Recordati S.p.A

"Preliminary Full Year 2019 Results Conference Call"

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati Preliminary Full Year 2019 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, Investor Relations of Recordati. Please go ahead, madam.

MARIANNE TATSCHKE: Hello. Good afternoon or good morning to everyone. And thank you for attending the Recordati conference call. Andrea Recordati and Luigi La Corte will be presenting and commenting upon our full year 2019 results, as well as our 2020 targets. Mr. Fritz Squindo is also with us here today.

For a better understanding of this 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, there will be a questions and answer period for any question you may have.

Please go ahead, Andrea.

ANDREA RECORDATI: Thank you. Good afternoon or good morning everybody connected. Thank you for joining this conference call. So I will get down to business for 2019 preliminary full year results. We believe we have delivered another year of very strong performance. We have revenue growth of 9.6% and EBITDA growth of 9% to €544 million. As you would see more detail later on in the call, growth has been broad-based across our businesses in all key geographies, with organic growth of roughly 5.7%, mostly driven by volume, with 1.3% slight uplift, mainly in U.S., Turkey and Russia and a negligible year-on-year FX impact.

Operating income grew by 5.2% with a slight reduction in margin, driven by increase in amortization of intangible assets and additional investments made in Europe, where we established local organizations in the Nordics, Benelux, and Baltics for our SPC business. And initial investments we have made to build our new endocrinology franchise.

Net income is up 18.1% versus the previous year and reflects benefits from agreement reached with Italian tax authorities in late December on the Patent Box benefit for our IP in Italy. We have a tax benefit of €27 million relating to years 2015 to 2018 and €8.3 million related to 2019. If we exclude this benefit related to prior year's net income would have been €341.9 million, therefore 9.4% above last year, and equaling 23.1% of sales.

The business has continued to generate strong underlying cash flow, with net debt increased to €902.7 million from €588.4 million, reflecting dividend distributed for an amount of €190.9 million and payments for acquisition, milestones and license fees for a total of around €425 million.

Apart from this strong performance we also further reinforce the group's 2 important business development transactions, being the acquisition from Aegerion Pharmaceutical range of the exclusive commercialization rights of Juxtapid in Japan and the important strategic transaction which we closed in Q4 with Novartis with the acquisition of Signifor, Signifor LAR and Isturisa from Novartis which contributed already €10 million on net revenue in Q4 of last year. Before handing over to our new CFO, Luigi La Corte, who will provide more details on our financial performance in 2019. Let me provide you some more update on the opportunity we have with the new endocrinology portfolio. So, please next slide. Slide 3.

This acquisition from Novartis is one of a most important transactions for the group or that the group has made to-date and will contribute that sizably to us becoming an important player in the rare disease space worldwide. We are in the process of building an endocrinology hub in Basel, to handle all regulatory supply chain medical affairs and commercial aspects and managed commercial aspects of this new franchise on a global level.

We are also setting up a specialized team in the U.S., with the objective of improving the performance of Signifor and ensuring a successful launch of Isturisa once it is approved. At the same time, we are also ramping up our organization in Europe and in the rest of the world in order to provide focus for our endocrinology franchise. All told more than 70 people are being added to the Recordati Rare Disease organization worldwide.

Next Slide 4, please. In this slide, we focus on Signifor, Somatostatin analogue for the treatment of Cushing's disease and acromegaly with potential peak sales of more than a €100 million. Last year, as you can see in the slide, Signifor grew by 4% in almost all key markets. We are proceeding with the re-launch activities linked to Signifor LAR especially in the U.S., as Novartis has deployed limited resources in recent years as I already previously mentioned.

More than 70% of sales are generated by the LAR formulation and a switch from the subcutaneous formulation shows an increasing adoption by Cushing's disease patients, as well as, a strong uptake in acromegaly patients. Opportunities in new geographies are also under evaluation. We would be able to sell directly to the market, once the marketing authorization are transferred from Novartis to Recordati Rare Diseases. This transition is expected to take place in Q1 in U.S., and in early Q2 in

Europe with other key markets following in Q3 of this year. Next slide, please.

