Recordati S.p.A.

"2018 Preliminary Consolidated Results Conference Call"

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MODERATORS: FRITZ SQUINDO, CHIEF FINANCIAL OFFICER

MARIANNE TATSCHKE, DIRECTOR, INVESTOR RELATIONS AND CORPORATE COMMUNICATION

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati 2018 Preliminary Consolidated Results Conference Call. After the presentation, there will be an opportunity to ask questions.

At this time, I would like to turn the conference over to Ms. Marianne Tatschke, Director, Investor Relations and Corporate Communication of Recordati. Please go ahead, madam.

MARIANNE TATSCHKE: Good afternoon or good morning to everyone, and thank you for attending the Recordati conference call today. Fritz Squindo, our CFO, will be presenting and commenting upon our full year 2018 preliminary results. For a better understanding of his presentation, please access the set of slides available on our website, www.recordati.com under the investors section and presentations tab.

At the end of the presentation, we will answer any questions you may have. Please go ahead, Fritz.

FRITZ SQUINDO: Thank you, Marianne. Good afternoon or good morning to everyone. Let's start with our Slide #2. And as we see that we are very pleased with our full year 2018 results which show sales and margin growth.

Let's start commenting our revenue; consolidated revenue for the year is €100...€1,352.2 million, up by 5% over the last year. Let me comment our sales projection or we say sales results. Sales include those of the metoprolol-based products that we have acquired from AstraZeneca last year and fully consolidated for the year 2018. Also...we are also accounting in our P&L, the sales generated by Natural Point, the company acquired in end of June in Italy. And…but I will like also to underline that in our results, there is also an estimated negative currency effect of

something which is close to €48 million. Excluding all these items, growth would have been up 4.2%, which is in line with our expected organic growth. Then sales contribution is important from consolidation of new company acquired but as usual solid performance of our organic portfolio.

A further improvement of our margins are on track, and then EBITDA at 36.9% of sales is for the year, €499.1 million which are up by 9.8%. Operating income at 32.7% of sales is €442.2 million, an increase of 8.8%. Net income at 23.1% of sales is €312.4 million, an increase of 8.2% compared to the preceding year.

Overall, a very...another improvement...further improvement of our margin in one year 2018 in which we had to overcome currency effects, mainly linked to the Turkish lira, and also some generic entry challenges, in particular for our combination of Lercanidipine and Enalapril and for Cosmegen and in U.S. Even in this scenario, we have been able to grow the sales and to have a further improve in our margin.

Going to the our net financial position. The net debt at the end of the year is €588.4 million which has an increase compared of 206.6 million compared to last year financial position. But let me remind you that in the period, we have had an important share buyback for an overall disbursement of €169.8 million. We had used to pay our dividend for an amount of €179.9 million, and we had acquisition of Natural Point in Italy and Tonipharm in France, for a value of €148 million. And we have also, at the beginning of the year, acquired rights from Mylan for Cystagon in Europe and in other territories for €20 million. And excluding this more important investments, we continue to have a very strong cash generation.

It's important the year it was also very productive regarding step for our development. So let me underline some of this. We have, as I said, acquired rights for Cystagon in Europe and in other territories from Mylan. We have acquired in end of June, Natural Point, an Italian company specialized in food supplement, and in particular with a very well-known brand of [indiscernible]. And at the end of the year, we have bought a company in France, Tonipharm is the name of the company which is marketing prevalently product over-the-counter…in the OTC environment and is further improvement in our OTC franchise.

During the last quarter, Reagila also...Reagila which is an important product for our specialty and primary care portfolio was launched in some European countries and we have also obtained…we have also obtained the rights…the worldwide rights, excluding the U.S., China, Hong Kong and Israel for the marketing of Ledaga, which is an important product for our portfolio in the treatment of rare diseases and always in the treatment of rare diseases is we have obtained the orphan drug designation for 2 products in our [indiscernible].

I would like to say that very important year 2018, very solid financial result and for us it is also important…important step in building the future of the company with important transaction, in both, in the specialty and primary care, in particular in the OTC environment and a reinforcement of our pipeline and product portfolio in the treatment of rare diseases.

