

Recordati S.p.A.

"Preliminary Full Year 2020 Results Conference Call"

Monday, February 22, 2021, 16:00 CET

MODERATORS: ANDREA RECORDATI, CHIEF EXECUTIVE OFFICER
 LUIGI LA CORTE, CHIEF FINANCIAL OFFICER
 FEDERICA DE MEDICI, INVESTOR RELATIONS AND CORPORATE
 COMMUNICATIONS

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati Preliminary Full Year 2020 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. Federica De Medici, Investor Relations and Corporate Communications. Please go ahead, madam.

FEDERICA DE MEDICI: Thank you very much. Good morning, good afternoon, everyone, and thank you for attending the Recordati conference call today. I am pleased to be here on this call by our CEO, Andrea Recordati and Luigi La Corte, our CFO that will be presenting our 2020 preliminary full year results and '21 targets. They will be running you through the presentation. As usual, the set of slide is available on our website under the Investor section. After that, we will open up for a Q&A. And I will now leave the floor to Andrea. Please go ahead.

ANDREA RECORDATI: Thank you, Federica. Good afternoon, ladies and gentlemen, and thank you for joining our 2020 results, preliminary results conference call and the '21 targets same conference call. So I would like to start by saying that I think that Recordati has delivered a resilient performance, despite the challenging condition in an unprecedented environment with revenues slightly down by 2.2% versus the previous year, and/or 0.4% up at constant exchange rates.

In 2020, our Group sales successfully overcame various challenges, some of which were expected such as the loss of the marketing exclusivity for 2 corporate products and the entry of a new drug competing with silodosin

[ph] in the U.S., whilst others emerged during the year at the onset of the COVID...of the COVID-19 pandemic.

The decline in the Specialty care, primary care reflected loss of exclusivity of Silodosin in Quarter 1 and Pitavastatin in Quarter 3. Strong FX headwinds especially on the Turkish lira and the rouble...Russian rouble and COVID-19 effect on key market segments, particularly on the cough & cold and products linked to hospital procedures and more discretionary items with products for chronic therapies holding up better, as you will see in more detail later in the call.

The growth of activities dedicated to the treatment of rare diseases was strong recording an increase of 27.9%. Now this business segment represents 22% of total revenues. Signifor and Signifor LAR reported double-digit in market growth, and we are very happy with Isturisa's launch uptick to date and the initial €12 million sales we booked in 2020.

The U.S. business was further strengthened with strong initial uptick of Cystadrops following its launch in Q4, and also with the Carbaglu new indication for organic acidemia which was approved by the FDA in January 2021.

Despite the pressure on top line, we were able to deliver solid operating performance. EBITDA growth was up 4.7% to €569.3 million, or 39.3 percentage of sales, significantly above last year, adjusted net income at €410.4 million, which was up 7.3% versus 2019, and equals 28.3% of sales from the 25.8% last year. The Group continues to deliver strong cash generation of around €360 million before milestones, net share purchases and dividends distributed.

We have also further reinforced our portfolio, specifically in support of our Specialty and Primary care business through a new licensing agreement. The license agreement with ARS Pharmaceuticals for ARS-1, is such an example, and also obviously the late...just announced agreement for the licensing of Eligard in Europe, Turkey, Russia and other countries from Tolmar.

Before handing over to Luigi La Corte, who will provide more details on our financial performance, let me provide some more updates on our endocrinology portfolio and some details on the Eligard, so please switch to the next page. So regarding the endocrinology franchise, the commercialization of Signifor and Signifor LAR is on track, recording net revenue of €67 million. The transfer of distribution from Novartis is now completed, major EU markets and many transfers were completed during June and July, and the smaller CEE markets that took place during Q4 of last year. We have new patient acquisition across all approved indications, and Signifor grew double-digit in end market sales compared to 2019.

Moving to Isturisa, the launch sequence was successfully initiated in the U.S. and parts of the EU, despite the many challenges posed by the COVID-19 pandemic which we can surely appreciate had quite an impact on the uptake of the launched product. We are satisfied with the early performance of Isturisa in this market, which is in line with our expectations, contributing net revenues of around €12 million, mainly in the U.S. and France. We have strong support from top KOLs and patient organizations. The regulatory process started in March of the new drug application in Japan, is on track and we are expecting to launch in the second half of 2021. Based on what we see so far, we confirm our longer term focus for Isturisa, therefore to achieve a leading market share with peak year sales estimated between €300 million and €350 million, and

potential further upside from the expansion of indications for Cushing Syndrome in the U.S. and through our geo expansion strategy in new territories.

Now let's move to our latest business development deal finalized in January 2021 with Tolmar International Ltd. Last month, we announced the closing of a license and supply agreement with Tolmar International Ltd to commercialize Eligard leuprorelin acetate, in Europe, Turkey, Russia and other countries. Eligard is a marketed medicinal product for the treatment of hormone dependent advanced prostate cancer. The agreement provides us with a new product that strengthens our presence in urological area and fits very well with our geographical footprint. Eligard is a very well established medication in a slightly [ph] growing market which is worth about €1 billion according to IMS in Europe, referring to 2019 sales, half of which is represented by leuprorelin based products.