So we are obviously very excited with the recent developments related Isturisa, the new therapeutic option for Cushing's Syndrome recently approved by the European Commission in January of this year and for which orphan drug status was confirmed late last year. We have started market access activities and plan to launch in selected European markets during late Q2 and early Q3 2020.

For the U.S., market, we have PDUFA date on the 7th of March of this year, which could lead to a potential launching 2020. In line with this, we are already gearing up our organization to support both the re-launch of Signifor, as well as, the potential 2020 launch of Isturisa in the U.S.A.

Regarding the Japanese market, we are planning to file in Q2, 2020. Isturisa is a potent inhibitor of cortisol production, with the majority of patients achieving and maintaining normal cortisol levels at the end of the 8th week withdrawal period as demonstrated by the LINC-3 Study results. A strong clinical profile and acceptable side effects…effects profile, lead us to be optimistic that this could be a very successful product. We have interesting potential sales level which could be materially above the €100 million preliminary evaluation already communicated. In May of the 'Capital Markets Day' when we will present our new 3 years Business Plan, we will provide a firmer estimate for the whole of our endocrinology franchise going forward.

I now leave the floor to the Luigi, to take you through with our 2019 results in more detail. Thank you. Luigi.

LUIGI LA CORTE: Thank you, Andrea. And once again good afternoon and good morning everyone. I am delighted to have this first opportunity to comment the Recordati 2019 results.

I will start with revenue on Slide 6. As Andrea said, total revenue grew by 9.6% in the year with a strong contribution from our corporate products including rare diseases, which overall now accounts for 68% of revenue. We are very pleased with the performance of the lercanidipine franchise in 2019 with combined sales of €193 million which is ahead of plan set out in May last year.

Zanidip sales grew by 11.3%, driven by growth in Germany, Italy, Turkey and Poland. We are also very pleased with the performance of Zanipress a combination with enalapril, which we covered following generic entry and where we started growing in the second part of the year and in 2019 broadly in line with last year.

Urorec sales are also slightly ahead of plan with sales growth of 6% due to the good performance of the product in all the main markets and significant growth in Turkey and Russia. Livazo sales growth of 16% is also in line with plan with good performance of the product in all of the main markets in particular Spain, Russia, Greece, Switzerland and Turkey.

We have also stabilized revenue of the metoprolol franchise acquired from AstraZeneca. With the franchise also providing a great platform to establish organization in geographies where we didn't have resources on the ground, particularly Nordics, Benelux and other markets.

Other corporate products grew by 11.8%, driven by strong growth of fenticonazole, CitraFleet, Procto-Glyvenol and other OTC products. But also thanks to the contribution of Reagila a new treatment for

schizophrenia with sales of just under €8 million for the year. Sales are slightly…of Reagila are slightly behind our initial expectations due to initial challenges or any delays that we have with market access in various European markets. We are now very encouraged with the trend that we see in markets where we have launched and particularly pleased with the early trajectory of markets where we launched more recently in Spain and Portugal.

Drugs for rare diseases generated €249.9 million of sales, a growth of 16.3%, and include a contribution of €10 million of net revenue from Signifor and €10 million from Juxtapid. Signifor of course up until the point of the market...marketing authorization transfer, we report under net revenue the net margin, which is transferred by Novartis.

Switching to Slide 7, which gives a picture of our portfolio; drugs for rare diseases have grown to 16.9% of total, up from 15.9% last year. OTC drugs have grown to 18.6% up from 15.7% next...last year. Thanks to the growth of Procto-Glyvenol, Casenlax, Magnesio Supremo, our new product which was acquired from the acquisition of Natural Point in the…in Italy. And of course, from the integration of Tonipharm in France. Our reliance on the local product portfolio as proceed in plan is decreased from 20% last year to now 17%, now remains an important part of the…of the business.