We can now move on the analysis of our sales, as usual on Slide 3, you have the analysis of the main products of the company and the performance of our corporate products, let's say are in line with expectations. And in this group of products, we are now…metoprolol-based product that we have acquired from AstraZeneca, as I said at the beginning as from July 2017.

Let's start as usual with our lercanidipine sales, Zanidip, is the most important brand of lercanidipine. And overall, lercanidipine sales continue to remain stable and we continue to keep at the level of sales of €120 million.

Regarding the sales of the combination of Lercanidipine and enalapril, Zanipress, these are down as expected due to the competition for generic version. And now, we have generic version as competitor in all the main Western European countries, but even in this environment in which we have for both…for Zanidip and for Zanipress generic competition, the overall sales of lercanidipine franchise in 2018 are €118 million sales.

Going back to Urorec which is the most important brand for silodosin, Urorec generated sales of €101.1 million…over then €100 million during the period and are up by 9%, and thanks to the good performance of the product in all the main markets.

Then sales of Livazo, the most important brand for our pitavastatin-based product, are €46.4 million and which are up by 18.3% and this due to the good performance of the product in Turkey and in all the other markets where it has been launched. The both, silodosin and pitavastatin continued to grow in line with our expectation.

I would like also to remind you that as I said now starting from July 2017, we consolidate also revenue generated by the product base following the acquisition of AstraZeneca right to Seloken and Seloken ZOK and Logimax which are the 2 brands for the metoprolol-based product. And this product, in 2018...sales of this product in 2018 are €98.9 million and this is also in line with our expectation. And this product contributes

significantly to the growth of our subsidiary, mainly in Germany, Poland, France, Czech Republic and Romania.

And it is important to say that we are keeping the value of this business and we are also developing, thanks to this...to the sales of this product in an area in which we have not direct presence, in particular in the Nordic area, in the Benelux area, in the Baltic area. This is the base for our entry with our own organization in these markets, which allow us now to have even more balanced and complete coverage of the European market. We are very pleased by the acquisition of Seloken, for both reasons which were strategically important for us to consolidate, to keep the sales but also to complete our coverage in Europe.

Then there are these lines of other corporate products which comprise 23 products sold in multiple territories, 8 of which are OTC products, included in these are the initial phase of Reagila, our new product for the treatment of schizophrenia, which in 2018 result are €3 million. But I think it's important for Reagila this initial result of sales which are in line with what we expected. But even more important, the market access activity which has progressed very well in 2018.

And in the...towards the end of the year, we have launched the drug also in Switzerland, Italy, Belarus, and Ukraine and in the Nordic countries. Just to remind you that the initial launch of Reagila was in Germany in April. But we have now starting selling the new product in almost all of the markets in which we have right, and we expect next year to complete market access in Spain and in Portugal.

Let's now move on the…our drugs for rare diseases, our specialties which is indicated for the treatment of rare diseases, generated sales of €214.8 million during the year which is an increase of 1.7%. I mean, we have

included in this number...in this growth there are sales in the U.S., which are down by 7.8%. But this is due mainly to the already announced competition from a generic version of our brand...of our product Cosmegen in the U.S, and let me say the result are in line with our expectations and this increase in the U.S. is also due to a negative exchange rate which could be estimated to be €4.7 million. Excluding this sales performance in the U.S., in and all the other parts of the world...sales in the rest of the world grow by 12%.

Moving on page...on Slide #4. As usual, here we present this graph with our very well-diversified product portfolio. And let me underline that now corporate products for the full year including the rare-disease drugs now account for 67.7%, and also thanks to the inclusion of the metoprolol franchise that we have acquired last year.

Slide #5, this slide shows sales performance by geography. Let's start as usual in Italy. Sales in Italy are up by 5.8%, due mainly to the good performance of Urorec and Cardicor. Cardicor is bisoprolol for which we have right for the Italian market. We have also a significant growth for the treatment of rare diseases but...and also, starting from July 2018, we have also the contribution of the sales of Natural Point, a company that we have acquired for an amount of €7.7 million.

In Germany sales are up by 11.7%, mainly thanks to the sales generated by the metoprolol-based product we have acquired from AstraZeneca. Sales in France here again are up by 5.7% and in our French market, it is worth mentioning the good performance of Urorec, in addition to the integration in the product portfolio, also in France, of metoprolol-based brand and also the addition of the gastrointestinal product, Transipeg and Colopeg, we acquired from Bayer at the end of 2017. Also in France, the treatment for rare diseases are growing strongly.