Amongst this product category, Eligard has around 20% market share. Annual revenues in recent years were €100 million. Under the terms of the agreement, we will have economic benefit from the 1st of January 2021. Reported net revenue in 2021 will depend on the exact timing of transfer of sales and distribution market by market. So for our estimation for 2021, net revenue is around about €70 million, with an EBITDA contribution of around €20 million.

We paid an upfront cash consideration of €35 million, plus milestones up to a total of €105 million, plus royalties on sales. Milestones are linked to submission of regulatory filing and subsequent approval of a new device which will be easy to handle, and is currently under development. €35 million first regulatory milestones is expected in Q4 2021, linked to the regulatory variation which is expected to be submitted by the 31st of

October 2021. So this...at this point, I will leave the floor to Luigi to take you through in more detail on our 2020 results. Thank you.

LUIGI LA CORTE: So thank you, Andrea, and good morning, good afternoon, everyone. So I'll start as usual by giving a little bit more granularity on our sales performance and starting with sales of our key corporate products which represents 69% of revenue. Zanidip, which currently remains our biggest product with €134.6 million of revenue in 2020 finished the year flat, marginally ahead of 2019, with a growth in...across several products, but notably in Italy, Germany, Poland and Russia offset by erosion in France due to new measures introduced at the beginning of 2020 in Article 66 which we mentioned a few times over past quarters and also due to the effect of currency changes particularly impacting Turkey and international markets, 40% roughly of Zanidip sales are to our international affiliates.

The Article 66 measures in France also accounted for most of the decline in the combination product Zanipress which again is declining by close to 18% for the year. Metoprolol franchise which is now our second biggest franchise for the Group grew nicely at 7.5% with total revenue of €105.7 million, with a broad-based growth particularly strong in Central and Eastern Europe and particularly in those markets where we have set up direct selling organization most recently.

Urorec reflects clearly the impact of loss of exclusivity. You recall generic entered a majority of markets in February of 2020 impacting particularly revenue in Italy, Spain, Portugal and Germany. In fact, in most of the markets, our Urorec sales held up better than expected. In fact erosion was somewhat lower than we had anticipated at the beginning of the year. Some of that unfortunately offset by again measures favoring dispensing of generics in France, issued in early 2020. Notably, Urorec continues to grow in markets where generics have not entered, Turkey,

Greece and Switzerland in particular. Similarly Livazo revenue down by 1.8% at close to €53 million reflects loss of exclusivity starting in August, which offset the growth that we saw in the first part of the year for pitavastatin. Again here, the product is still growing in markets where generics, I mean we don't expect generics mainly Turkey, Greece and Switzerland.

Other corporate products of €270 million roughly is where...as we commented in previous calls, we saw the brunt [ph] of the impact of the COVID-19 restrictions. Other corporate products includes OTC as we will recall. And here we see and we commented before significant impact in our cough and cold franchises, which is particularly strong in Russia and other markets in Central and Eastern Europe, impacting sales of Isofra and Polydexa, and equally, pandemic restrictions also impacting the sales of anti-infective products in general. Many...in many cases across Europe, we saw restrictions and reductions...significant reductions in elective hospital procedures, which impacted sales of CitraFleet and Enema Casen in Spain and Portugal and generally a lower consumption of over the counter drugs and more discretionary medications.

Within corporate products, to note, the good growth of Reagila up more than 60% versus previous year, and growth also of some of our key products within OTC Procto-Glyvenol and Casenlax in particular.

Finally, drugs for rare diseases were up significantly, with growth of close to 28%. They now represent close to 22% of our revenue. Majority of the growth being driven clearly by our endocrinology franchise and Signifor in particular, which added €57 million to revenue which already recorded in Q4 of last year. And Isturisa contributed as Andrea mentioned €12 million of revenue.

Noteworthy, we saw growth during the year also on Carbaglu, Cystagon, Cystadrops, Ledaga and Juxtapid also amongst the several of our product franchises, which offset the erosion in the U.S. on Panhematin following the launch and our competitor, we're pleased to see that following somewhat sharper than expected decline over the April to June month at the peak of the restrictions we have seen sales stabilized and with a degree of erosion which is now more in line with our expectations as patients flow readjusted to the COVID restrictions.

So then, on the next slide on Slide 6, you'll see a growth show the composition of our portfolio. As I commented, rare diseases now represents 22% of group revenue up from 16.9% in 2019. OTC slightly down to 18.1% from 18.6% in '19, and the incidence of local product portfolios also continues reducing and is now under 16% from 17% in 2019.