Moving to Slide 8, and looking at the revenue by geography. Great, obviously to see all of the major markets contributing to growth in the year. Sales of Italy are up 5.4%, reflecting the full year of the Natural Point business, but also thanks to the good performance of Cardicor and Urorec and the launch of Reagila.

Sales in France are up 19.4%, thanks mainly to the addition of the product portfolio of Ginkor and Alodont, products belonging to Tonipharm the French company acquired in 2018. In Germany, sales are up by 1.3% despite the competition from generic versions of Zanipress and Ortoton, worth mentioning is the strong performance in market of lercanidipine and metoprolol and also the good performance of the OTC portfolio, and again here a good contribution from the launch of Reagila in the spring of 2018.

Revenue generated in Russia, Ukraine and other CIS country is €120.3 million, up 13.8% versus last year. That includes an estimated positive FX gain of €3.4 million mostly in the later part of the year. Sales in Russia in local currency are up 11% with strong growth of corporate products Livazo, Urorec and Procto-Glyvenol.

Sales in the U.S., which as, you know, is dedicated to products for treatment of our rare diseases are up 8.5% or 2.8% in local currency with strong growth of Carbaglu and CYSTADANE offsetting a competition from generic entries eroding Cosmegen…erosion which we are pleased to say has now stabilized in the later part of the year.

Spain sales are €94.7 million, up 6.5%, mainly due to the performance of CitraFleet, Livazo, Urorec, Casenlax and Urorec and also our OTC portfolio. Turkey had a very strong year with revenue growth in local currency of over 33%, driven by both exceptionally high price increases realized at the beginning of the year, but also of around 20% and also strong underlying volume growth of the business, both of our corporate products and also local product portfolio.

The significant increase in sales in other European countries is mainly due to the growth of sales in Poland and Czech Republic, as well as, the direct

commercialization by Recordati organizations in the Nordics, Benelux and Baltics where sales were previously through licensees.

Other international sales growth of 1% reflects the integration of the local portfolios in the local markets as just said, which offsets strong growth of lercanidipine and pitavastatin in the international markets. North Africa as was the case in prior quarters slightly down due mainly to import challenges in Algeria, which offset underlying growth in our local Tunisian business.

Moving on to Slide 9, as you will see our distribution of revenue remains well balanced across, across different geographies with Italy now accounting for less than 20% of total revenue. Well it's nice to see contribution of markets with stronger underlying growth in Russia, Ukraine, Turkey and other Central and Eastern European markets slightly growing in terms of total percentage of the group sales. As commented international sales decreasing because of the localization of business where we used to in the past sell through distributors.

Moving to Slide 10 and to the P&L, I commented already on our revenue, gross profit of 70.5%, slightly lower to gross profit margin last year as commented in prior quarters due mainly to mix and currency effects.

SG&A of 30.1% includes selling expenses at 25.2% of sales up 11.8% due to the marketing expenses for the launch of Juxtapid, Reagila and the new commercial organization we have established in different market I have already mentioned in Europe. As well as the reinforcement of a rare disease organization during the fourth quarter in order to grow sales of Signifor and prepare successful launch of Isturisa. G&A remains at around 5% of revenue.

R&D expenses at €130 million are in line with the target of being between 8% and 9% and are up by 18.5% due to the advancement of the development programs and the amortization of amounts allocated to intangible assets following the acquisition of Natural Point and Tonipharm during 2019 and the 2 months worth of the amortization of the intangible paid to Novartis for the acquisition of Signifor.

EBITDA at 36.7% is €544 million an increase of 9% with amortization charges of €53 million and depreciation charges of €24.9 million, which I have mentioned in past also reflect the application of IFRS 16 as of the beginning of this year. Financial charges in the period of €21.1 million an increase of €3.3 million mainly due to additional borrowing in the second half of the year to fund the transactions with Novartis.

Net income as Andrea explained of €368.9 million reflects the exceptional benefit achieved through the finalization in late December of an agreement around patent box benefit for our Italian affiliate, which is in total €35 million of which €27 million relating to previous years' period 2015 to 2018 and €8.3 million related to 2019.