Revenue generated in Russia, Ukraine and CIS countries is €105.6 million, which are down by 1.3% and includes, this is the reason for this decrease, an estimated currency exchange losses of €11.4 million. Sales in Russia which is the major market in this part of the group…of Europe in local currency, grew by 4.2%, decrease in euro terms basis, but we continue to have growth in our business in Russia. Also thanks to the good performance of our corporate product that we have launched in this market, in particular, Urorec, Zanidip, Livazo and Procto Glyvenol are performing well.

Then the group...we have our U.S. business. Let me again to underline that our U.S.A. business is only dedicated to the marketing of products for the treatment of rare diseases. Sales in 2018 are €101 million which as I already commented are down by 7.8%. And this is mainly to the competition of the generic version of Cosmegen and also to a significant exchange rate. In local currency, our U.S.A., business decreased by 8.3%.

Sales in Turkey are down by 12.9%, and this is only due to the negative currency effect which could be estimated in €27.1 million. Local currency...in local currency, our Turkish subsidiary grew by 20.5%. That solid performance locally has been aided by the devaluation of Turkish lira, in particular, in the second part of the year.

And then sales in the Central and Eastern European countries benefit significantly from the consolidation of the metoprolol-based product acquired in last year, and this is another important contribution for metoprolol, because now in Poland, in Romania and in Czech Republic we have increased our critical mass in terms of sales and now...thanks to...in particular to a very well recognized brand for metoprolol-based product we have acquired from AstraZeneca.

Slide #6; as usual, we present in this graph the geographical breakdown of our pharmaceutical revenue. Nothing...no major changes, but we continue to have a very balanced portfolio with our Italian business which represent around 20% of our sales.

Slide #7, we have P&L full year results 2018. We have already analyzed and commented our revenue for the period. Moving on the margin, gross profit in the period is €956.7 million with a margin of €70.7 million...70% on sales. And here we have an improvement over that of the preceding year due to the further growth of product with higher margin and to the positive effect of the metoprolol-based product acquired last year.

Selling expenses at 24.7% of sales increased less than our sales and are therefore down as a percentage of revenue compared to the preceding year. And this is thanks to the increased efficiency and continuing leveraging of our group commercial organization. G&A expenses are up by 3.3%, but are down as a percentage of sales, and now as a percentage of sales our G&A of 5%.

R&D expenses in the period are €109.7 million, which are up by 9.4% due to the advancement of the new development program, featuring the rare disease space and also to the amortization of the acquired rights to the metoprolol-based product.

Next financial charges, up €24.3 million and significant increase compared last year, but let me comment on this increase because €6.9 million are due to late payment interest linked to the settlement that we have had with the Italian subsidiary in the last quarter. And let me comment on this.

During the year, particularly in the month of November, to settle...we have a settlement with the internal revenue service with Italian authority. The agreement covers the complete definition of all the disputes which are not only related to the Italian subsidiary, but are also related to the Irish subsidiary and the Luxembourg subsidiary. And we have stated last year in the note of our balance sheet, but then in November, we have a complete definition of all this disputes with an impact in both interest charges due to the late payment interest related to this definition, but we have also...in the agreement also provided a further transfer to the following period of €9.2 million, which is on top of what we have already accrued in our balance sheet in the end of 2017.

Then the in term of...we have the full definition, we had an impact in our P&L in 2018, which is €6.9 million due in the interest charges and €9.2 million in our net taxes charge for the year.

Let's now comment on our taxes. The effective tax during the year remained 25.3% because on the one hand we had this definition and this with [indiscernible] in Italy. On the other hand, the cost is partially offset by the recognition of a tax credit in Turkey. They are linked to our investments in the plant in Turkey for an amount of €4.8 million.

Let's now move on our net income. Net income in the period at 23.1% of sales is €312.4 million, and we have an increase compared to last year of 8.2% of our net income. As I said at the beginning, very important and further improvement even in the figure for the net income, we have included in the cost of doing the full settlement of this dispute that we have had with the fiscal authorities.