Switching to Slide 7 and looking at revenues for key geographies, the picture is very much consistent with one that we commented in the last...the quarter and illustrates the differential impact that the pandemic has had on different parts of the portfolio and therefore also different markets.

Sales in Italy were down close to 5% reflecting generic erosion on pantoprazole in Lanso [ph] which started in the second half of 2019, but also the loss of exclusivity of Urorec and lower market levels for some of our OTC products and therefore, we did see in Italy, a strong performance and growth of more chronic medications namely Cardicor, Zanidip and of Reagila, and also clearly, a strong contribution of the rare disease portfolio offsetting some of those pressures from the COVID restrictions.

France down by 8.4% and this was one of the painful notes of 2020, as we commented throughout the year with measures introduced in January of 2020, which favored the dispensing of generic medicines. This impacted both lercanidipine and combination sales and particularly impacted Urorec revenue upon generic entry where erosion was higher than expected. All of this is partly offset by what we saw being a very strong growth of rare diseases, and also of the local Methadone franchise.

Germany, revenue held up better at minus 2.1%, with most of the decline actually being due to generic competition on tenders of Orthotone [ph] with good growth in Germany here once again from the addition of Signifor, and also initial sales of Isturisa, which is off to a really strong start in Germany. U.S. revenue up by 14% in local currency or 11.8% on a reported basis at €122.5 million, we did see a strengthening of the euro against the dollar in the back part of the year.

Growth as we have commented mostly driven by the endocrinology franchise, but also good growth of Carbaglu and Cystadrops following its launch in the later part of the year, once again all of those more than offsetting the erosion on Panhematin.

Russia, other CIS and Ukraine revenue of just over €100 million, these markets really saw an impact...combined impact both of COVID restrictions on the cough and cold portfolio but also of FX...with FX impact in Russia in particular of 11.7% which lead to...accounted for a significant part of the decline in reported figures there. Sales in Russia, as I said before have a significant incidence of cough and cold medications and medications for acute conditions which were amongst the most impacted by the pandemic. We did see in the market double-digit growth in a local currency on Procto-Glyvenol, Alfavit, Zanicidip, Urorec and Livazo, which part of setup.

Revenue in smaller Central Eastern European markets and Western...other Western European markets, both grew by double-digit driven by the strong growth of metoprolol, particularly in Poland, Czech, Baltics and Romania, but also good growth of Livazo and Reagila in Switzerland and in Nordics and of course, here again, the contribution of rare diseases.

Revenue in Spain, down by 11.5% to just under €84 million, Spain reflecting both the loss of exclusivity of felodipine and pitavastatin. But also, as I said significant impact from hospital procedures being put on hold for a large part of the year, which impacted sales of CitraFleet, which is one of the biggest franchises in the market and use for endoscopies and Enema Casen and also softer market for pediatrics and probiotics products.

Turkey continues to grow double-digit in local currency terms with local growth of 11.6% but reflects a staggering 23% headwind in terms of foreign exchange with significant erosion and decline of the Turkish lira over the course of the year. Growth of the Turkish business was broad based and really driven both by our corporate products and also the local product portfolio.

Portugal, revenue of 42.7 down by 3.9% reflect very similar dynamics to the ones that mentioned for the Spanish market with good growth of Reagila both in the case of Portugal and Spain, partially offsetting the pressures from the loss of exclusivity on felodipine and pitavastatin.

North Africa sales are up by 2.3% reflecting...actually slightly down versus double-digit growth in the first part of the year, reflecting a bit of weakness of currencies against the euros in the later part of the year and

also some restrictions to exports towards some markets in North Africa in Q4.

And finally, other international sales of just over €200 million broadly flat with 2019. With growth of rare diseases in particularly in MENA and Mexico offset by impact of foreign currencies weakness against the euro and also some discontinuation of licenses for markets where we've taken back distribution of our products over the course of 2019.

On Slide 8, once again, the composition of revenue by key geography, very much unchanged, very similar to the snapshot last year, and just confirming the diversified footprint of the Group, which we believe this year allowed us to put...to deliver the kind of solid and resilient performance, that Andrea alluded to, with revenues slightly down to plus 0.4% at a constant exchange rate basis.

Switching over to Slide 9 and looking at the P&L. The slight decline on the revenue line is...as you see, almost fully offset already at the gross profit level, thanks to improvement in gross margin to 71.9% of sales, driven mostly by the shifting mix of our portfolio towards Rare Diseases.

SG&A at €421.9 million is down versus '19, reflecting lower level of activity spend in the face of COVID, we estimate that we had roughly €35 million of savings, which we achieved this year versus 2019 in...to offset the impact on the top line particularly on selling costs, which are around 24.1% of sales with G&A expenditure of 5% sales, broadly flat with 2019.

R&D expenses are up by 12.8%, at 10...just over 10% of revenue, with the majority of the increase being driven by the additional amortization charges arising from the new products that we acquired from Novartis and also from some of the studies that we inherited. We do expect R&D

expenses as percent of revenue to stay broadly at this level, as we go into 2021.

