Recordati S.p.A

"2020 First 9 Months Results Conference Call"

Thursday, October 29, 2020, 16:00 CET

MODERATORS: ANDREA RECORDATI, CHIEF EXECUTIVE OFFICER

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati 2020 First 9 Months Results Conference Call. As a reminder, all participants are in listen-only mode. After the presentation, there will be an opportunity to ask questions. Should anyone need assistance during the conference call, they may signal an operator by pressing "*" and "0" on their telephone.

At this time, I would like to turn the conference over to Ms. Marianne Tatschke, Director of Investor Relations and Corporate Communications 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. Andrea Recordati, our CEO, and Luigi La Corte, our CFO, will be presenting our first 9 months 2020 results. For a better understanding of this presentation, please access the set of slides available on our website, www.recordati.com under the Investor section and Presentations tab. At the end of the presentation, we will answer any questions you may have. Please go ahead, Andrea.

ANDREA RECORDATI: Okay. Thank you, Marianne. Good afternoon or good morning, ladies and gentlemen, and thank you for joining our first 9 months results call. So despite the continued challenging environment, performance across the Group has shown notable resilience.

Net revenue is slightly down by 0.6% which is mainly due to the pandemic impact on our reference market and severe foreign exchange headwinds which stand at minus 1.7% for the first 9 months, and minus 3.9% in the third quarter. Profitability remains strong as a result of cost containment and improved product mix. EBITDA in first 9 months is €438.8 million or 40.1% of sales, which is up 7.1% versus last year. Net income is €274.1 million or 25.1% of sales, again up 8.1% versus 2019 in

the same period. And adjusted net income is €317.5 million or 29% of sales which again is up by 12.23% versus the first 9 months of 2019.

Sales of Signifor and Signifor LAR and the launch of Isturisa show strong progress contributing with €53.8 million of net revenue year-to-date. Isturisa is now on the market in the U.S., France and Germany with sales generated in line with the objectives, and we expect more than €10 million for the full year 2020.

Activities leading to the addition of new products have also gone ahead, in the recent time. We have launched Cystadrops in the U.S. following the FDA approval, and this provides an important treatment option for cystinosis patients with corneal cystine crystal deposit. Our pipeline was a reinforcement to an exclusive license obtained from ARS Pharmaceuticals, a private U.S. company for ARS-1, an epinephrine nasal spray in late stage development for emergency treatment of severe allergic reaction that can lead to anaphylaxis. The Agreement grants commercialization rights for Recordati in the EU, UK, Russia, CIS, Turkey, Middle East and other markets.

Returning to the financials, our net debt at 30th of September stands at €845.9million, a reduction compared to the €902.7 million at the end of 2019, which reflects strong cash generation of around €267 million before milestones, net share repurchases, and dividends paid.

Just as a reminder, on the 1st of October, Recordati's Board of Directors approved the proposed incorporation through reverse merger of FIMEI S.P.A and Rossini Investimenti S.P.A in Recordati S.P.A. As we mentioned in the dedicated call that we had on the subject, there would be no change to the respective share ownership in Recordati of its majority shareholder and other shareholders. There will be no change to

Recordati's financial position, strategy or capital allocation policy, and the merger plan is subject to shareholder approval with a plan effective date in the first half of 2021.

I will now leave the floor to Luigi La Corte, our CFO to take you through in more detail our first 9 months results. Please, Luigi.

LUIGI LA CORTE: Yes, thank you, Andrea, and good afternoon and good morning, everyone. On Page 3, I'll start as usual with our corporate product sales which account for close to 70% of revenue. And I'll start with our lercanidipine franchise.

I am starting with Zanidip. Zanidip continues to grow by mid single-digit in most if not of all of the markets where we have direct selling organizations. The year-to-date growth of 3.8% being lower than previous months due in part to the FX impact in Turkey, which is our third largest market but also and primarily due to the normalization of shipments to our international licensees which has been commented at the end of June had higher than usual shipments in the first months of the year.

Zanidip sales also reflect the drag in France from measures which were announced at the beginning of the year, which favored the dispensing of generics in pharmacies, a measure which account actually for the majority and if not and most of the reduction in Zanipress, lercanidipine and enalapril combination year-to-date.

Our sales of Urorec of €58.5 million are reflective of generic entry in key markets as of February of this year. And I am pleased to say actually Urorec is holding up in line, if not slightly better than plan, in the face of the generic entries, with a sales in Turkey where we don't have generics continuing to grow.