We can now move on Slide 8, in which we present our revenue by segments. And now we present EBITDA and EBIT between our 2

business segments. Then EBITDA margin are 50.5% for the rare disease segment and 34.3% for the specialty and primary care segment. Both segments show margin improvement at EBIT margin. EBIT margin are 48.1% for the rare disease business and 29.8% for the specialty and primary care segment.

Slide #9, net financial position. We continue, as I said, to have a strong cash flow generation, which has been used for investments in the business. At the end of the year, the net financial position show a net debt of €588.4 million, which compares...with an increase compared to last year of €206.6 million. But as I said, it's important to underline that we had invested part of our cash flow generation in the development of the company.

Here again, I would like to remind you that we have invested €20 million for the acquisition of the rights of Cystagon. We have acquired own share for an overall amount of €169.8 million. We have paid dividend for an amount of €178.9 million. And furthermore, the Italian company, Natural Point; and the French company, Tonipharm, were acquired.

And here in our balance sheet situation, we have the full disbursement for the acquisition of Tonipharm and then overall, the value of the 2 acquisitions is €148 million. Therefore, we have strong generation in excess of €300 million, if we exclude these extraordinary or investment event, which imply over 100% of net income to cash conversion rate, which is in line with our historic cash conversion rate.

Then to finish my presentation on Slide 12. Here, we have our financial projection for the full year 2018. These targets were disclosed on the 21 December of last year, and now we are confirming our target for the full year. In particular, we expect for the all 2019 to achieve sales ranging

from €1,430 million to €1,450 million. We expect EBITDA of between €520 million and €530 million. EBIT of between €460 million and €470 million, and the net income of between €330 million and €335 million, which means margins are in line with those we have achieved in 2018.

Here I finish my presentation. Thank you, all for your attention and now I am available for any questions you may have.

MARIANNE TATSCHKE: Operator, could you please open the question and answer period.

Q&A

OPERATOR: Thank you. Excuse me; this is the Chorus Call conference operator. We will now begin the question and answer session. The first question is from Martino Ambroggi with Equita. Please go ahead, sir.

MARTINO DE AMBROGGI: Yes, thank you. Good afternoon, good morning, everybody. The first question is on the guidance for the current year. So just to know what are the assumptions on FOREX and R&D and the consolidation of newly acquired assets for this year?

FRITZ SQUINDO: [Indiscernible], Martino?

MARTINO DE AMBROGGI: No that was the first one. So the second is on the gross margin, I was wondering if there is a roof under the current perimeter for the expansion of your gross margin which exceeded the 70%. And the third one and more generic, I don't know if it's too early to ask about it. But now that the change in the majority shareholding structure has been finalized, could you share with us what is going to change in your strategy? Or we need to wait for the presentation next May?

FRITZ SQUINDO: Okay. First question regarding the assumption in our 2019 guidance. Regarding R&D, the assumption is to keep essentially the same level in term of percentage on sales that we have achieved, that we have in 2018. There are no major changes in term of R&D expenses as a percentage of sales. Having said that, the R&D are also linked to program and then depending on how are evolving the program, we can have slight changes in our R&D cost. But essentially, assumption is to keep the same level of cost.

Regarding assumption implied in our projection, there is a further minor but further negative impact due to the devaluation of the Turkish lira because as I said during my conference call, the devaluation was really important in the second half of 2018. And we expect something which could be considered close to 1% as an impact for the full year, based mainly to the full year impact of what is the level of Turkish lira today. And we also assume in line with consensus, a further devaluation of the Turkish lira going forward. Then this is not based on...our assumption is not based on the Turkish lira that there is today, but we have considered a further devaluation going forward during 2019. Second question was related to the gross margin.

MARIANNE TATSCHKE: [Indiscernible] newly acquired assets…

FRITZ SQUINDO: Gross margin then, we are very pleased now with our margin which is above 70%. Frankly speaking, this...we don't expect major changes in the gross margin. And we expect to keep our gross margin in the range of 70%. Regarding the assumption in term of sales, let's say we had, for sure, included in our projection in term of sales the consolidation of the full year of Natural Point and Tonipharm, which has an impact that which could be estimated around 2%, 2.5%. And year-to-date, we have...the other 2 are mainly license agreements because both Ledaga that we've

signed at the end of 2018, and also the Juxtapid license for the Japanese market and these had been...but we've been included initial sales for Ledaga and also initial sales for the new license in...of Juxtapid. The third question was?