Other expenses of €4.9 million reflect mostly the non-recurring cost of roughly €6 million, which we had in 2020 being mostly the COVID-19 related donations and also include €0.5 million of non-recurring costs are linked to the reverse merger transaction, which we announced earlier in the year. That leads to an operating income of €469 million, 32.4% and slightly above prior year, an EBITDA of €569.3 million, or 39.3% of sales, up 4.7% versus 2019, which once again we believe is very strong performance in a challenging environment. And as we've commented in the past, the difference in growth rates between EBITDA and operating income being driven by the increased amortization year-on-year and also the non-recurring cost, which are adjusted in EBITDA, but not at an operating income level.

Net income of €355 million, down 3.8%, but the reduction really due to the exceptional and non-recurring benefit of...tax benefit of €27 million related to Patent Box linked to prior years, which we recorded at the end of 2019. We did have a small positive non-recurring tax side of €2 million in 2020. Adjusting for these, growth of net income would be 3.2% and adjusted net income at €410 million, is up 7.3% relative to 2019. This is on the back of the strong operating performance, but also thanks to lower financing charges and this as well as of currency movements did put particularly in the back end of the year a bit of pressure on our operating margins, they did have a positive impact, which is accounted for in financial expenses, due principally to the positive impact that these had on transactions no longer treated as hedges, which were recorded in the first half of the year and which were closed in April, and also to some exchange rate gains on settlement of currency transactions.

Switching to Slide 10, clearly rare diseases, you know, account for a growing share of both revenue and operating results, over 25% of both EBIT and EBITDA is contributed from our rare disease business with margins that clearly in 2020 reflecting also a little bit the launch investments behind Isturisa. And noteworthy, though, on Specialty & Primary Care business, despite the [indiscernible] and COVID impact delivered an absolute basis operating results, which were almost in line with 2019, which again...once again, we believe is very resilient and solid performance.

Last from my side, net financial position with net debt on Slide 11, net debt of just under €866 million, down versus €902.7 at the end of '19. This equates to roughly 1.5 times EBITDA, which is in line with where we said we would be in our plan assumptions, and really reflects the strong underlying cash flow performance of the Group. Over the course of 2020, we paid \$90 million of milestones to Novartis for the end of franchise transaction, €50 million to ARS Pharmaceuticals for the rights to ARS-1. Dividends of €212.5 million and had net share repurchases of €12.2 million, with therefore an underlying cash generation of €360 million approximately, which remains in line with our track record of delivering cash at roughly 100% of net income.

And with that, I will hand over to Andrea to talk about the expectations for 2021.

ANDREA RECORDATI: Thank you very much, Luigi. So if you could please turn to Page 12 of the presentation. So the assumptions behind our '21 targets are summarized in the slide, Regarding the 2021 guidance, assuming that and this is very important, assuming a gradual recovery of our reference markets after the COVID-19, we expect this to occur in the second half of 2021. So we still expect obviously some degree of uncertainty and volatility in the markets

until the end of the first half. And obviously also, despite the continued adverse [indiscernible] roughly minus 2%, we expect to achieve net revenue growth of 10% in 2021.

Our key assumptions are the following. So Specialty & Primary Care returning to low single-digit organic growth following Silodosin and Pitavastatin loss of exclusivity in 2020, and an assumed return to more normal market conditions, like I said, in the second half of the year.

Of course, please keep in mind that the Q1 of 2020 was mostly free of COVID impact, and in fact reflected overstocking by wholesalers, and was only also...only partially affected by the loss of exclusivity impact on Silodosin. We expect Eligard's revenues of around €70 million or over €70 million I should say, subject to the exact timing of the in-market distribution, as already highlighted. High double-digit growth of our rare disease business, driven by continues strong uptake of Endo franchise. Signifor and Isturisa net revenue is expected to be around €120 to €140 million for the year, with further growth also coming from Cystadrops, Ledaga, Juxtapid off-setting Panhematin decline in the U.S.

We expect R&D costs to remain around 10% of revenue, reflecting incremental investments [ph] to support the Endo franchise and amortization charges related to the recent asset acquisitions.

Assuming partial normalization of activates post-COVID-19, EBITDA margin will be above 38%, reflecting as well the transition cost on Eligard. Financing costs of around €22 million to €24 million are expected with no FX gains/losses assumed on this item.

Tax rate to be around 20%, reflecting also €12.9 million, a non-recurring ACE benefit from the reverse merchant transaction. To be noted, that no

new undisclosed acquisitions of business development initiatives are included in our 2021 targets. And last but not least, dividend payout policy is confirmed at 60% of total net income.

To complete switch to the last slide of a presentation Slide 14, which sums up the 2021 targets. So we expect to have revenues ranging from €1.470 million to €1.620 million. EBITDA in a range that goes from €600 million to €620 million and adjusted net income of between €420 million and €440 million. As previously mentioned, we also plan to provide an update to our 3-Year Business Plan in May.