Similarly, Livazo also continues to grow, in this case with generic entering our key market in particular Spain and Portugal in the month of August, but with revenue in Turkey, Switzerland and Greece and again other markets where we are not expecting generics continuing to grow.

Our metoprolol franchise is continuing to grow at high single-digit, primarily in Central and Eastern Europe and particularly in Poland, Romania, the Czech Republic and CIS and those markets where we have established direct selling organizations most recently.

Other corporate products actually are the ones which had faced a bit of brunt of the COVID impact over the past months and other corporate products include also corporate OTC but actually the largest part of the reduction versus last year is driven by a select number of products which are particularly affected by the pandemic, and the main ones being as we commented before, CitraFleet that's impacted by a lack of hospital procedures over the last months, Tergynan and Isofra [ph] respectively and infectives in cough and cold medicines which are particularly impacting Russia and Ukraine, and other and probiotics and pediatric products in Spain.

Drug for Rare Diseases of €232.4 million grew at 31.2% clearly reflecting the strong contribution to revenue from our new endocrinology franchise, with both, as Andrea mentioned, Signifor and Isturisa progressing well and in line with expectations, specifically Signifor, Signifor LAR on a like-for-like business that continued to grow above 10% relative to 2019 and Isturisa revenue now above €5 million and on track to deliver on the full year objectives that we set.

Other products in the Rare Disease portfolio also driving growth, Carbaglu, Cystadrops and Ledaga and Juxtapid are just to mention the main ones, with growth of our legacy business somewhat held back by the erosion on Panhematin in the U.S. which however I am happy to say we've seen stabilize and in fact over the last couple of months recover to the level of monthly sales achieved in the month of March and April. And therefore, are bouncing back from a drop that we saw over the summer months, where patient traffic to infusion centers in the U.S. was more challenged.

So that's in terms of the key products on Slide 4 you will see as usual, the breakout of revenue for the key component parts of the portfolio. Noteworthy here obviously is the continued growth of rare diseases in the mix, which now accounts for over 21% of revenue. And with the share of OTC actually broadly stable relative to previous months, and in fact, obviously year-to-date was impacted by the pandemic, it's declining by little single…low single-digit and starting to show signs of stabilization.

On Page 5, again, as usual, our revenue by key geography. It was a picture very similar to the one shared at the end of June, with the exception of the other international sales, which as I mentioned already, largely reflective of normalization of shipments to international licensees of lercanidipine and also of the strengthening of the euro versus most currencies. But starting from the top, Italy with sales of close to €203 million a decline of 5.7%, yes, some impact of COVID on Rhinopront [ph], our cough and cold medicine, and to some extent, on the OTC portfolio. But for the large part, a decline which is in line with expectations due to the generic entries on silodosin and the generic competition in the back end of 2019 on pantoprazole and lovastatin. We've seen good growth in Italy over the period of Reagila, Cardicor and

of course of Signifor contributing to revenue really across the geography but equally being an important one.

France I have mentioned already a large part of the decline is really driven by the new measures which were introduced at the beginning of the year, which has also [indiscernible] to a slightly higher, somewhat higher than expected erosion on silodosin offset by the performance of silodosin in other markets, but particularly punishing the French business. Once again here a strong contribution from Signifor and also in France, a good start of sales of Isturisa over the last few months.

Germany, revenue and the German business in general, somewhat less impacted by the pandemic with revenue broadly in line with last year, the strong erosion really being due by generic competition in tenders on Ortoton.

U.S. sales obviously reflecting, as I commented previously, the growth of the rare disease portfolio and in particular the contribution of Signifor and now also Isturisa and other products partly offset by Panhematin.

Russia other CIS and the Ukraine are amongst the markets where the impact has been toughest. The sales of €69 million down 17.3% versus the first 9 months of 2019 reflect 7.3% FX impact in Russia, where sales declined by 11.4% in local currency, once again driven by the impact of the pandemic on cough and cold medicines and medicines for mild infections, offsetting the growth of the broader portfolio in particular Zanidip and Procto-Glyvenol and Livazo, which continued to grow.

CIS and Ukraine impacted by very similar dynamics and also down by 15% year-to-date. Spain, again with a few products in the portfolio that have been impacted by the very strict lockdown in the market, which

offsets the growth of Reagila, which was launched in the later part of 2019, and the contribution from rare, rare diseases.