MARIANNE TATSCHKE: The shareholding…

FRITZ SQUINDO: The shareholding. Then, you have also seen our press release that now there is a new situation in terms of ownership of the company, and we expect the new ownership will continue the company business strategy keeping as always we have said management and people in place and also the strategy going forward, we expect to be in line with both our historical strategy. Then we can confirm that the group strategy is to continue to grow organically and through acquisitions in the future, which may see an acceleration, but these is also linked to availability of targets in the market and also into linked to our financial strengths. Then no major changes, and the company will continue within the same direction, and the company will continue with the same management. And this is in line to what we have announced when there was the closing...the signing and then the closing of the acquisition of the FIMEI stake by CVC and the other investors.

MARTINO DE AMBROGGI: Okay, thank you Fritz.

OPERATOR: The next question is from Jo Walton with Crédit Suisse. Please go ahead.

JO WALTON: Thank you. I've got a few product questions and a couple of financial questions. On the product questions, I wonder if you could tell us...you've given us the initial sales of Reagila. Could you tell us what sort of pricing you have been able to achieve outside of Germany? So in Germany, you've been able to choose whatever price you like but now you've got

approvals in the U.K. and the Nordic region, presumably where you've had to effectively agree prices. Are they the price levels that you've expected? Are they in line with other modern, antidepressant stroke, antipsychotic drugs? And I'm pushing my luck here but would you give us a peak sales estimate for your 2 new drugs that you have in-licensed, the Ledaga product and Juxtapid? And on the U.S. Cosmegen, have we now reached a stable position so that all of the erosion that you would expect post the patent expiry has happened, or will there be a continuing negative effect continuing into 2019. And on the financial side, I wonder if you could tell us what your expected product amortization charge will be in 2019. I assume that you are going to have some extra intangible asset amortization that comes from some assets in Tonipharm, maybe a full year of Natural Point and maybe your 2 licensed products will give you some amortization. And finally, on your net financial charge, if we take out the one-time €6.9 million, we're back to about the level of charge you had in 2017, is that a good guide for the financial charge for 2019? Thank you.

FRITZ SQUINDO: Okay, a lot of questions, Jo. Okay, then. First question was related to Reagila. Then, as I said in the call, sales achieved in 2018 were €3 million, in line with expectation. We have now had the approval in Nordic, in Italy, in Benelux, in the U.K., and let's say that for 2019, the expected sales of Reagila are at least €10 million. And that I would like again to underline, this is a chronic disease and the uptake of a new product, if there's no one, we don't expect an explosion of new drug in particular in '19, but we expect progressively to start selling our product in all the marketing in which we have rights.

Regarding prices, we are pleased by the price that we have obtained. But I cannot comment on this call, but we are pleased. We have a premium price compared to the generic competitor, but I don't want to disclose

because we have not yet finished in all the markets our market access activity

Cosmogen in the USA, then the range of the generic of Cosmegen account last year at the beginning of the year, then the majority of the effect is already done, is already...has already impacted our P&L, then we can expect a slight further erosion at the beginning of this year. But then overall, we expect the full impact has already occurred and that we expect a sort of stabilization of our sales of Cosmegen. Just a slight reduction compared to sale that we have achieved in 2018. But this is mainly due to the fact at the beginning of the year; the competition was less aggressive than it's been in the other part of the year. But no major impact for Cosmegen.

Regarding fixed sales of the Reagila, and then we believe that both are 2 important products in our portfolio. Let's say that Juxtapid is a product which is limited to the Japanese market and Ledaga is a license that we have for what...is global, excluding U.S., China, and some other minor market. Then in term of potential fixed sales, Ledaga is more important than Juxtapid for the dimension of the market. But let's say, we have not included in our press release peak sales and therefore, I don't want to comment peak sales today, but yes, we believe that one could be in the range of €20 million, €30 million, the other could be in the range...we are talking about Juxtapid, the other could be in the range of €50 million, but these are preliminary evaluation. As we are now to start selling and promoting the drug. Last...the other question were?

