we feel we have a very strong neurology franchise in the US with Onfi up 100 %, Xenazine up 14 % and Sabril up 27 % and we are sort of around DKK 7-800 million as performance. Northera then is approved in neurogenic orthostatic hypertension which is significant. This is with unmet medical needs. We will launch this here during the fall. It is a growing market with an ageing US population and we expect Northera to exceed DKK 2 billion.

Next slide, please. So again, why are we so excited? This is the only chronic oral therapy treating the root cause of symptomatic nOH plus it is well documented from a safety and efficacy point of view. It is a great synergy with our strong neurology franchise and we have a differentiated product label.

Next slide, please. So when we look at the new psychiatry portfolio that we have, obviously Abilify Maintena, we are very, very pleased with the progress in Europe and international markets and we are seeing some early launch successes. It is still very early but it looks very, very promising. Brintellix – we feel that the feedback from the prescribers has been very positive in the US. We also feel that we wanted to benchmark since this is a new field for us. We wanted to benchmark with Forest and obviously Forest launched Fetzima at the same time and we are almost outperforming them by a factor of 1.7-2 so we feel that we are off to a good start here and now we are getting ready for some launches in international markets and Europe during the second half. It is important to say you should not expect significant international sales in the second half of the quarter and obviously Brexpiprazole we have filed and as usual data will be presented at conferences later in 2014.

So if I move to slide 7, clearly the branded value share for Brintellix continued to develop favourably. We have had great new studies presented for Brintellix in the quarter and obviously cognitive data is very important. We will proceed to take advantage of bringing this to patients as rapidly as we can in the different markets where there is regulatory filing in many places, but it is also important to say here that in the US it is a novel concept, it is not a new pathway, a defined pathway and we need to work with the regulatory community and the scientific community to define the best way to bring this to market but obviously it is a very significant finding. It is highly recognised in scientific communities and it is one of the things that make Brintellix so unique.

Revenue in the quarter was DKK 38 million and we expect this to grow quickly and obviously market access processes in international markets and Europe are on track and for us an important launch in the fall will be the launch in Canada.

Next slide, please. So just to summarise on Brintellix, we feel 125,000 prescriptions in less than 6 months we think is a good performance. We have treated more than 50,000 patients. Feedback on the product has been very good. We have now roughly 20,000 unique Brintellix prescribers and Brintellix has the highest number of new writers among the branded agents so a lot of things are going our way here and obviously it is important for us coming in new in the market with Takeda to build on the positive momentum we have and to continue to increase the share of Brintellix we have in the US. So with that I would like to hand over to Anders Götzsche to talk about the quarter.

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09.05.4

Anders Götzsche

Thank you. Please turn to slide 9 and as you have seen from the release is that core revenue has a modest decline and that is – it is important to highlight that it is mainly due to the fact that we have had headwind from a currency point of view and that has impacted after hedging with around 300 million so if you adjust for that, then we would actually have seen growth and as many other European companies we are seeing the headwind from currencies, Canada, Japan, Latin America as well as Euros.

New products were up in the quarter, continue to grow and for the year-to-date figure it was up 36 % and together with the growth in the US portfolio that is of course one of the strategic focus areas and we expect that we will continue that growth also in the coming second half. Expenses continue to be under control and we have had a quarter with a flat development in total cost when you adjust for the last year's one-offs and that actually means that we have been able to manage our spending so we are at the same level as last year and that is despite the very heavy investments in new product launches. And, of course, the investments we are doing now and will continue is in Brintellix, it is in Abilify Maintena and please be aware that we are now starting to invest in launches of Selincro in Spain, in France, in Germany and afterwards in the UK so that will of course also impact the second half of 2015. Administrative expenses have decreased with 18 % and that is of course due to the continued focus on getting costs down and our project Fit-for-the-Future and general cost awareness. You should expect from an SG&A point of view that we will have an increase to around 47-49 % for the full year and that is of course a result of the decision we have made to actually invest heavily in product launches. R&D you should expect around 20 % and you can see that the decline this quarter is more or less due to fluctuations between the quarters and therefore we are actually – if we adjust for these one-offs – we have – our core EBIT was 439 and we reported DKK 274 million and we are pretty happy with that as a good start and therefore we will also be able to deliver on the financial guidance for the year. It is important to make a remark about the tax rate. You can see it has been 40 % for the first half of the year. Due to the acquisition of Northera you should expect and also the low earnings numbers for the full year you should expect a higher tax rate for the full year and going forward you should expect that our structural tax rate due to the more heavy earnings from the US that it will change to between 28 – 30 percentage points and that is of course due to also the non-deductibility of the Northera acquisition price and amortisation of that.