Well, very similar dynamics also in Portugal, where again, I mean, a site from the pandemic that we've seen, obviously the effect of generic entry of Silodosin both…effective both Spain and Portugal, and now most recently Livazo.

Turkey, Central Eastern Europe and Western European markets together with North Africa, all growing at double-digit. Turkey, in particular, in local currency growing by 14.6% with a very broad base the growth of both our cold and cough products and our local products. But Turkey, unfortunately, being faced with all-time weakness in the lira, and an FX impact year-to-date of 19%, clearly holding back our progress on a reported euro basis in the market.

A growth, a double-digit growth in Central Eastern Europe and other Western European countries is really driven by double-digit growth in metoprolol, which is growing very nicely and in Poland, the Baltics, Czechs and the Nordics, particularly, once again, those markets where we've established direct selling organizations in more recent times, and North Africa sales growing both on the back of export sales to the regions of our [indiscernible] portfolio, but also double-digit growth of our affiliate in Tunisia's, Opalia Pharma.

On Page 6, you'll see again, as customary, the breakout of our revenue, which is unchanged, broadly relative to previous quarters, and it illustrates the diversified footprint of the Group.

Moving to Slide 7, and looking at our P&. As commented, revenue, marginally below last year, or plus 1.1%, at constant exchange rate. But

despite that, despite the smaller…the marginal drop, our gross profit is actually up versus 2019 at €785.6 million or 71.8% of revenue, with the margin improvement driven by the improved mix, both in terms of country but also obviously, in terms of composition of revenue with rare diseases representing a greater share of the business.

SG&A expenses are favorable to prior year, with a reduction of close to 5%, being mostly driven by selling expenses of…which stand at 23.5% of revenue, down 6% versus last year really driven by the impact that COVID has had on levels of activity in the field in particular, in Q2. We have restarted as we commented in the past, activities in the field in June, July in most markets, but clearly are at somewhat reduced pace, and now face once again with restriction in some markets obviously received the news of France of today.

G&A cost of 4.9% marginally up to sales, are marginally up versus last year, behind the additional investments that we made behind our [indiscernible] franchise. R&D expenses at 9.7% of revenue are growing mostly due to the increased amortization of intangibles that we acquired from Novartis [indiscernible] and also other intangibles we added over the course of '19, but also growing on the back of the studies that we took over from Novartis.

Other expenses of €4.9 million are really reflective of the non-recurring COVID related costs would stand at €5.2 million at the end of September, and which are for the vast majority made up of the donations which the Group agreed at the start of the of the pandemic. The improved mix and the discipline around cost has helped to lead operating income of €364 million at 33.3% of sales. And EBITDA of €438.8 million, it still stands at above 40% of revenue, with the growth of operating income slightly

lower than the 7% growth that we're seeing at EBITDA level, because of the increased amortization and the non-recurring cost.

So, again, from our perspective, a very strong operating performance, which coupled with, as commented in prior quarters, lower financing charges and lower tax rate benefiting from the Patent Box and different country mix of our business is leading to net income growth in the 9 months of 8% and adjusted net income growth of 12.3%.

Shifting to Slide 8, and just looking at the different contribution of our 2 businesses, 3 things that highlight; one clearly the growing relevance of rare diseases, which now accounts for close to 27% of both EBIT and EBITDA, #1.

#2, both of our businesses, both rare disease, and the specialty and primary care business continuing to show margin improvement relative to the same period last year.

And third and actually this you do not see from the slide, but for those of you who will read the final details of our financial release, you may notice that our EBITDA for the specialty primary care business of €322 million in 2020 is exactly in line with the performance in the first 9 months of 2019, which in the year impacted by COVID and with the loss of exclusivity of silodosin, I think is a significant performance of that business.

And finally from my side on Slide 9; alongside the continued positive operating performance at a sort of profit level, we continue to see strong cash delivery of the business. A reduction in €56.7 million in our net debt reflects our payments of €110.5 million in dividend, $90 million of milestone that to Novartis for Signifor and Isturisa, and net €15.6 million

of our share repurchases implying and underlying cash flow before these items of €267 million, which is close to 100% of net income. Net debt is rough…is just below 1.5 times trailing 12 months EBITDA with cash on hand of €278 million, so a strong balance sheet position.

And with that, I'll turn over…turn back over to Andrea on the…for the guidance for the remainder of the year.