MARIANNE TATSCHKE: The amortization…the product amortization.

FRITZ SQUINDO: Sorry, that is not with me, the exact number then…but we will have some increase in the amortization for the new drug, but forecast…not here with

me the number, Marianne will send to you if you want the real number...but we are not talking of big, big number. We could be in the region of €5 million, €8 million of cost. But the right…for all of these Tonipharm, full year Natural Point and initial amortization for Ledaga and Juxtapid.

Regarding the net financial charges, then we exclude taxes, then the cost is in the region of €16 million which I believe could be sustainable. Sometime, unfortunately we have also some negative effects, but excluding these, let me say that interest charges in the range of €6 million...€17 million...€16 million is something which is sustainable going forward.

JO WALTON: Thank you very much.

FRITZ SQUINDO: Thank you for your question.

OPERATOR: The next question is from Ryan MacDon [ph] with Damira [ph]. Please go ahead.

ANALYST: Hi, guys. Thanks for the presentation. Just a couple of questions from me. So in terms of your full year 2019 guidance, I note that the EBITDA range that you provided implied some slight EBITDA margin decline. Is that just mix effect from acquisitions or what's driving that?

FRITZ SQUINDO: Okay, then we have a range. And then we have...in term of guidance, as usual, we announce ranging revenue in EBITDA and EBIT and net income. But let me say if you cross all these number, we can say that overall this is our assumption we expect to keep all our margin, EBITDA, EBIT and net income to the level that we have achieved in 2018.

ANALYST: Okay. But...I mean, if you take the €520 million and €530 million, divided by the revenue range of €1,430 million to €1,450 million, it shows a bit of a margin decline?

FRITZ SQUINDO: Okay, Ryan, depending which kind...if you...which kind of calculation you were doing. But let's say these are range overall, let me say that we expect to keep our margin at the same level that we have achieved last year.

ANALYST: Okay.

FRITZ SQUINDO: And depending with what...depending what will be revenue and what will be EBITDA in term of...because giving a range depending on the calculation that you have done. But let's say, this is the range, [indiscernible] is that we expect to keep our margin at the same level we have achieved in 2018.

ANALYST: Okay. And then second question is on the leverage through the Holdco. Could you disclose what you're calculating Holdco leverage to be?

MARIANNE TATSCHKE: Sorry, no.

FRITZ SQUINDO: We don't want to comment something which is linked to the bond which was issued by Rossini. Then if you are asking me, what is the level of debt, then as usual we...I can say that Recordati, we are only talking about Recordati. Now, we have one…net financial position at the end of 2018, which is €588.4 million in which we have included €75 million disbursement for the acquisition of Tonipharm. We paid this acquisition at the end of 2018 without any positive impact in terms of margin, and then if we exclude this payment, our leverage, our margin, we have a net financial position close to 1 time EBITDA. Then, we have a strategy in which we want to continue to reinvest free cash flow generation and then

the expectation is to continue to...the inorganic growth, but as I said, in my conference call, this is mainly to opportunity. And then we...I cannot comment we have no specific target in term of leverage by the end of 2019. But we expect to invest the free cash flow generation and if we can find interest opportunity, we can slightly improve our debt. But as usual, we continue with our discipline in approaching the acquisition and the level of debt is more driven by opportunity which could create value in the company rather than a specific financial objective for...in term of leverage. We will issue a specific...an update into our Business Plan, this is common for Recordati is May in which we could be even more detail in our objective in term of leveraging the Recordati, back…it's okay?

ANALYST: Thank you.

FRITZ SQUINDO: Thanks.

OPERATOR: The next question is from K.C. Arikatla with Goldman Sachs. Please go ahead.

K.C. ARIKATLA: This is KC from Goldman Sachs. Thanks for taking my question. I have one regarding the margin. You've managed to expand margin significantly in...

MARIANNE TATSCHKE: KC, can you talk louder, please, we can't hear you?

K.C. ARIKATLA: Can you hear me now?

MARIANNE TATSCHKE: Yes, better.

K.C. ARIKATLA: Yes. So I had a question on the margins. You've managed to expand margins significantly in 2018 despite currency headwinds. If I were to

look at it in the longer term, what would you say are sustainable margins for your primary care segment and your rare disease segment, in terms of margins? Thank you.