With that please turn to page 10 so as I said before despite headwind in FX and heavy investment in launches and now also a continued – or an investment in a Brexpiprazole pre-launch investment and Northera we stick to the guidance that we laid out in the spring and a forecast of around 13.5 for revenue and an EBIT range of 0 to 0.5 and core EBIT of 0.9 to 1.4.

With that I will hand over to Anders for making the conclusions and remarks around the pipeline.

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0.13.36

Anders Gersel Pedersen

Thank you Anders. If we turn to slide 11 with our pipeline overview you will see that notably over the quarter Brexpiprazole has with an arrow move from actually being only in phase III to being beyond phase III moving into the regulatory effort. On top of that we had some disappointing outcomes of the DIAS 3 study as Ulf has mentioned. Disappointing in the sense that we do not meet our primary endpoint and therefore do not have a defined agreed regulatory path for that product forward, however, we did see that for the target population clear evidence of effect of the drug. We will discuss these figures in greater detail both with external experts and regulatory experts. We will also look to outcomes of the DIAS 4 study when we get those and discuss with authorities if there is a possibility of looking at these combined data in a regulatory process. We have to remember that the condition we are talking about here is one for which there is absolutely no treatment that has been approved so far. It is a deadly and highly invalidating condition so we will have opportunities to discuss the outcome of these findings we believe in an open manner with various regulatory authorities. That process will take time so you should not expect to get any news on this front at least for another six months or so in this respect.

If you turn to the next slide, I will just briefly recap what we earlier had reviewed with you in terms of the very strong data we have on the effect on cognitive dysfunctioning in depressed patients. We have now substantial evidence generated through four separate studies the earliest one being the study of the elderly patients in which we had findings in a secondary endpoint on cognition where we in contrast to another anti-depressant showed clear cognitive effects. This was replicated first in two different dosages as primary endpoints in the focus study and secondly now also as a primary endpoint in a study also with another anti-depressant as reference drug where we could see the effect whereas the other drug was ineffective against the cognitive symptoms and also as a secondary endpoint in the previous study that has already been filed on the 3116 where on some quality measurements we could clearly see readouts on the cognitive effect so we have a whole set of data in different ways that describes the cognitive function not only from scales but also from objective measurements on functioning in connect study and we will go into discussions with regulatory authorities globally so that we can review to what extent it will be a possibility for us to include that in the label in the various countries. These data will all become and some of them are already widely available through scientific publication so obviously physicians also will familiarise themselves with these data as they become more widely known and we can see from some of the feedback we get from patients and physicians that the clinical impression that they have is reflecting the findings that we have had in these studies so we are very positive about this as a base characteristic of the molecule and we will work very diligently not only in the US but also elsewhere on getting this recognised so that we can talk more freely about it in the promotional setting globally.

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On the next slide, slide 13, I will just remind you that we did submit our files for regulatory review by the FDA. We had a spring meeting, a pre-NDA meeting with the FDA in which both Otsuka and Lundbeck concluded that this was convincing enough that we would submit for both indications here. We have consequently submitted that and there will be a technical process for this submission just as there is for any other submission where we expect on day 74 to get feedback from the FDA as to the completeness of the file. I just want to emphasise this is not a scientific review but a technical review. You have to realise that filing of this magnitude as we have done here is a very comprehensive file with a lot of technical elements to it so it is important that the FDA gets what they are looking for in this process so until we have that completely confirmed at the end of September we cannot conclude what the time lines will be on this but if we assume that we are okay on the filing time line we have the PDUFA date on 23 July 2015.