ANDREA RECORDATI: Thank you very much, Luigi. So regarding the full-year 2020 outlook, with respect to our full-year outlook, we are still expecting EBITDA and adjusted net income to be near the lower end of our 2020 guidance range that issued in February, which I remind you was €580 to €590 million for EBITDA and €408 to €418 million for adjusted net income. So the reduced operating expenses due to the reduced field activity and Recordati's cost discipline offset the lower revenue. And the incremental investments in the U.S. for Isturisa launch…has to confirm that EBITDA margin improvement is on-track and to be able to maintain the lower end of our EBITDA and adjusted net income targets.

Revenues are expected to be marginally below the previous year due to COVID-19 emergency continuing to impact demand also in the fourth quarter. And strong FX headwinds are expected to affect sales by minus 2% to minus 3% for the full-year.

Signifor, Signifor LAR, Isturisa reported net revenue are on-track to deliver €18 million in the year of which Isturisa as mentioned before sales are expected to be above €10 million. The COVID-19 lockdown impact on activity spend is expected to continue offsetting lower revenue and incremental investments like I mentioned just before. And we expect tax rates to be between 22% and 23%. Thanks to a slightly better country mix and higher ongoing Patent Box benefits. Dividend payout policy is

confirmed that 60% of the total net income and an interim 2020 dividend of €0.50 per share is to be distributed in November.

Lastly, before we move on to the Q&A, being her last investor call, as she's retiring at the end of this year. I would like to take this chance to really and heart fully kind of thank Marianne Tatschke for the outstanding job she has done over 20 years in managing the investor relations for the Recordati. Marianne, really thank you so much for your dedication, hard work, and professionalism, and for all that you have done in all these years for Recordati. You would be great, so thank you Marianne.

MARIANNE TATSCHKE: Thank you, Andrea for your kind words.

ANDREA RECORDATI: Welcome. So I think we can break up now to the Q&A session.

MARIANNE TATSCHKE: Operator, can you please open the Q&A section?

Q&A

OPERATOR: Excuse me. This is the Chorus Call conference operator. We will now begin the question and answer session. Anyone who wishes to ask a question may press "*" and "1" on their touchtone telephone, to remove yourself from the question queue, please press "*" and "2." We kindly ask to use handsets when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Jo Walton of Credit Suisse. Please go ahead.

JO WALTON: Thank you. I too would like to express my thanks for Marianne's help over many years. A really excellent IR, and your successor has got big shoes to fill. And my 2 questions, please. Looking at the third quarter, it

looks like if we exclude the first time contribution of Signifor, Isturisa and we take out currency, then it looks like your underlying sales have declined around about 7%, which is actually a bit more than we saw in the second quarter. I wonder if you feel that there were any onetime aspects to that, whether that is a reasonable rate of decline to be thinking of for the fourth quarter.

My second question is to do with the costs. You've obviously managed to offset the lower than expected sales with lower than expected costs. Are there any elements of this that you think you can carry on into 2021 and beyond i.e. are there any new sort of marketing processes or things that you found, because clearly we're trying to look at, how we should be forecasting margins into 2021 and beyond now? Many thanks.

LUIGI LA CORTE: Yes. So in terms of…so your question on the sort of Q3 revenue growth, Jo. I think it's a little bit hard to predict at the moment. What we're seeing because of the evolving nature of the pandemic, I mean, what we're seeing today is that to the extent that the top line is impacted, costs are impacted as well. And if you like, there is a natural hedge there. Of course, the revenue in Q3 is impacted by a number of factors that we'd expect to normalize in Q1 of next year being mainly the generic entry on Silodosin and also being the drop and the erosion that we saw in France upon measures that were introduced at the beginning of this year.

So what we're not going to be sort of updating today any sort of longer term guidance of 2021. My short answer would be, no. I wouldn't take that sort of Q3 trend, which clearly…has impacted by the pandemic to extrapolate.

In terms of the cost, as we've commented…as we commented in the past, I mean, we do…I do expect and what we said in the past is 2 things. One,

you know, a large part of the savings are driven by lower activities in the fields, which we have already started to see returning or coming back in the last few months which is also shown by the sort of slightly higher selling cost as a percent of sales in Q3, but some are also due to many events…large events conferences et cetera being cancelled and/or becoming sort of digital in nature. And I would expect this probably to become a more lasting theme if you like, as people learn to interact particularly for these events virtually as opposed to face-to-face.