Moving to Slide 11, as we said, treatment for rare diseases now account for close to 17% of revenue and now account for over 22% of EBITDA and 23.5% of EBIT, our share which is…we expect to further grow in line with our planned ambitions in 2020. Thanks to the addition of the new businesses. Some reduction in margin for rare diseases over the course of 2018 due to the investments that we have made to support these new launches and for increase in amortization arising from the recent acquisition. Margins on specialty and primary care remain broadly in line with last year.

Turning over to Slide 12, in terms of…looking at our net financial position, net debt of €902.7 million is an increase of €314.3 million versus 2018 that reflects €190 million paid in dividend during the year and €425 million paid for acquisitions and milestones, mainly €36.4 million, which were paid for the license agreement with Aegerion Pharmaceuticals for the exclusive rights to Juxtapid in Japan.

Milestones of around €47.5 million paid to Helsinn for the license agreement for Ledaga and €350 million paid to Novartis for the acquisition of Signifor and Isturisa. Net financial position also reflects as previously commented impact of application of our IFRS 16 which adds €37.7 million to our net debt. Group's underlying cash generation excluding dividend and transaction remained strong and around 100% of net income.

On a pro forma basis, adjusting for full year EBITDA of the acquired Signifor business, net debt to EBITDA will be around 1.5 to 1.6 times which is in line with the target we set for our plant. So once again, a strong year of financial performance.

And now, I hand over to Andrea, who will discuss the outlook for 2020.

ANDREA RECORDATI: Okay. Thank you very much, Luigi. So moving on to the guidance for 2020. The first slide, Slide 13, basically recapped all the financial key assumptions behind the guidance.

So as already indicated in our Business Plan which was announced last May, we will be facing generic competition starting this year for 2 of our products, Urorec and Livazo. However, the continued underlying volume growth of the rest of our specialty and primary care portfolio is expected to offset the impact of the entry of generics for these 2 products.

We also expect double-digit growth for our rare disease business. Thanks to the good performance of Ledaga, Juxtapid and Cystadrops, offsetting the expected erosion of PANHEMATIN in the U.S., due to the launch of givosiran. And also clearly we are expecting this double-digit growth due to the incremental revenue from Signifor…from the Signifor franchisee and the initial launch of Isturisa in Europe. No U.S., sales for Isturisa are included in our guidance at the moment. As already mentioned our targets include additional investments also to support the re-launch of Signifor and launch of Isturisa. R&D cost increased between 9% and 10%, mainly due to the amortization charges related to recent asset acquisitions and the ongoing endocrinology products clinical trial.

There is a slight improvement in EBITDA margin due to a product country mix and stable operating income margin, which shows sustainability of our margins also in 2020 with a slight improvement actually. Income tax rate is expected to decrease between 23% and 24%. Thanks to the patent box tax benefit in Italy. And in our numbers and guidance as always we have not included any acquisition or business development initiatives for 2020 target. However we do have a rich pipeline of opportunities under evaluation currently. Our 2021 plan financials announced at our 'Capital Markets Day' in May last year for 2021 is confirmed.

Moving on to the last slide of the presentation, with the actual guidance targets; as you can see we are...the 2020 target show based on the proceeding assumptions that I just showed in the slide before, we expect revenues between €1,550 million and €1,580 million and EBITDA between €580 million and €590 million, and EBIT between €490 million and €500 million, and net income between €360 million and €370 million.

Again, we have not included initial sales and we have not included full promotional costs for the Isturisa launch in the U.S. We have obviously included some premarketing activities and preparation for the launch, but not a fully-fledged promotional cost that you would expect in the launch plan. And as mentioned before, and I would like to stress this one last time, these targets do not include any business development initiatives of any sort, being after deals, acquisition of companies and so forth.

So this leads...takes me to the end of the presentation. And I think at this point we can open for the Q&A session and our presentation. Thank you.

MARIANNE TATSCHKE: Operator, please open the Q&A session.

