Recordati S.p.A

"2021 First Nine Months Results Conference Call"

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FEDERICA DE MEDICI, INVESTOR RELATION AND CORPORATE COMMUNICATION

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati 2021 First Nine 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. Federica De Medici, Investor Relations and Corporate Communications of Recordati. Please go ahead, madam.

FEDERICA DE MEDICI: Thank you, Sabrina, and good morning and good afternoon to everyone, and thank you for attending the Recordati conference call today. I am pleased to be here with our CEO, Andrea Recordati and our CFO, Luigi La Corte, that will be presenting the 2021 first nine months results. Then we will be running you through the presentation. As usual, the set of slides is available on our website, under the Investors section. After that, we will open up for Q&A.

I will now leave the floor to Andrea. Please go ahead.

ANDREA RECORDATI: Good afternoon or good morning, ladies and gentlemen, and thank you for having joined us for the Recordati 2021 first nine months results investor presentation.

So if you could please move to the first slide of the presentation, the key highlights. So I am pleased to have the opportunity to announce another quarter of very solid results for the Group. Q3 confirmed the trends recorded during the second quarter, with a progressive recovery in the main reference market, and operating conditions trying to return to near normal, even though limited access to medical personnel in many

countries and social distancing measures continue to impact certain product categories.

The recovery of several therapeutic areas in SPC, combined with the contribution for the new product, Eligard and the continued growth in the rare disease segment, resulted in a net revenue increase in the quarter of 15.5% or 17% at constant exchange rates in Q3, compared to the same period clearly in 2020, which had the that I remind you being the most significantly impacted by the COVID-19 restriction measures.

If you look at EBITDA, on quarter-on-quarter, we grew 15.4%. Net revenue in the first 9 months of 2021 closed at 1€.156 billion with a growth of 5.7% versus previous year, reflecting an adverse current exchange rate effect of around €31.6 million and the contribution from Eligard for €59.4 million. Net of this effect, growth was at 3.2%, with good momentum in recent months, more than offsetting the full year impact of the 2020 LOEs of silodosin and Pitavastatin, which show a decrease of €23.8 million, and the impact of the pandemic especially on seasonal flu medications in the first quarter 2021.

The growth of our rare disease portfolio was significant in the first 9 months of 2021, at 20.2%, thanks especially to the increase in Signifor and Isturisa, which basically closed at €90.5 million versus €53.8 million in the same period last year, but also to the solid performance of our metabolic portfolio product. And actual results are in line with expectations with EBITDA at €447.9 million, up 2.1% compared to the first 9 months of 2020, and with margin at 38.7 of revenue. Growth was driven by the very solid revenue performance, partially offset by planned increases in investments to support the endo portfolio growth, the cost related to integrating and promoting Eligard as well as the gradual

recovery in operations in the territory. With face-to-face promotion across markets now tracking at 75% to 80% of a normal [indiscernible].

It should be reiterated that margins for the first 9 months of 2020 benefited from the sharp drop in commercial operations in the territories following the introduction of lockdowns and of social distancing measures over most of this period. Net income at €296.4 million increased by 8.1%, compared to the first 9 months of 2020, reflecting the greater impact of net financial expenses due to exchange rate losses of €6.8 million and the non-recurring tax benefit for €26.2 million recognized in Q2.

As you will see later in more detail, the first 9 months of 2021, we delivered roughly €352.9 million of free cash flow, an increase of around €70 million versus the same period last year, thanks to the increase in operating results and careful management of working capital.

Just a few words on sustainability rating. I am pleased to say that our continued focus on the ESG agenda results and MSCI rating improvement and inclusion in the Euronext MIB ESG index.

Consistent with our dividend policy, the Board has approved an interim 2021 dividend of €0.53 per share, to be distributed in November. Lastly, the Board today approved a share buy-back program to service stock option plans.

Before handing over to Luigi La Corte, who will provide you more details on our financial performance in this first 9 months, let me provide some more update on the Eligard and the endocrinology portfolio.

You can move to the next slide, please. So Eligard, the integration of Eligard is progressing well, with close to €59.4 million of revenue in the

first 9 months of the year, which is slightly ahead of the plan, and with just under half of this being direct sales of our organization. As of 30th of September 2021, the transfer of the marketing authorization of sales, licenses for Recordati occurred in most countries subject to the license agreement with Tolmar except for Russia and Ukraine.