Now again, what we've said before is that our margins are tracking…underlying margins are tracking slightly favorable to the guidance which has been set in 2019. By again, we will give a sort of full revision on that when we announce targets for 2021.

JO WALTON: And could I just confirm, you have not got Signifor control now in all of the markets. Has the registration being passed over to you, because I know earlier this year some of the revenue was being sort of booked in other revenues rather than in sales, when you didn't have the full rights to it. Is that complete transfer happened now?

ANDREA RECORDATI: This is Andrea, Jo. Yes, the transfer has been completed now. I confirm.

LUIGI LA CORTE: There is some small market…international markets…

ANDREA RECORDATI: All the major countries will be operated with [technical difficulty].

JO WALTON: Thank you.

OPERATOR: The next question is from Niccolo Storer of Kepler Cheuvreux. Please go ahead.

NICCOLO STORER: Yes, thank you. Thank you and good afternoon, everyone. My first question actually was on 2021 expectations, probably, I know, that you cannot answer and you will explain as…more on the year with the update of the plan, but just as a feeling probably the targets that you gave to the market at this moment seems out of reach, in particular in terms of revenues considering the FX effect, the effect of COVID, and also the fact that, since you are late on M&A. So if you can comment a bit on that?

And the second question is a curiosity about the new epinephrine that you will distribute in Europe. My understanding is that, one on the main issue with epinephrine is the fact that, it deteriorates with it. And so, my question is, does this new product in view of this kind of problem or not? Thank you.

ANDREA RECORDATI: On the first question…let me do the first question, and then if you can repeat the second one, because honestly, I wasn't really clear on what you asked, maybe Luigi got it. So we planned to communicate guidance for 2021 in February, like as per establish practice, okay. And so, it is a better [indiscernible] to kind of, you know, give you any guidance from 2021.

Regarding for an updated plan for beyond that, so basically our 3-year plan, we believe that for this to be helpful and meaningful, it needs to be done on the basis of…it needs to be done on the basis of a somewhat more stable macroeconomic and market outlook which obviously now it is extremely difficult to predict considering the situation Europe and the global situation with pandemic. It is clear now that the pandemic will continue to take the market through Q4 and potentially also into first half or part of the first half of 2021. So it is likely…we would do this a bit later than in the year, hopefully in the month of May as done in 2019. We will do the Capital Market's Day for presentation of our 3-year plan.

Regarding, [indiscernible], I did not really get the question and it is entirety.

LUIGI LA CORTE: Niccolo, I mean clearly…the clear advantages that we see from [indiscernible] is the mode of administration and the speed with which it is absorbed by patients were administered. We are not sure that we heard exactly what you reference as a key issue of current.

ANDREA RECORDATI: Yeah, exactly, this is what I meant. So this is a nasal spray obviously.

NICCOLO STORER: No…I mean the problem with EpiPen which is…what is available now for patient suffering anaphylaxis, is that, it cannot be kept at above 25 degrees, because otherwise it deteriorates, because epinephrine deteriorates with it. So I was wondering if this new product could in some way fix this issue which is quite relevant.

ANDREA RECORDATI: Yes. I don't believe we have that at the top of our heads. Niccolo, I am sorry. We need to come back to you on that one.

NICCOLO STORER: Okay. No worries. Thank you.

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

MARTINO DE AMBROGGI: Thank you. Good morning, good afternoon everybody. First of all, I also thank very much Marianne for her collaboration over several years. Thank you. The first question is on Isturisa. If you could provide an update on the timetable for next launches, and just to double check if I am right in estimating next year 30 million-40 million as a range for Isturisa standalone or if you prefer together with Signifor as you prefer?

The second question is on the guidance. Just to understand if…since we are back to lockdown in some countries, if your guidance is factoring in some restocking as it happened in the first quarter or if you proceed something is happening in this sense or not?

ANDREA RECORDATI: Yes. So on Isturisa and to your question, I mean we are not going to give sort of 2021 guidance. I mean, what we said is Isturisa, we expect to deliver more than €10 million of revenue in the course of 2020. We won't give guidance for 2021. I think, I heard you mention €30 million, €35 million being your number, again. Maybe the only comment, I will make that seems a bit on the low side frankly, but we are not going to be more specific in that at this stage.

In terms of…I couldn't pick up the first part of your question on Isturisa, in terms of what the next milestone, but let me…

MARIANNE TATSCHKE: For the next launches, the timetable for the next launches for Isturisa in the different centers.