Q&A

OPERATOR: Excuse me. This is the Chorus Call conference operator. We will now begin the question and answer session. Anyone who has a question may press "*" and "1" at this time. The first question is from Niccolò Storer with Kepler Cheuvreux. Please go ahead.

NICCOLÒ STORER: Yes. Thank you and good afternoon everyone. The first question is on 2020 guidance, if we go...if we can go a little bit more in depth, because if I strip out the impact of Signifor, I would basically be left with a very, very moderate growth. So which assumptions you used on your main products that in particular on Urorec and Livazo, which are expected to go off patent? The second one is on cash generation, basically if I start from your net income plus G&A, I end up with €450 million roughly minus dividend, minus the €425 million of M&A and related activities, minus IFRS 16 impact at the end of the day I am still €100 million short of your €900 million reported. So if you can elaborate on that. Thank you.

LUIGI LA CORTE: So in terms of…this is Luigi. Thank you for the questions. I will take them to start with. In terms of assumptions on products I will point back to the slide that show about the growth drivers for this year, which basically remain valid for 2020 with the exception obviously of Urorec and Livazo. On Urorec, you know, we have seen generics enter the market as expected. And we expect the generic impact of around €40 million for the…net revenue for the year, and Livazo we are still expecting generics as of August of this year with an impact of around €7 million. So that's to address your question with regards to generic impacts.

In terms of cash generation, I am not sure on the math you have got. Let me just point out that net income obviously the €35 million of our tax benefit which we have highlighted is a non-cash item for 2019. We will see the benefit in terms of cash flow mostly in 2020 and then 2021.

ANDREA RECORDATI: Let me just add something to this. So obviously we are expecting the numbers that Luigi mentioned on potential impact on sales for the generics of Urorec and silodosin. However, like I mentioned before, we do expect continued underlying growth also in the SPC. This is mainly driven by a moderate growth on some of our key corporate products, let them be lercanidipine, metoprolol and the Casen portfolio. We are expecting to double the sales of cariprazine in 2020, and we are also seeing strong growth coming from our OTC portfolio especially in Central Eastern Europe. Some also…some key local portfolio products and some of our subsidiaries you know that we have some key local products are also performing and growing on last year. And obviously also let's not forget that we have Central Eastern Europe, Russia, CIS and Turkey which are still showing a strong underlying growth. Finally, clearly like what I mentioned in the presentation of the assumptions that we are seeing and expecting double-digit growth on our rare disease portfolio.

NICCOLÒ STORER: Brilliant.

ANDREA RECORDATI: An idea what the growth drivers of going forward in 2020 are expected to be.

NICCOLÒ STORER: Thank you.

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

KC ARIKATLA: Hello, everyone. Thank you for taking my questions. I have 2 please. The first one, you mentioned that your guidance includes expected PANHEMATIN erosion in U.S., given competition from Givosiran. Can you give us a sense of how big the product is for the...in the U.S., for you, and also how are you thinking about erosion in 2020 and how should we think about it going forward, is it only going to be a 2020 event or do you expect it to last for several years? And the second one looks like on osilodrostat, you are advancing your timeline guidance in the U.S., from 2022 to 2020. How do you think this will impact Signifor franchise please, if any...if there is any impact at all? Thank you.

LUIGI LA CORTE: Okay. So…thank you, KC, Luigi again here. I will start with the first question. In terms of givosiran impact, I think it's...we see it...obviously it will take time for the product to have impact. So to your specific question, is it more a 2020 event or beyond? We see it as…it will be more beyond the 2020. We do think PANHEMATIN will remain an important treatment option for patients, not all like acute intermittent porphyria patients will have a number of attacks that will givosiran use and even where it will be used, patients will still require hemin during acute phases. So to…we are not going to give specific numbers on PANHEMATIN

sales for the for the U.S., but let's say we have built in a level of erosion this year but, we expect the majority of erosion to happen in 2021 onwards.