So this brings us to the end of our presentation, and I think we can at this point move to the Q&A. Thank you.

FEDERICA DE MEDICI: Operator, we are now ready to take the questions.

Q&A

OPERATOR: All right, perfect. 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." Please pick up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from James Vane-Tempest from Jefferies. Please go ahead.

JAMES VANE-TEMPEST: Hi, thanks for taking my questions and I'll start off with 2 and then I have a follow-up, if I may. Just on the guidance, the consolidated guidance, the organic growth of around 10%, and thank you for the detail

on the slides. I'm just curious what does this assume for Livazo and Urorec. And so, these are losing or are these losing exclusivity this year? And then secondly, it's just on EBITDA guidance. At least looking what this might be x the Eligard and Isturisa, is it basically declining to flat in 2021 and if so what's driving that? Thank you.

ANDREA RECORDATI: Yes, hi James. So I thank you for the question, so first of all, just to be clear, the overall revenue growth, which is quoted on Slide 12 of about 10% is the total revenue growth, which does reflect though a adverse 2% FX, you will see underneath it we also mentioned the Eligard revenue, so just to be clear, overall revenue growth of around 10% is the total growth and it's consistent with the range that we've provided for total revenue. You asked about Silodosin and Pitavastatin a further erosion next year, I would assume an extra €10 million for both with Silodosin obviously being larger product, but having gone generic in the early part of the year.

With regards to Eligard, we are expecting a EBITDA contribution this year of around €20 million, which reflects this being first year also some transition costs. I'm not going to give sort of detailed EBITDA number for Endo. So hopefully, that gives at least a sort of answer to most of your questions.

JAMES VANE-TEMPEST: Thank you. And then just a follow-up, so €35 million of SG&A savings from COVID, and how much of that is expected to return as normal activities resume, and does your guidance assume any further price erosion in Europe, please?

ANDREA RECORDATI: I'll answer this one, James, so we expect basically 50% of operational savings that we delivered in 2020 that will be retained in 2021.

JAMES VANE-TEMPEST: Thank you.

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

MARTINO DE AMBROGGI: Thank you. Good afternoon, everybody. My first question is on the R&D. Because in 2020 it was 10% of sales, mainly because of lower sales, so I suppose the total amount was more or less in line with your expectations. You are guiding for another 10% in 2021, which is a quite high level compared to the past few years, never achieved the 10% for many, many years. So should we take these as a normal level going forward or is it because of specific studies that you are financing right now?

ANDREA RECORDATI: Thanks for the question. Martino, I mean, the growth also in sort of 2021 will be in part the additional amortization that comes from the Eligard deal. We're assuming a 20-year sort of a amortization and assuming that on both the upfront and the additional milestone which will be paid we assume over the course of 2021. There is a little bit of additional investment behind the Endo franchise, but the majority really is the amortization, which is doing that, but again the forecast is for it to remain sort of flat in terms of percent of revenue. There's a little bit of studies, as we said that sort of are continuing on the Endo portfolio as well and we do have some of our programs, which are progressing [indiscernible] in particular, but again the majority of it is amortization increase.

MARTINO DE AMBROGGI: Okay. So we can take 10% as an indication also going forward or it's probably declining?

ANDREA RECORDATI: We haven't sort of...we are not providing that updated with the plan today, but I mean it'll depend a little bit also on the type of deals that we may do in the future as always which is...would they come with significant...if it

were to be an M&A transaction with a significant part of the purchase price allocated to Goodwill, we won't have any amortization, we'll have an sort of increasing R&D, with intangible specific assets then, which is why we've sort of kind of shifted the emphasis on EBITDA and adjusted net income, which adjusts for amortization, if that makes sense.

MARTINO DE AMBROGGI: Okay. Thank you. The second question is on the 2021 guidance. In the past, you provided guidance including acquisitions. I know, I'm not asking you anything because it's impossible to predict, but do you feel confident to reiterate the guidance including acquisitions because...I ask you, because last year I remember the M&A processes were a little bit slowed down because of the COVID pandemic and so on, so probably, I don't know, maybe you are more confident today in either new in licensed drugs or acquisition, so just your feeling?

LUIGI LA CORTE: Well, I mean, I'll answer that. I mean in 2020, we delivered on the acquisition side because we know acquisition/business development. Obviously, I'm talking about Eligard which is a substantial business development initiative for Recordati and to...and that we are reinforcing our SPC business. There was a slowdown, but we did not perceive such a slowdown in 2020 due to the COVID pandemic honestly, so it can be on the business development and M&A kind of flattish progress. We looked at various opportunities, but clearly not all opportunities pan out for a variety of reasons and they're all different from one another. We don't give guidance in our yearly targets; we give guidance in our 3-Year Plan targets. We've always done this in the past and we will keep on doing this, so obviously we will build in some sort of objective on the M&A targets in our Business Plan, which we will present in May.