ANDREA RECORDATI: Right. I feel we are launching in France and Germany. It is available on a…[indiscernible] in Italy, and we expect it to…

LUIGI LA CORTE:…U.S…of course, it is launched…we have launched in U.S. since May, and we expect it to…I think the big question in Europe is not so much to launch is sort of the availability of reimbursement which will be…will sort of happen over the course of the next months and mostly in 2021, and I believe we have mentioned for Japan 2022…or in Japan it is slated for backend for 2021-2022.

In terms of restocking, no…I mean frankly, we are not anticipating a restocking at this stage in Q4. Our sense is that the stocking that we saw

in Q1 was mostly as a result of the trade fearing restrictions to transport and supply of medicines, which we saw was not really an issue at any point over the last few months, I mean, some, generic companies were impacted for a short period of times, but [indiscernible]. So I don't believe and we are not anticipating in our guidance any significant restocking in the next week leading up to the end of the year. At least that's the current view.

ANDREA RECORDATI: Sorry, just to complete the question around Sweden, as I said, we will give you more kind of color on the 2021 targets and clearly you know, to rollout and, you know of a plan…the launch plan and like, Luigi kind of pointed out correctly, what really account is reimbursement [ph]. But for the moment, we're expecting for 2021 to launch in the Nordics, Netherlands, Switzerland, and Central Western Europe, okay. These are the main markets that we are expecting for 2021. And the others would follow-up in the years to come.

But clearly this is a moving process, as opposed to a lot of moving parts. So there might also some changes with the addition of several countries in 2021. But at this moment in time, I can give you these markets.

MARTINO DE AMBROGGI: Thank you. And if I may, a follow-up on the Urorec and Livazo just to understand, if there is an update on the P&P [ph] normalized level of sales after the generic write-off? So I don't know if you can remind us, what was your view? And if it changed after the first stage of genetic versions?

ANDREA RECORDATI: No, I mean, it's unchanged, we expect €7 million for this year obviously having generics having launched in August. Their impact was relatively a bit higher next year, but so far in line in fact, they're slightly better than

the plan, also Livazo and for silodosin, but marginally…they are marginally better than plan.

MARTINO DE AMBROGGI: Okay. Thank you.

OPERATOR: The next question is from Isacco Brambilla of Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Hi, good afternoon, everybody. I have 3 questions. The first one is on U.S. elections, is there for you any outcome, which may be seen as more favorable than the other based on electoral programs and so on of the 2 parties. The second one is on your CAPEX, if I saw correctly in the financial report there was quite a substantial increase in capital expenditures this quarter. I guess maybe there is the cash out for the license with ARS included? If yes, then you…can you quantify how much was related to this cash-out. And that's it for now. Thanks.

ANDREA RECORDATI: U.S. election. We don't have anything to comment at the moment in time, now we have to see [indiscernible] and so, we have…we have no particular expectations one way or another regarding our portfolio and in region in the U.S.

LUIGI LA CORTE: Now, in terms of the second question on CAPEX. Looking at the sort of cash flow statement, investment in the PP&E in terms of cash flow was €13 million in first 9 months of 2020, €14 million, in the first 9 months of 2019 and so broadly comparable. The increase is obviously on the intangibles side, €92 million relative to €61 million last year. And that's really reflective of the milestones that we paid for the approvals of Isturisa in Europe, and then in the U.S., and also a first commercial milestone of $10 million for the launch in Germany. So that's really the main items in terms of CAPEX, if you like.

ANDREA RECORDATI: Okay. So can I just add then finish off and answer for [indiscernible] before. I only mentioned the countries broadly in the EMEA region, when it comes to the launch of Isturisa that we expect in 2021. We're also expecting to launch in Japan for the '21 and also [technical difficulty] in Colombia, Israel, and Argentina, just to give you the full picture of our expectations, and that was clear achievement in our [indiscernible].

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

KC ARIKATLA: Thank you. Thank you for taking my question. First of all, I would like to thank Marianne for all the help and support she extended over the years. Thank you again, Marianne. On to the questions, I have 2 please. And the first one, in Turkey beyond obvious FX impact; are you seeing any headwinds in the region? Do you expect demand to be impacted going forward with personal finances dwindling there? And the second one, if I look at your other international sales in 3Q, looks like it's declined around 20% in sales after growing around 11% in first-half, was there any product or region, which will explain this significant change in performance, please? Thank you.