With that I will hand back to Ulf for concluding statements.

19.51.3

Ulf Wiinberg

So just to say that obviously we feel that we have started the year well from a financial point of view, from an operational point of view and from an R&D point of view and the second half of the year besides the Brexpiprazole, is all about new product launches. We have 28 different launches of Brintellix, Selincro, Abilify Maintena and of course also the US launch of Northera so clearly this is an unprecedented launch activity for Lundbeck but we are very excited about that and obviously we feel good about being in a position to have secured market access during the first half enabling us to have 28 launches in the second half of the year. And that is the key point for us and for us to secure long-term growth for Lundbeck so with that I would like to open up for Q&A. Operator.

21.04.9

Operator

Yes, thank you. Ladies and gentlemen, if you have a question for the speakers please press 0 and then 1 on your telephone keypad. You have to press 0 and then 1. And we have our first question coming from Mr James Gordon from J.P. Morgan. Please go ahead sir.

21.20.9

James Gordon

Hello, thanks for taking my question. This is James Gordon from J.P. Morgan. A couple of questions please. One was on Brexpiprazole. We only can see the data from the additional three phase 3 studies – when the data is presented presumably at the end of the year or might you announce more details of what you have seen at the time the filing – in

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September when the filing is accepted. And ahead of that can you just say big picture what you are seeing as the key differentiation for Brexpiprazole in terms of are there particular side effects or its efficacy? My other question is on 2015. If we were to assume that Brexpiprazole is going to be – is going to have the filing accepted what is the big picture outlook in consensus modules and core EBIT margin expansion next year? Is that plausible?

22.10.5

Answer from Ulf Wiinberg

Let me just start with your second question – I mean obviously we are not in a position to give guidance for 2015 yet. A lot of that depends on where we are with the new product sales but the one variable that has changed is obviously that in addition to the previously planned launches for Brintellix, Abilify Maintena and Selincro we are now also launching Northera and Brexpiprazole so we have always said that 2015 will be a year of significant investments and we know that that is the case now as well with those two additional launches coming through and Anders, do you want a comment on Brex?

22.58.2

Anders Gersel Pedersen

First and foremost it is correct that the data will be disclosed at conferences later on this year. We do not have any plans at this moment to disclose data in any greater detail prior to these conferences so you should not expect to get more granularity on that at the time of the expected filing date from the FDA. I think, was that the...

23.29.0

Ulf Wiinberg

I will just add, you know, on... this is Ulf. The profile – yes. Do you want to comment on the profile?

23.34.5

Anders

I can say that we have clearly – from the outset of this, we looked at the pharmacology and what we have seen in the clinical data is clearly supporting the clinical profile. I think you have a very good picture of what we have seen so far in the already disclosed study that was presented at the spring meeting this year and basically we see a good low level of acathesia, we see a low side effect, lack of sedation, lack of weight gain, good lipid profile

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as a side effect profile and we see that in a population with very good efficacy so I think the risk benefit balance for patients here is very attractive both for the schizophrenic and for the adjunct therapy population.

24.39.5

James Gordon

Thank you.

The next question please

24.45.7

Operator

Yes, our next question is coming from Mr Tim Race from Deutsche Bank, please go ahead sir.

24.50.1

Tim Race

Hello gentlemen, two questions. I suppose first one a bit on Brintellix. You kind of benchmark it against the launch of Viibryd but that was kind of an okay launch and then it tailed off quite rapidly. How do you ensure that you continue on this sort of 45 degree slope of RX increase rather than that flat-out with Viibryd so why do you think Viibryd really did flat out? Do you actually know? And can you avoid that yourselves? And any comfort you can give us perhaps just on what you have seen in terms of script trends - it may not be obvious to the sort of higher level data that we see. And then a question on just Northera, obviously it depends on when you launch it, etc. and your choices here but could you just help us think about how you price this therapy? Is this a therapy where you are sort pushing on an open door and you can effectively set the price where you want and it won't impact demand very much like we see with ??? and ??? or is it more sensitive than I am perhaps thinking here? Thank you.