Clearly, we have...we continue scouting...we have a very kind of focused and intensive scouting activity both in SPC and direct business. And

honestly, we're not seeing any shortage of opportunities, so obviously the objective is to deliver also this year, but as I said, you cannot kind of you know, celebrate until you have the [indiscernible]. So you see some more outlook on this for the...in the 3-Year Plan.

ANDREA RECORDATI: Sorry one follow-up, I sort of just realized that I hadn't fully addressed. I think there was a third element to earlier question from James around profit evolution in...as implied in the guidance for 2021 X the Eligard portion. Let's just not forget in the context, we are still factoring in, in our guidance, a 2% headwind of FX versus 2.6% of this year. We are anticipating and I think this is consistent across the sector, COVID still to impact to some extent the first half of the year. And obviously, as I said, the sort of detail of the loss of exclusivity impact on [indiscernible] and so clearly, they are still a little bit of a hand width from that as we go into 2021. Operator, next question.

MARTINO DE AMBROGGI: If I may, am I still online. No. Hello.

ANDREA RECORDATI: Yes, yes. You are.

MARTINO DE AMBROGGI: Okay. Sorry, just the very last question on Signifor, Isturisa, could provide a split between the 2 like last year, and just to understand that Japan will be launched in the second half, but probably this year it doesn't represent a significant contribution. And for Eligard, is it possible to have a big sales potential or a €100 million is the reference point for the long-term?

ANDREA RECORDATI: Okay. Let me answer that. Regarding the first question of a split of our guidance of 120-140 million from the end of franchise, we will not be providing a product split of 2021 estimate. We have given the split of 2020 results and an indication of 2020 growth rates we have seen so far on

Signifor...the sales achieved in 2019. Clearly, we also...it's important to say that we are also expect Isturisa to account for a significant part of the growth in 2021. Japan, yes, I would like to correct, yes, that is not going to be a major contributor in 2021. So no...I will confirm that.

And regarding Eligard, for the moment, I think we will confirm that you know the 100 million sales...full year sales that we mentioned before starting from 2022.

MARTINO DE AMBROGGI: Thank you very much.

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

KC ARIKATLA: Hello everyone. Thank you for taking my questions. I had a few modeling ones please, and one big picture question. On the modeling ones, if...is the €13 million tax benefit, the nonrecurring one that you have mentioned. Is that part of your adjusted net income guidance or not, please? And second one, if I look at the M&A environment and the appetite from your side to do M&A. Is it fair to say that we can expect some M&A in this year beyond what you have announced or is that not likely to be the case?

And the third one on Eligard, you have mentioned €70 million and sales and €20 million in EBITDA. Assuming you get the marketing rights all transferred that becomes €100 million in sales. What would be the right EBITDA number please, is that still 20 million? Thank you.

ANDREA RECORDATI: Hi KC. Thanks for the question. So first of all in terms of adjusted net income guidance, so the 27 million nonrecurring one off was for 2019 item just to be clear. We have included in our guidance. In fact, as you

know adjusted net income is...does not include nonrecurring item. So we have mentioned it...we have reminded you of the nonrecurring benefit from the reverse merger, so that if you are wanting to model net income, you know that we have got additional benefit which doesn't go into adjusted net income. So again, the €12.9 million of our recurring benefit...tax benefit from reverse merger will not be included because it would be adjusted in the guidance that we have provided.

On...I will take the Eligard regard one, expectations on EBITDA, thereafter I think you should model on the basis of a normal sort of SBC level margins whether or not how quickly we get to that, whether that's already 2022 we will see, and we will provide an update when we do the other 3 year plan, but the number that we are quoting for this year is very much reflective of transition.

And for M&A, in terms of expectations, for this year, I mean, all I can say is M&A remains an integral part of the surge.

LUIGI LA CORTE: I replied to the question before, I mean, it remains an integral part of our business development [indiscernible] in let's say growth strategy as a fact that no shortage of opportunities that we are seeing, but again, you know, until they materialize, it's difficult to maintain a prediction [ph], so I am not going to give...like we are never getting projects for M&A for one year target. We will give you an outlook on what we expect for the 3-Year Plan.

And so, just to be clear, the targets we have read out do not include M&As. That was mentioned in [technical difficulty].

KC ARIKATLA: Thank you.

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

JO WALTON: Thank you. Just a few, please. On Isturisa, you've told us that you are off to a great start in Germany. I wonder if you could just help us with a landscape in the rest of Europe, where you have got pricing, where you have got reimbursement, whether that reimbursement level that you are getting in other countries is coming in at the same level...I mean in Germany, you can sort of choose your level counting [ph] from at least a year or so. So just give us a little more of the flavor for landscape please, Isturisa in Europe.