ANDREA RECORDATI: Yes, in terms of Turkey demand, I mean, yes, there has been some impact, because you recall local currency term, we've seen Turkey grow in previous periods at a much higher rate, but…I mean Turkey is a high market which is rather sensitive to promotion, but the underlying fundamentals remain positive. And despite the upheaval, we're still seeing the business growing by 14% on a local currency basis. So we still see Turkey being a key growth driver for the Group. Of course, hopefully at some point, the devaluation of the lira will hit a ceiling and in fact a rebound. But I think in terms of underlying demand in the country, our

view is that, that remains positive and our business continues to actually perform positively or even sort of vis-à-vis the market in Turkey.

Our international sales are really driven by what I mentioned, which is the timing of our shipments to licensees can tend to be a bit lumpy. I think I commented at Q2, we've seen some very high purchases in the first part of the year in some of our international businesses, and we've seen that normalize now in Q3, and that's really the…and this is particularly on lercanidipine. And that's what you're seeing there on the sort of international sales line, when looking at sales by geography.

KC ARIKATLA: Thank you.

OPERATOR: The next question is from Harry Sephton of Jefferies. Please go ahead.

HARRY SEPHTON: Yes. Thank you for taking my questions. I do say I'd like to start by thanking Marianne for her support over the years. She has been extremely helpful and I'm wishing her a very happy retirement.

MARIANNE TATSCHKE: Thank you, Harry.

HARRY SEPHTON: Just to start with, can I start from the endocrinology franchise. You mentioned that you've seen double-digit growth in Signifor and Signifor LAR. Just curious whether you're seeing that in Acromegaly patients or Cushing patients or a bit of both. Also on endocrinology with Isturisa launch. I know its early days, but can you give us a sense of whether you're seeing patient's uptake in the Cushing syndrome, a wider indication outside of the Cushing disease indication? As I understand, your guidance is really predicated on just the Cushing's disease indication.

And then, my third question is just a bit more of a broad market question, but are you anticipating any drug pricing headwinds over the next year or so, in any of your major markets, and any color there would be much appreciated? Thank you.

ANDREA RECORDATI: So thank you for the questions. So on endo and the Signifor growth in particular, really that's across both the indications. And in fact the thing that we're most pleased is in the U.S. where we've obviously we're more advanced, a little bit more advanced in the launch of Isturisa. And the fact that we've seen new patient acquisition on Signifor in parallel to that is obviously very encouraging because one of our assumption is that actually the 2 can be complimentary, even if there will be a little bit of inevitable cannibalization, but actually that the portfolio sale [ph] can work well and certainly the early signals are that is the case that because we have seen a step up in number of patients in Signifor and Signifor LAR and that is across the 2 indications.

In terms of your question in Isturisa, and which type of patients and the patients that are coming from, I really think it's too early and we're not going to try and dissect that more to sort of second guess whether some physicians may be seeing the benefit of Isturisa beyond the current level…label. I mean, we wanted to be clear on what our guidance is pegged to. But, you know, we know it is a space where physicians are, historically have been using products, which we not strictly studied for Cushing's. But it's too early days to dissect that any further.

In terms of drug pricing, I mean, it's been a fact of life in the sector over the last decade or more. So I don't know…that we're not expecting that to be to be any different. And, you know, various countries with a different points in time introduce different, different measures. So we haven't sort of built into our thinking, you know, a significant change from what has

been status quo over the…in terms of year-on-year erosion over the past years

LUIGI LA CORTE: [Indiscernible], for the next 12 months or so we don't…we don't have any particular assumptions on price cuts. Unfortunately like we've seen…like we have seen in France this year with introduction of Article 56 that came up out of the blue. So it's difficult to predict, but I think that Recordati has shown over the years that it's been able to kind of withstand and adapt with…you know, situation and chances [ph].

HARRY SEPHTON: That's very helpful. Thank you. I just like one quick follow-up on the generic impact the year like in Livazo. I just like to…if you could give us a sense of whether you've been able to offset some volume impact by cutting prices or I guess the question would be, have you seen a significant volume impact to both of those products with generic entry or have you been able to offset that with pricing?