24.58.4

Tim, thanks for your question on Brintellix. You know, we said at the end of last year that we wanted to benchmark against Viibryd. It wasn't so much benchmarking against Viibryd. It was about benchmarking against Forest which we felt were the best antidepressant

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company on the market and we felt if we can be competitive with them the first six months then we have a lot of organisational learning that we can use to make sure that we can become the leader in the field. And I think from that viewpoint when you consider what they have also done with Fetzima, I think we have done a good launch in the first six months. I also think when you see how the data is evolving and the cognitive profile and also the feedback we get from prescribers on Brintellix that if anything Brintellix looks better now than it did six months ago. So as a CEO am I 100 % happy? No, I think also that the negative that we have seen is that the market has been a little slower to embrace new products in the US than what we have expected. So I think we will continue to work. I think when you look at the data we have on Brintellix and the feedback we have on Brintellix, I believe this is a very significant innovation and that it will be embraced by the market and so I expect it to continue to grow in the marketplace. And obviously critical here now when you compare with when Viibryd was launched you know they had higher immediate coverage and it is a little slower now which indicates that it is a slower uptake in that sense. Looking forward I think we believe in the same peak sales based on the strength of the molecule and the feedback we have but it is probably going to be a little slower initial uptake before we get there. With respect to Northera I don't really want to comment on pricing at this point but clearly we see this as an area of unmet medical needs and this is a significant disease so it really can help patients get a good life when they do not have that today and we think it is kind of like orphan drug type pricing. I am not sure I can say much more than that.

29.05.5

Fair enough. Thank you.

Operator

Our next question is coming from Mr Peter Welford from Jefferies. Please go ahead sir.

29.16.3

Peter Welford

Oh hello, yes, a couple of questions please. Firstly on the Desmoteplase DIAS 3-4, just intrigued by your comment regarding DIAS 4, my understanding was that was still well into the early stages of enrolment given the difficulties there and should we infer therefore that you are now closing down and looking at the data or I guess I am curious as to how you are going to take those data and put them within the next six months in front of regulators. And just the second question then on Brexpiprazole. Am I right in saying we should infer from the filing that of the three phase threes that we were anticipating all three were positive and that the primary endpoint. I presume that is the case. And finally then just a couple of quick ones financials, if I can? Could you possibly tell us what the Lexapro Japan revenue was this quarter and just a point of clarification – did I hear

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correctly that you said tax should be 28-30 % in 2015? Is that right? Sorry you broke up a little bit. Thank you.

30.18.6

Peter, I can start with the tax. You are fully right 28-30 %.

And then Anders if you could take Desmoteplase?

30.27.8

Anders

The first question on Desmoteplase. We will be closing down the DIAS 4 study for us to look at the numbers there and what we will do is we will do it in a way that we will have clarity as we go along with regulators on the best way forward for the analysis of this if we will hold the analysis before or after we have had discussions with some of the regulators on that. But we will be closing down the DIAS 4. It has a significant number of patients enrolled but we can also see that the enrolment rate is extremely slow and extremely difficult and we can see that it is increasingly difficult in countries where we would be most pleased with having the enrolment, and that is why we have made that decision. In a combined way you would have a larger database for us to look at this and we need to discuss with authorities if there is a way we can take advantage of that as we move along. I think that is as much light as I can shed on where we are right now with it because we are doing some additional analytical work clearly to be better prepared for this and also in collaboration with some of the external experts on that so I actually don't know more than what I am saying right here. With respect to the Brexpiprazole, then basically we have – the finding is based on all of these studies that is quite correct. And in terms of positive findings in all of these studies so that we think what we need to make sure is we have a common understanding with the agency in both of effect seen at the relevant dosages in the relevant populations. You have to remember these are complex studies in terms of how they are run so that is the discussion we need to go through with regulators before we can finally disclose these data.