The second question would be the trough level that we could get down to for Livazo and Urorec. Now, I know, they are not your product like Zanidip, Zanidip years past patent expiry is still an incredibly important driver for you. I am just wondering whether the 10 million of erosion that you talk about for this year is where new countries are getting some generics or whether you feel that is continued erosions.

I am just trying to get the sort of level we should be thinking of going forward with the level of support. And I am thinking particularly because you did so well with Seloken up 8%, again is Seloken now do you think at a stable level or do you think that you will be able to get some further growth from that product as you move it into some of your more peripheral markets.

My final question would be about the savings. As you know, I have got 2 more, I apologize. The savings from COVID, you talk about €35 million of marketing savings. How quickly do you think that you will come back to spend that again? I assume not in 2021, because you told us that COVID will keep going for at least part of the year, but if we were to look further out and given the fact that you have got new more specialist

product coming through. Do you think we should be ramping up our SG&A?

And my final question is a big picture question. You talked about the new measures that came in, in France, last year which eroded some of your products more than you expected, because the minute there was a patent expiry it went to full genericization given that European governments are going to be short of cash post-COVID. Are there any other markets where you have any visibility of the same sort of, let's use a true generic rather than a branded generic coming in that we might have to think about. Thank you.

LUIGI LA CORTE: Okay. Thank you, Jo. I will do my best. A lot of questions there. So I will start with your last one, and because it is a relatively straight forward one. No, we are not foreseeing actually significant new measures being introduced across Europe as a result of the pandemic. Yes, government are facing, you know, significant budget deficit, but one, at least from our sort of vantage point. They don't seem in a hurry necessarily to claw those back and hopefully they are working on a number of front in partnership with the Pharmaceutical Industry. And I think I realize also the importance of the wealth fund and healthcare system. So I think I have mentioned in prior call...we have mentioned a number of anecdotes where we see actually things going the opposite way. So of course, it can happen, and it does happen from time to time, and it has been the history of the sector over the last 10 years, but we are not anticipating at this stage, you know, very significant pricing pressure or new generic measures across key markets.

Isturisa and how it is going in Europe. First of all, my apology, probably, I put the emphasis on Germany, and of course, we are on track in Germany as well. France is right now the market where the launch is most

advanced across Europe and that's on the back of the strong...the access program that was in place in the country that also benefits from a more centralized management of these patients. So both France and Germany is where we are seeing strong initial adoption. We are anticipating Isturisa to gain reimbursement in a number of European markets over the course of the year, but it will be later in the year. It is currently, let's say, we are still in negotiation...pricing negotiation discussions across France and Italy. Germany as you mentioned we are allowed to launch our sort of set price and then initiating good negotiations one year post. So that's all to play out frankly.

I mean, all I can say to that is that, you know, the product as Andrea mentioned has strong endorsement from KOLs. It has a strong endorsement from the European authorities themselves when confirming your contract [ph] status. So we have no reason to believe we will not be getting the kind of recognition of the value of Isturisa that we think the product deserves.

Livazo and Urorec, just to be clear sort of, when I said 10 million sort of further erosion, that was 10 million on each of the 2, and that's really just due to the...being a full year impact more than anything. In fact, we started to see, you know, in market where sort of generics have entered for example in the case of Urorec in February, early March of 2020, we have started to see volumes stabilize. So, I think those are more sort of full year effects rather than the reflection of significant further erosion to come on a market by market basis. Seloken was a good growth driver, strong growth driver this year. We do still see opportunity for growth there, particularly in those markets Central Eastern Europe, Nordics, Baltics where we set up our own direct selling operations more recently. I won't provide a sort of exact sort of number for that, but certainly we do see an opportunity there. And I think in terms of the savings on COVID, I think we have been quite

consistent actually...course of 2020 we signaled that not 100% of the savings we would be able to retain, but certainly some we think are potentially here to stay, I think inevitably we all physicians will get used to doing, particularly a lot of our spend was linked to large events and gatherings, well hopefully we will return to face-to-face at some point, I don't think that would be at the same scale as in the past. I am sure, international travel would be, you know, restricted for [indiscernible]. I would not be sort of ramping up and again we haven't sort of done a sort of 3-Year Plan update, we will do that in May, but you know, I would not be sort foreseeing a sort of major ramp up of spend in the years to come. Hopefully, that has addressed most of your questions...all of your questions so [indiscernible].

JO WALTON: Thank you.

OPERATOR: The next question is from Giorgio Tavolini with Intermonte. Please go ahead.

GIORGIO TAVOLINI: Hi, good afternoon and thanks, everyone. Thanks for taking my question. I would like to have some color on the intangible amortization, I mean, in order to proper modeling the adjusted...the adjusted net income line for 2021, on what period do you expect to amortize the license regarding Eligard? If you are set to assume an overall €80 million amortization of intangible assets before taxes, I mean €65 million for 2021 net of tax.