MARIANNE TATSCHKE: I'm sorry it's very confusing, we didn't get support. Could you just make it shorter, what's the point that you're getting at?

K.C. ARIKATLA: What would you say are sustainable margins in your primary care segment and rare disease segment in the longer term?

FRITZ SQUINDO: Okay, then. We can...I have commented guidance for 2019 and for sure, for 2019 imply in our...in our target. There are the achievement and the maintenance of the margins that we have achieved in 2018, and then for sure for 2019 we expect to keep our margin. We have already announced that going forward...also going forward we expect to keep this margin, but we will be more detailed in…either in margin evolution when we will present our Business Plan in May. Then, I want to reassure you that we expect to keep our margin 2019, we don't see major changes in our profitability going forward, but to comment in detail margin evolution, I will remind you…I will postpone you, sorry to the presentation of our Business Plan in May.

K.C. ARIKATLA: Thank you.

OPERATOR: The next question is from [indiscernible] with Wells Fargo. Please go ahead.

ANALYST: Hi, a couple of questions on my side. Firstly, do you have a guidance for the 2019 tax rate? And my second question is about, again, the 2019 cost line. Do you feel that you do need to reinvest a little bit on your marketing…I mean, the sales and marketing cost?

FRITZ SQUINDO: Okay. The first question was related to the tax rate and our guidance for 2019 is to continue towards tax rate around 25% and it is inline 25%, 25.5%. And then we don't expect.

The other point, we have...I don't want to comment in detail margin, percentage of sales for 2019, but imply in our assumption which is…we expect to keep our margin in line with what we have achieved in 2018. We have also commented that we don't expect major changes for R&D, which means that essentially we expect our margin structure for 2019 to be very similar to what we have achieved. In 2019, in particular, we have now had a percentage of sales in our selling expenses a rate which is...we have achieved in 2018 a rate of 24.7%. And we have our G&A, which are 5%, and we don't expect major changes. And this is also implied in our guidance, which is to keep our margin stable for 2019.

ANALYST: If I can squeeze in just another point on...thank you very much for giving us sort of a FOREX sensitivity at the revenue level. I'm sorry, but I'm a little bit new to your company. But is your FOREX sensitivity greater at your EBITDA level or EBIT level compared to the top line?

FRITZ SQUINDO: Okay, then, we have an impact in our revenue line which is mainly linked to the translation of the local sales in Turkey, Russia or...for 2018, even the U.S. market in our euro-denominated P&L. While this impact is, for sure, mitigated at operating level, EBITDA level, due to the fact that in all these business, we have a natural hedging, which is represented by cost, which are denominated in local currency. And in all these markets, we have all the commercial organization, which is a local one, which is...the costs are denominated in local currency, we have also the majority of our production cost, which are denominated in local currency, in particular, we have an important production plant in Turkey. Part of our portfolio is

produced through third-party manufacturing in Russia. And in our business in the U.S. market, we have a third-party...we have third-party agreement for all our portfolio with local manufacturers, which means that our cost is denominated in U.S. dollar, which means that we have an impact also on operating level, but this is lower than what we have communicated in our revenue line, thanks to the natural hedging.

ANALYST: Okay, that's very clear. Thank you very much for answering all my questions.

FRITZ SQUINDO: Okay, thank you for your questions.

OPERATOR: The next question is from H. Yupino [ph] with Societe Generale. Please go ahead, sir.

ANALYST: Good evening to everybody. Could you please give us a rough indication of 2018 EBITDA including the full year effect of the buyer [ph] acquisition done during the year?

FRITZ SQUINDO: Sorry.

MARIANNE TATSCHKE: Including?

FRITZ SQUINDO: Including what?

ANALYST: Including the full year impact of the acquisition done during the year.

FRITZ SQUINDO: Okay, then. We did...frankly speaking, in the only provision we had in term of March in 2018 is the acquisition of Natural Point. We bought one company in June. This was in term of sales. We are talking about €7.7 million sales, and then it's up to you to do the calculation considering our

margin and considering also that this company has a higher margin compared to our EBITDA margin, then you can keep 50% of this if you want and that's the only contribution. If you want to have the full year, including the acquisition, you have just to add this EBITDA which is linked to the acquisition of Natural Point. On the other hand, we have also acquired a company in France, which is Tonipharm, but these are not being consolidated because we have signed and closed the deal at the year-end.