32.31.1

With regard to Lexapro in Japan the figure is around a little more than 40 million for the quarter and has been impacted by fluctuations in stocking levels and currencies but the underlying trend is continuing from the previous quarters.

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32.53.0

All right. Thank you.

32.57.0

Operator

Our next question is coming from Mr Michael Novod from Nordea. Please go ahead sir.

Sorry. It is from Mr Riccardo Lowi from Credit Suisse. Please go ahead sir.

33.11.9

Riccardo Lowi

Yes, hi, good afternoon. A couple of questions, one I wanted to ask whether there were any stocking or sampling effect behind the Brintellix sales you booked in the second quarter and whether these sales corresponded effectively to 30 % of the in-market and user sales and the other question was on dividend because I think you in the past talked about a dividend policy based on reported EPS so because there was going to be such a volatility on the full-year EPS I was wondering whether you have any thoughts on the dividend for the full year 2014. Thank you.

34.00

This is Anders Götzsche

If I start with the dividend, so far what has been agreed with our board of directors is that we have a policy and we have stated that in the annual account that we will have a dividend policy paying out 25-35 % of net result and we have also said that in this period we would expect to be in the high end, and that is what we are sticking to for the time being despite lower earnings levels.

For Brintellix I can say we do not have specific data around sampling and all this kind of stuff, but I can promise you that the underlying trend in the script as we reflected in the figure, so you will also see, hopefully, that we can accelerate growth in the upcoming months. It is not that we have a peak in Q2 and then it would have fallen back in Q3. Then we would be really disappointed, that is not what we are expecting.

35.00

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Perfect. Thank you very much.

Next question, please

35.06

Operator

Our next question is coming from Mr. Michael Novod from Nordea, please go ahead.

35.10

Michael Novod

Yeah, hi, it is Michael from Nordea. Just two questions. One is to the launch of Brintellix from the emerging markets where you had a very strong foothold previously, like Latin America, Turkey and so on. Can you comment a bit more specifically on when you expect this to take place? And then secondly on Abilify Maintena. You have previously said that you have initiated initiatives or taken initiatives to ramp up sales in the US. Do you still think we should expect the market share trend to change, and then how do you see also the competitive environment going into 2015?

35.50

A: Ulf Wiinberg

Michael, I think, you know, thanks for the question. I think you should expect to see us increase the share in the US and you should expect that to happen over time, you know, it is a complicated business in the US the way the market is structured. I think if we get competitive entries coming in to the US in 2015 is not really that relevant for us, the key has been the many things we are doing to bring the benefits of Abilify Maintena to the prescribers and patients in the US. I expect you should see that. I think in Europe in many ways it may actually be easier with bringing Maintena to the market and obviously getting reimbursed for them. Prices have gone as planned or better and the benefits of Maintena with its good efficacy and good safety are very attractive in the European environment so there is a lot of enthusiasm. Obviously early days still but we should see that as very positive. With respect to Brintellix, obviously we are expecting to start launching in Canada and Latin American countries before year-end but we don't have all the approvals in place yet but clearly Canada is one of our best markets so we are excited about that. Again, even if we get all of these markets, the sales in Q4 are not going to be material, but it will be very interesting to see from a product reception point of view when we come out.

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37.48.7

Michael Novod

Okay. Thank you.

37.53.8

Operator

I remind everybody: if you have a question for the speakers, please press 0 and then 1 on your telephone keypad. If you have a question for the speakers, please press 0 and then 1 on your telephone keypad. Our next question is coming from Ms Eleanor Fung from Goldman Sachs. Please go ahead.

38.10.8

Eleanor Fung

Hi gentlemen. Three questions please, if I may. Firstly, given that your key European launches for your new products are starting in the second half 2014 can you comment on how you expect the shape of the SG&A curve between 2014 to 2016 to evolve and when you might expect absolute marketing spend to peak. Secondly, I was just wondering if you could remind us on your best estimate for the timing for the European Brexpiprazole filing and then finally just on Brintellix, your Brintellix scripts have been tracking **slowly ??? upwards** but to get to your peaks of guidance it suggests to me that there is probably going to be an inflection point upwards at some point. I am just curious on when you expect this to happen and what options you are thinking about if you don't see this inflection point. Thank you.