Your second question I think is around the revised guidance for Isturisa. And just to be clear, we have said…what we have said today is that we are cautiously optimistic around the potential launch of Isturisa in 2020. Of course we are waiting now for a final feedback from the FDA with the PDUFA data in March, on March 7 of this year. We do see continued opportunity to grow Signifor, particularly in acromegaly and to position Isturisa as a key treatment options for patients in Cushing's…for Cushing's disease. I hope that answers your question.

KC ARIKATLA: Yes. Thank you.

OPERATOR: The next question is from Martino De Ambroggi with Equita. Please go ahead.

MARTINO DE AMBROGGI: Thank you. Good morning, good afternoon, everybody. The first question is on 2021 guidance because you include some acquisitions undisclosed while 2020 already includes the acquisition announced. My question is, are you able to achieve the 2021 targets under the current perimeter? Or we should expect additional acquisitions in order to achieve the 2021? And eventually what is missing in terms of…I don't know, sales roughly EBITDA?

FRITZ SQUINDO: Well, Martino, Fritz speaking. We…on the call, Andrea has confirmed the strategy to continue to develop the Company also through inorganic development and we would like to continue to close the new…to acquire new assets going forward. As usual, in the targets for the current year, we don't include M&A because it's short-term and we have also stated it in

Slide 14 that the target of 2020 excludes any new acquisition and we will continue to pursue this kind of deal, while for clarity, we have also confirmed that in our plan we expect to continue to do acquisition. And then we expect to achieve not only through the current portfolio and the acquisition of Novartis deal, but also through other deal, the target in 2021. Then the answer is in the objective in 2021, we had still included new business that we expect to close going forward.

MARTINO DE AMBROGGI: Okay. Thank you. I was asking you this question because looking at Bloomberg consensus it's already close to the target without announcing any other acquisition?

FRITZ SQUINDO: Okay. Then I cannot comment on the Bloomberg consensus, but for sure, the Bloomberg consensus and some analysts include M&A, some other, they don't include M&A. Then for sure, the statement of the Company is this one, target 2020 are without any of this. Target 2021 in line with our plan includes other deals that we expect to close going forward. Maintaining our objective is to have essentially a level of debt which is in the region as we have stated is 1.5 our EBITDA.

MARTINO DE AMBROGGI: Okay. Very clear, Fritz. The second question is on the 2 new products you bought from Novartis. Because Andrea, in your initial remarks you mentioned for both the potential is in excess of the €100 million that you guided at the beginning and for 1 of the 2, if I remember correctly, you have even underlined significantly higher than a €100 million.

ANDREA RECORDATI: [Indiscernible]

MARTINO DE AMBROGGI: Yes.

ANDREA RECORDATI: So, I mean, if you take the let's say the 2 already commercialized products, Signifor, LIAM and LAR, these product grow, like we told in the presentation around €74 million in 2019, okay? And I already stated that our expectation is to continue to drive growth due to lack of promotion and Novartis put behind these products in recent years. But we still see some upside and we expect these products to have in excess of €100 million of peak sales. These are the 2 already marketed products. For Signifor…for Isturisa, we had already stated during…when we announced the acquisition that we were expecting product sales along €100 million, peak sales. But now we have…we feel convinced even though as I said we will communicate a firmer kind of outlook on this franchise which includes all products in the endocrinology franchise, but we expect this product to be materially above this €100 million peak sales going forward.

MARTINO DE AMBROGGI: If I may, just a follow-up on this, you are guiding for €70 million additional sales for the 2 Isturisa and Signifor and LAR. How much of this is for Isturisa this year in 2020?

ANDREA RECORDATI: We don't plan to disclose this sort of detail as you know very well on the product. It's a small part, let's consider that in 2020, as I mentioned before, we did not put any numbers for the U.S. because we still haven't had the approval in the US. But we are cautiously optimistic that we will have the approval in March, but until we had it we cannot build this into the numbers. And in Europe, due obviously to the whole reimbursement kind of pathways that we need to follow for market access, having just got the approval of the product in January, we expect to start launching late Q2, and onwards in a selected number of countries, which allow let's say…which have market access pathways, which are faster than in the majority of European countries. So we don't expect to have significant sales for Isturisa in 2020.