ANALYST: Okay, thank you.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone. One again, if you wish to ask a question, please press "*" and "1" on your telephone. The next question is from Katrina Rakowsky [ph] with BlackRock. Please go ahead.

ANALYST: Hi, can you give an indication whether the tax settlements that you had with the Italian authorities is...it's final? Do you expect any more payments related to that?

FRITZ SQUINDO: Okay, then, with this, the agreement was final for the period, which was under investigation, which was [indiscernible] in 2009 and 2015. Then, we have also included accrued in our cost. The cost which is linked to the application of the new conditions, which we have agreed with the Italian authority for '16 and '17 and '18, then it's finally...so it's paid. Let me say in this way, it's paid. We've paid in November the settlement for the period of '09 and '15, and accrued but in line with what are the agreement for the other part of the period, which is the 3-year '16, '17 and '18. And we don't expect other cost linked to this settlement for the future.

ANALYST: Okay, thanks.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone. For any further questions, please press "*" followed by "1". The next question is a follow-up from Jo Walton with Crédit Suisse. Please go ahead.

JO WALTON: Thank you. Just wondered if you could give us an update on Carbaglu in organic acidemia in the U.S., whether you've now been able to file that and if so, should we begin to see sales at the end of 2019? Many thanks.

FRITZ SQUINDO: Okay, thank you for your questions. We had filed Carbaglu organic acidemia in the U.S. end of '18, and now we are in the process of discussing with FDA and then the expectation is to have, let's say, set by the end of this year, initial 2020. But we have filed the dossier in November last year.

JO WALTON: And do you know whether you have received a priority review?

FRITZ SQUINDO: Not yet. Also because based on the shutdown, there was the activity of the APA [ph]. The FDA was not fully...I don't know.

MARIANNE TATSCHKE: Operational.

FRITZ SQUINDO: Oh, it's not fully operational. But we have filed. There was a...let me comment on this. Jo, there was a long discussion with FDA for this filing, and then we expect to have the product approved by year-end of 2019. And then we will update you during this year on the progression of this filing.

JO WALTON: Thank you very much.

FRITZ SQUINDO: Okay.

OPERATOR: The next question is a follow-up from Martino De Ambroggi with Equita. Please go ahead, sir.

MARTINO DE AMBROGGI: Just if you can remind us what are the peak sales for Urorec and Livazo, considering we are not far from the patent expiry. So if you confirm the old or the original indication? Or there is some revision upwards, downwards?

FRITZ SQUINDO: Okay, then, the peak sales were more than €100 million, then we have already...we're really pleased to achieve in '19 and to exceed the phase of silodosin, very strong in our P&L, above €100 million. We expect the further growth of the product in '19, which means that we are in line, even slightly above our previous expectation.

MARTINO DE AMBROGGI: And for the other one?

FRITZ SQUINDO: For Livazo, we are then...for Livazo, it's a different story because the previous expectation was linked to the opportunity to launch Livazo also in Italy and France. For price reason, we have not been able to have the product reimbursed at the premium price in this...to market. Now we are achieving in...€47 million in 2018. We continue to grow the product double digits. We are very pleased by the performance of Livazo in Turkey. And even in Russia, which we have...we've launched, also in this market, we have seen good performance. And then, we have no...we will be, for sure, below the expectation that was...that were €100 million, but we are very pleased by this performance. And we expect to continue to have double-digit growth for Livazo.

MARTINO DE AMBROGGI: Till the expiry, okay.

FRITZ SQUINDO: Till...until the end of generic competition.

MARTINO DE AMBROGGI: Okay. Too early to have visibility on this?

FRITZ SQUINDO: Too early in term of availability of generic, yes. Just to remind you that the exclusivity in using clinical data for silodosin expired beginning January 2020 and for Livazo, August 2020. It's clear. But if and when generic will enter, today there is no visibility. Too early.

MARTINO DE AMBROGGI: Okay, thank you.

MARIANNE TATSCHKE: Okay, if there are no further questions, I think we'll say goodbye to everybody, and thank you for attending our call.