39.04.9

A: Ulf Wiinberg

Eleanor, you know, we have launched Brintellix in the US as a very good antidepressant with a unique model action and we have a high prescriber base, we have a high user base, we have good feedback on the drug. Obviously we want to continue to use this momentum going forward but at some point we also expect to bring in the very favourable cognitive data into the US setting and we think when we do that we think that will be obviously something that no other drug has done in the US market before and hence that is important. Exactly when that happens I cannot say but I would say, you know, if you look at historical launches, which are probably a little slower in the early years, but we expect to sort of hit the same peak as we have said before and Anders do you want to comment on the Brexpiprazole?

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40.07.7

Anders Gersel Pedersen

The Brexpiprazole filing in Europe. We don't know exactly when the filing will happen in Europe precisely. There are two different indications that may have different timings in that respect. They may coincide but they may not and we expect them to happen either in 2016 or 2017. And the delay in Europe compared to the United States is predominantly based on the requirement in Europe for long-term data which is a demand. We have possibilities of these two studies to materialise slightly out of time with each other and we need to assess to what extent is this time gap such that we will file with one or wait for the other because you have to remember that if you file for one you basically lock yourself up for a full year before you can file the next one or even more than a year. So we need to assess when we see the data and the timing of the readout here which is the right path there.

Ulf Wiinberg

Next question please. Oh sorry you wanted to comment on the SG&A, Anders

41.23.8

Anders Gersel Pedersen

I think that from an SG&A point of view 2015 will be a very heavy investment year due to the fact that at that point of time we will have full speed on Abilify Maintena. Launching will more or less be a global launch. We will have full speed on the major European countries for Selincro and we will also be in a launch phase for most international markets for Brintellix and for some European markets and then we will have a full-year impact of Northera launch and we will also have a more heavy pre-launch activity and potentially launch activities for Brexpiprazole. But the exact level, I think it is too early to say because it will also depend on market access caucuses around the world but from an overall perspective the activity level will be increasing dramatically into 2015.

Ulf Wiinberg

Next question please

42.29.0

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I remind everybody again; if you have a question for the speakers, please press 0 and then 1 on your telephone keypad. Our next question is coming from Mr Carsten Lønborg Madsen from Carnegie Bank. Please go ahead.

42.38.4

Carsten Lønborg Madsen

Hi, this is Carsten from Carnegie Bank. Two quick questions. First on M&A with the recent acquisition here are you done or are there any sort of franchises where you would like to add additional strength via M&A. Ulf, probably for you. And then for Anders on the tax rate, when you mention in the release that it should be significantly up versus the previously communicated 40 % in relation to Q1, what is that? Is that the +5 percentage points, or what are we talking about? Thanks.

43.20.6

Ulf Wiinberg

Then on M&A, you know, I will give you the – I mean, the situation we have is one where we now have lots of opportunities to execute on with the Brintellix launch, Selincro launches in Europe, Abilify Maintena, Northera launch, so all things being equal our focus should be on executing on these launches. If something very attractive comes up that would fit very well with us we will obviously look at it but the threshold for doing something now is obviously much higher than it was maybe 3 or 4 years ago when we were so actively wanting to create all these new opportunities but now we have this going on, now we need to execute and deliver on what we have taken on. So that is kind of where we are at, so not impossible but improbable is probably the summary of our M&A strategy and tax.

44.32.2

Anders

It is not only 5 %, it can be more. You need to and normally I would like to be much more precise but the problem is that the earnings mix is very difficult to predict and we are down to very small numbers from a net result point of view and therefore 5-10 million in difference or in change in earnings will impact the tax rate because if more is coming from the US where the IP rights are taxed at 40 % compared to Denmark where it is much lower then it will change so it could be up 10-20 %. I don't know. But it will be higher due to the amortisation from Northera, definitely.