And the second question is on the financial cost, in 2020 what is the detail on this line? And the third one is on the vaccines, I mean are you interested in accommodating at your production plant, some production for Vaccines by acquiring rights for license in order to contribute today speed up of the vaccine rollout? Thank you.

ANDREA RECORDATI: Simple one, if I understand correctly, you are asking if we are doing anything with our manufacturing subsidiaries to actually participating in the manufacturing of vaccines. Is that correctly understood?

GIORGIO TAVOLINI: Yes, yes.

ANDREA RECORDATI: Well, no, that is, let's say industry is a very specific one and you need especially the manufacturing facilities with a very kind of, you know, adept and designed specific for manufacturing of vaccines. So, no, it's not something that we would be able to be...at least to setup, notwithstanding all the regulatory approvals and so forth. And they had a CAPEX investment, so it's something which is completely out of our scope of business

GIORGIO TAVOLINI: Okay.

LUIGI LA CORTE: Okay. Yes, on amortization charges for 2021, we are amortizing the Eligard upfront and first milestone over 20 years. Of course, we will start amortization on Isturisa sort of in a by country basis as of the time when the product is launched in the market. You should assume an amortization absolute charge in 2021 of over €70 million roughly, Giorgio and....

FEDERICA DE MEDICI: Financial items...

LUIGI LA CORTE: Sorry, financial items for 2020, the gains from currency moments were in the range of €6 to €7 million to give you an indication.

GIORGIO TAVOLINI: Okay. Thank you very much.

OPERATOR: As a reminder, if you wish to register for a question please press "*" and "1" on your telephone. The next question is from Isacco Brambilla with Medicobanca. Please go ahead.

ISACCO BRAMBILLA: Hi, good evening. Just a couple of questions from my side, the first one is on, you know, let's say your new additions to the orphan drugs portfolio, I mean Cystadrops and second indication for Carbaglu. Can you remind us how we should look at these products if we were to rent your treatment for rare disease in terms of market opportunities? And the second question is on, your cash deployment, and for the large acquisition [indiscernible] other or cash out lower than what we were expecting for acquiring €100 million annual turnover. How do you intend to deploy this additional cash power, which we add now available? Thanks.

ANDREA RECORDATI: Yes. So, I think it's...so Cystadrops in the US we see a sort of opportunity is sort of in terms of just to give it a scale below 20 million, U.S. dollar over time. The launch started quite well actually, in fact if anything it's ahead of our expectations. So, so far so good, but that is the indication. It is a fairly, in a sort of quite rare conditions, it's great news for patients. But, yes, it's clearly sort of more limited in scale relative to some of the other more recent additions and Carbaglu OA similarly I think it will contribute to the continuous growth of Carbaglu in the U.S. But, the indication is for use in acute setting and therefore, it's not going to be a sort of very material driver on its own.

In terms of cash, I mean, you know, clearly we are looking at fire power, we don't just look at sort of cash on the balance sheet. But, you know, where we are in terms of leverage overall and understand we've 1.5 times EBITDA which is very much in line with where we said, we would be, we did say when the plan was refreshed that would go up to a maximum of 3, but only if and when very specific opportunity of...came

about, and so nothing has changed really in terms of, you know, from our perspective. And, you know, we did a very significant deal in 2019 with over €400 million sort of cash outlay. And we have done this one now, and of course, we will continue to scout and we are continuing discussion for same type of opportunities that we discussed in the past, both on the SPC side and the rare disease side. So, I am not sure we see it as a being and in a sort of very different position in terms of cash and leverage from where we thought we were going to be. I think we are pretty much in line with where we said, we would be actually from that perspective. I hope that makes sense.

ISACCO BRAMBILLA: Yes, sure. Just one little bit follow-up, if I may, in terms of market multiples, have you seen any kind of change, because of the healthcare emergency or nothing really material compared to the past?

ANDREA RECORDATI: No, honestly I would say no, we haven't seen anything.

ISACCO BRAMBILLA: Okay. Thank you.

ANDREA RECORDATI: In market multiples and due to COVID. Thank you.

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

JO WALTON: Just a quick one on your share buyback program. Is that purely to offset the expected share issuance or does that have, you know, some element of you thinking that the shares are particularly undervalued and you haven't got anything else that you need to spend your money on at the moment, and therefore, you are making a deliberate share buyback? Many thanks.

LUIGI LA CORTE: Now, thank you for the question Joe, but it is really a technical one, we have existing sort of stock option program in place. Our programs actually do not foresee the issuance of new shares. So, the programs that foresee that any exercises would be, you know, fulfilled through treasury shares and all we are doing is sort of making sure that we have what is required to fulfill any potential sort of share vesting which are the already vested or vesting between now and May. So, you know, it's not because of, as you said, comes from our perspective where we are in terms of net debt is exactly where we thought we would be in the plan.

JO WALTON: Thank you.

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

ANDREA RECORDATI: Thank you very much. Thank you, everybody, for listening-in, take care and be safe. And with this, bye-bye.