FRITZ SQUINDO: And just to be clear, just to add on what Andrea said and to make sure the point was clear, our 2020 revenue for Signifor thus include…will include up to the point of marketing authorization transfer a sort of net profit from Novartis and revenue, so it's not a sort of full sales number.

MARTINO DE AMBROGGI: Okay. Thank you.

ANDREA RECORDATI: We are expecting, we are planning to receive marketing authorization in the U.S.in the first quarter one of this year. And so we are going to start booking sales from that moment and full sales, and for Europe it's going to be in Q2, sometime in Q2 also or the second half of the Q2.

MARTINO DE AMBROGGI: Okay. Thank you. If I may, just a quick question on the net working capital in order to finalize the bridge for the net debt in 2019?

FRITZ SQUINDO: So your question in general for the net working capital.

MARTINO DE AMBROGGI: Yes. The contribution of the net working capital in 2019 for the net debt bridge.

FRITZ SQUINDO: Yes. We will come back in more details on that when we sort of publish the sort of full results. So just to be clear one, in the bridge, I'm not sure…again, I didn't take note when you were reading it out, I don't know if you missed the €28 million adjustment which is done this year for transition to IFRS 16, #1. #2, we have seen an increase in…we did have a sort of increase in inventory towards the back end of the year as we prepared the business, so particularly for serialization in Russia where we sort of built…had to sort of build stock, but again in terms of full balance sheet details, you have to expect…we come back once the full results are available.

MARTINO DE AMBROGGI: Okay. Thank you.

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

JO WALTON: Thank you. Just a few questions, please, just a clarification to start with. You have told us that you booked about €10 million of Signifor, Signifor LAR in the quarter. This was the net profit, so the end-user sales would have been a bit higher than that, so when we are thinking about the underlying sales of the quarter, if we were to look at that, they would be, I don't know say 20% higher. I am just…my question is related to whether you are still happy with the guidance that you have given historically for some of the other drugs. Juxtapid for example, do you think that that will still get to the $20 million to $30 million in Japan you originally thought? Ledaga, are you still happy with the €50 million peak sales. If we look at the patent expiries that you are expecting for Urorec and Livazo, can you give us…is it going to be Europe-wide of these products where it will be…when it goes to the country or go completely. Do you think that there will be some residual sales? And what we are trying to look at is not just the impact this year but effectively what a sort of tail value of sales could be for these products?

And I have got 2 final questions, if I could, please. If we look at your guidance level for this year and I just take the midpoint of your revenues and the midpoint of your EBITDA and I see the EBITDA margin of 37.4% which is higher than you achieved in 2019. Just wondering how realistic that is when you are losing a couple of products which presumably have been either reached a high level of profitability and at the same time you are investing heavily in a new launch. Is it the mix shift materially to move towards more specialty or how can we be confident

that you can have a margin uplift in what should be an investment year? Thank you.

ANDREA RECORDATI: Yes. So thank you. I think I have caught them all, but if not. I will Marianne to help. Thank you. Thank you, Joe. So maybe I'll start with your question around can we reconfirm our peak sales ambitions for Ledaga and Juxtapid. And the short answer is, yes, we do. So in terms of the guidance on the EBITDA margin, yes, you are right, and I think we said we do expect slight improvement in our EBITDA margin for the next…for this year. Yes, of course, we'll face the erosion from the generic entries. But as you said, the mix of our portfolio is improving. We will have a greater share of the business in higher margin rare diseases business. We have a higher contribution from the regions with slightly higher than average margin.

And again as we said, and just to be clear, what we have built in the numbers some costs too for pre-marketing and to prepare the re-launch of Signifor. We have not reflected either revenue nor the full cost of launching Isturisa in the U.S. So hopefully that addresses your question. And yes, we do aim for a slight improvement in EBITDA margin for this year with EBIT margin remaining broadly stable. I think I may have missed your first question, which was…

MARIANNE TATSCHKE: Regarding the €10 million net profit…

ANDREA RECORDATI: Yes. We do have to gross up the €10 million realized in quarter four as this is sort of the net…gross profit transferred from Novartis. We will get back to you on what that exact sort of gross up should be eventually, I think it should be a bit more than the 20%.