45.17.4

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Okay. Thanks.

45.18.6

Ulf Wiinberg

Next question, please.

45.19.8

Operator

Our next question is coming from Mr Tim Rice from Deutsche Bank, please go ahead sir.

45.26.8

Tim Rice

Hi, guys again, Tim from the queue again. Just clarity on the cognition data for Brintellix, when could we realistically expect that to be published in a journal and what sort of journal are we looking at here? A little sort of neuropharmaceutical, I can't pronounce the word, but you know what I mean, a specialist journal, are we trying to go big here with a New England journal or something else like that, one that more primary care doctors might read? Then a second question just on Cipralext actually and its decline. Can you just talk about which markets are now fast significantly emerging or which ones we are waiting for for the rest of the year, etc.?

46.10.2

Anders Gersel Pedersen

In terms of the cognition data, I presume that you are thinking of the data from the Connect study because the others are already out there published. The data from the Connect study I don't know exactly which journal it is going to get into, but we are not looking for a third level journal. I think we are considering impact as much as speed with respect to getting this one published so that will be a priority to have an impactful journal to take it on.

Okay

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Transcript

:: Bilag ::

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And Tim, with respect to Cipralex, I think it is – we are not willing for the time being to go into details with each and every country. What we can see is based on the first two months of June and July with the generalisation it is fully according to what we have expected so we still expect a total decline for Cipralex globally of 20-30 % and then we also believe that the erosion we have seen for Ebixa will more or less be mirrored in the Cipralex erosion rate. So I don't think it is relevant to have a discussion around different markets but more from a totality point of view so I hope that gives you some kind of guidance for that.

47.36.6

Kind of. Thank you.

47.39.2

Ulf Wiinberg

So that brings us to – oh sorry – we have one more question.

Operator

We have one more question and it is coming from Mr James Gordon from J.P. Morgan. Please go ahead sir.

47.52.9

James Gordon

Thanks for taking my follow-up questions – just two follow-up questions. One of them was on Brintellix and the breakdown of the doctors specialty who are prescribing the product. I can see the majority are psychiatrists. Is that as you had expected the ratio? Or are you – is it getting better with the psychiatrists and are you disappointed in terms of how it is staying with primary care doctors and is that sort of where you had hoped to see more of an acceleration? And the second question was Selincro. How confident are you in your previously stated peak sales going to DKK 2 to 2.5 billion and would we need to see a very sharp acceleration for you not to consider revising that at the end of the year or do you still have a high level of confidence in that guidance?

48.35.1

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Transcript

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Let me start with Selincro, you know. We know that we have huge – that alcohol is a big problem in Europe and it is a huge unmet need. We know that we are getting the prices that we are asking for which from a GP product point of view – there is not that many products getting around for Euro today – so we know there is a lot of interest for this. The key issue whether we do 1.5, 2.5, 3.5 billion in peak sales is not going to be so much about the uptake – I mean, clearly it is very exciting to see the uptake in countries like France, Spain and Germany but the ultimate success is dependent on the refill of scripts and that we will not see – that we will not understand before we get into next year but I will say I am very excited about the upcoming launches for Selincro and look forward to seeing how that goes. And the other question was on

Cipralex ??? the mix of size and ??? 49.59.4

Ulf Wiinberg

You know, I mean the first I was part of launching was Effexor in this category which is so long ago that you are afraid to tell anyone but what normally happens is when you launch a drug here is that the psychiatrists pick it up for patients where they have unmet medical needs and as the psychiatrists build their clinical experience and they see that it is good drug and they like it then the GPs will see it more and GPs will often rely a lot on what the psychiatrists are doing. So my sort of picture is typical from that point of view. Obviously going forward for us to realise our targets we have to also build the GP part of the business because ultimately that is going to be the large part but being where we are now is what you typically expect in this situation.

So with that thank you very much for following us. Again, we are excited about the 28 upcoming launches we are doing this fall and we like where we are from a financial point of view but what really is important are those launches and we look forward to keeping you abreast of that. Thank you.