ANDREA RECORDATI: Yes, so the consistent strategy of the group has been to reduce price continuing to promote to fight for volumes. And that is proven successful in the past, and I think is holding up true also in this in this case, with unfortunate, again, the one exception of France, where, unfortunately, we've not seen the volume recovery, that that we would have hoped and in fact, have seen a bit more erosion offset by the performance in other markets when it comes to [indiscernible] because of the measures that, that we've referenced in a few times, trying to give an outlier. But other than that the answer is, yes. We've seen volume holding, and most of the impact being price related, and usually it is price which impacts upon entry. So again, we would expect that after a year or so to start normalizing.

HARRY SEPHTON: That's very helpful. Thank you.

OPERATOR: The next question is a follow-up from Jo Walton of Credit Suisse. Please go ahead.

JO WALTON: Just a few, please. I think, I'm right, you said that there was a 10 million milestone that you paid on the launch of Isturisa in Germany? Are there any other significant milestones that we should be factoring into the cash flow going forward?

My second question is on the cushing's syndrome, you haven't…it isn't clearly in your label, is there work that you are going to be doing? Would you envisage doing, you know, initiating R&D to formally expand that indication? And if so, what timeframe might you do that?

And my final question is, one to do with M&A. So, historically, you had roughly half year growth from acquisitions and half year growth organically. And we've had a period apart from the Signifor, Isturisa deal, which is obviously significant, where we haven't seen much in terms of deals. I wonder if you could just tell us whether your pipeline is, as full as, it normally is. If there's a particular reason why we haven't seen anything, maybe prices are too high, or you've been too focused on executing what you're doing. And whether we should still be looking for a balance in terms of deals for both getting new products in the Isturisa type deal, and also getting more tail products in from other companies, you know, the more like the [indiscernible] type deal.

ANDREA RECORDATI: Okay, maybe I'll start with this last question, Jo. Clearly, we are, you know, our corporate development machine is quite efficient, and believing when I say that we are constantly looking at different deals, and we've looked over a lot of deals, and also partially negotiated some throughout the year. Clearly, it happens with some deals that we don't find, you

know, the common ground on pricing and so forth. Sometimes because it's expensive, sometimes because there's also other issues that's behind the actual portfolios or products that we're looking at, which are not related to price only, and they come out, obviously, from due diligence from, you know, very far due diligence that Recordati as you know, is quite far of that.

This remains part of a strategy. Okay, so I have to reaffirm that, again, this remains a key part of a strategy going forward. We have things that we are progressing on at this moment in time, I don't know…obviously, I cannot tell you and give you, you know, any guidance if they're going to materialize or when they are going to materialize, but let's say that we are, we are in the process of you know, of negotiating some deals in order to kind of, you know, bring in new assets for business development activities.

We are still going to be looking also at products, you know, that tail products, but also coming up you know, for OTC [ph] business. But not only also, you know, for assets similar to you know, Isturisa or Signifor kind of [technical difficulty]. And there is obviously you know, over licensing and kind of, you know, floor products and there were lot of…very strong licensing [indiscernible], which is really looking at all of those season opportunities. So the answer is, yes, there's been some time since we've done the deal on Novartis sometime, I wouldn't say it's been such a long time, because we did in Novartis last year. Hopefully, we will see, if we managed to close something in the later part of this year. If not surely, in 2021. But let's say that the machine is working non-stop on this.

LUIGI LA CORTE: Yes. And maybe from my side on your first 2 questions in reverse order. If you allow me. On the…on your question around the guarding of the indication, we certainly plan to engage with FDA around the broader

indication. We believe the data is already robust enough, and we have the data available to support a potential filing for the new indication. But until we will have had those full discussion with the FDA, it is difficult, obviously, to know. So in other words, we don't necessarily feel that we need another study for to achieve that. And also the proof of that is the fact that has been approved in Europe with the broader label, we now also have the results of the link for study.

In terms of…on your question around, around milestones, I mean, you may recall the milestones were not disclosed at the time of the deal. However, when we are already in our end of year accounts, we published a sort of in the notes to the accounts, both the, the milestones, which were likely the link to the approval, and those which were the improbable being for milestones of equal amounts on approval of pricing in the 4 key European market. These are the main ones outstanding in terms of on Isturisa. Potential other milestones down the road are linked to some of the technical transfers of Signifor LAR in particular, which however, will depend on how and if that transfer occurs. So hopefully that addresses your questions around Isturisa.

JO WALTON: Thank you.

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

MARIANNE TATSCHKE: Okay. Thank you all for attending the call. And we'll keep in touch somehow. Thank you. Bye-bye.

ANDREA RECORDATI: Thank you. Bye-bye.