JO WALTON: If I could just also ask then in terms of the SG&A, presumably the fourth quarter SG&A which was a little bit higher than we have seen in the prior three quarters, that is still not a good guide for the SG&A that we should be expecting in 2020 because it doesn't include any effort effectively on your part to reinvigorate the Signifor franchise…

ANDREA RECORDATI: No. No. It does include…sorry Jo, to interrupt, it does include already an effort because it goes without saying that we started gearing up the organization already after the summer last year because it goes without saying that we cannot wait for the approvals to arrive. We have to start preparing ourselves in our portfolio marketing authorization transfer. So the reference I made to that organization that we would put in-place in Basel, which is the fully fledged global BU headquarter with a substantial headcount, obviously has an impact on that. And we also started recruiting already people on the field in Europe and in the U.S. Because again, we could not wait because obviously we are cautiously optimistic on Isturisa, but we also have Signifor that we need to take back in control and start growing. So, there was already quite an impact in Q4 on our Q4 numbers on SG&A regarding investments in the endocrinology franchise.

JO WALTON: So the SG&A in 4Q is a reasonable guide to how we should think going forwards, because you incorporated the majority of let's say the fixed, if not the variable costs in to your numbers already?

LUIGI LA CORTE: Yes. You have to remember that, the recruitment takes time, I'd say yes, but obviously you know it's a scale up. So, obviously it takes a bit of time, but yes, I'd say generally, yes, but, broadly speaking, the answer is, yes. Thank you.

JO WALTON: And on Isturisa in the U.S. you have presumably…you say you are now more cautiously optimistic. Is the outstanding question still whether the

FDA needs that confirmatory LINC-4 study or will be happy with the same amount of data that the European's had?

LUIGI LA CORTE: We are cautiously optimistic with LINC-3study data that was requested. It's going to be enough.

JO WALTON: Thank you very much.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone. Once again, if you wish to ask a question, please press "*" and "1" on your telephone. The next question is from Isaac Brambilla, Mediobanca. Please go ahead.

ISAAC BRAMBILLA: Thanks for taking my question. I have a couple. The first one is on the performance of lercanidipine franchise; it was stronger than expectations especially in the second half of 2019. I was wondering some indication on how to model the evolution of this franchise for 2020, whether are you expecting same growth from this portfolio? And the second one is on the evolution of EBIT margin, so implied in your guidance we have roughly 31.5% in 2020 and you reiterated your target of 33% for 2021. So could you give us more color on the drivers of this material margin expansion in 2021, whether it is organic or driven by margin accretive M&A?

ANDREA RECORDATI: Yes. So in terms of sort of by-product sort of guidance for 2020, we will provide more detail in May. But having said that, we do see continued growth in the lercanidipine, if not up the sort 2118, 2019 levels, but not too far from that. In terms of the EBITDA, EBIT margin of 31.5% and in relation to the target of 33%, again, we have today to confirm that what the plan for 2021 was as presented in May, we will be sort of updating the plan in May of this year. We did…we are…as a result of the type of acquisitions that we have made, we are incurring high amortization

charges and therefore we are putting our focus on EBITDA margin delivery where EBIT will be somewhat penalized because of the degree of amortization coming from the asset deals which we had done in 2019.

ISAAC BRAMBILLA: Okay.

ANDREA RECORDATI: Thank you.

OPERATOR: Gentlemen, there are no more questions registered at this time.

MARIANNE TATSCHKE: Okay, than…

ANDREA RECORDATI: Thank you very much, everybody, for connecting and have a good Valentine's Day and a good weekend.

MARIANNE TATSCHKE: Goodbye.

ANDREA RECORDATI: Bye-bye, everybody.