We have 30 Marketing Authorization Transfers already completed, and 24 countries directly plus 6 countries indirectly selling, where Eligard is not being promoted with encouraging feedback from HCPs. It is very early days, but we are pleased to see the promotion has started since a few months, encouraging signs of changes in the sales trend, they were all getting market sales returning to growth in Spain and Germany, and improvements in other markets including France and Italy. The development of the new device by Tolmar is progressing, the new device regulatory filing now expected in the first quarter of 2022. Thanks to the early transition to direct selling, with focus fully on revenue just over €80 million in part due to the fact that transition to direct sales.

If we can move to the next slide, please. With regards to the endo franchise, the commercialization of Signifor and Signifor LAR is on track, recording net revenue in the first 9 months of around €58.5 million. We have strong new patient acquisitions in all regions and across all approved indications. And Signifor grew around 10% in in-market terms compared to 2020. We are also still very much on track with Isturisa launch and new patient acquisitions are progressing in line with our expectations, contributing to the net revenue of around €32 million as of 30th of September 2021, mainly in the US, France and other key EU markets.

We continue to have strong support from top KOLs and patient organizations. Reimbursement was agreed, the reimbursement price was agreed in Germany in line with expectations and discussions are ongoing

in other European markets. Also importantly, we have launched now in Japan where we are performing according to plan.

Furthermore, as economic conditions continue to improve, we are trying to see improvements also in the gross to net in the US. We remain on track to deliver on the target that we set for the franchise this year, which is between €120 million and €140 million.

So at this point, I will leave the floor to Luigi to take you through in more details on the first 9 months results. Thank you.

LUIGI LA CORTE: Thank you Andrea, and good morning, good afternoon, everyone. I'm pleased to as always take you through in more detail the financial results for the quarter. And on the back of another quarter of solid growth, much in line with the trends that we saw in the second quarter of this year, with the continued recovery of specialty and primary care portfolio, a good contribution of Eligard and strong growth of our Rare Disease franchise.

Starting with main product sales on Slide 5, and with what is still are a key franchise of lercanidipine, you will see that lercanidipine sales at roughly at €107 million was slightly up versus prior year, plus 1%, with good volume growth across markets and initial sales to our distributor in China, offsetting a slight decline in Italy and the FX impact on the Turkish business. Turkey accounting for roughly half of the decline on the combination product, Zanipress, which is also…continues to see some level of volume erosion due to a generic competition and competition from other combination products.

The metoprolol franchise are at €73 million and is down by 6%, now this is on the back of you'll recall strong growth in 2020, where metoprolol grew 7% also in part to due to a temporary lack of availability of

competitive-products in some markets and was seeing as a result, a slight decline in some geographies, in particular, in Germany and Poland this year. As Andrea said, Eligard is continuing to progress very well, the integration is on track and in fact it-has been running ahead of plan. Revenue in the first 9 months of €59.4 million include €26 million roughly of revenue that was recognized by Tolas and €33 million of direct sales by our own organization, with all of our key markets now selling directly, as Andrea said, the earlier transition to direct sales has allowed us to slightly increase the guidance for Eligard for the full year to now just over €80 million.

Silodosin and Pitavastatin clearly continue to reflect the full year impact of the loss of exclusivity in 2020. We do expect both products now to start stabilizing, you'll see the erosion on Silodosin just slightly higher than the one we had forecast at the beginning of the year, due mainly to somewhat higher decline in Turkey. Once again, in part due to the headwinds from a foreign exchange perspective in the market, I would add, it's great to see Pitavastatin still growing in markets where generics have not entered, namely Turkey and Switzerland.

Other corporate products at €198 million broadly flat versus previous year, and starting to recover. You recall, these are products that bore the brunt of the COVID pandemic, and the decline both last year and in the first quarter of this year. It's great to see the first signs of recovery of the cough and cold portfolio, particularly in Russia, which remains, however, still below the levels of last year and significantly below the levels of 2019. But in this portfolio, we're also continuing to see very strong growth of the GI portfolio you recall, significant impact in 2020 on products like CitraFleet and other GI products and ones related to elective hospital procedures all of those that started to rebound and grow high double-digits, and equally starting to see and continuing to see double-

digit growth of key products in our OTC portfolio, call out Procto-Glyvenol in Central Eastern Europe and Turkey. Good growth also Reagila all of these are growing double-digit year-to-date.

And finally, drug for rare diseases growing by 20% at €279.4 million, with very broad based growth, yes, a significant contribution from the growth of the Endo franchise of Signifor but particularly Isturisa, but also they are legacy metabolic portfolio, which is also growing. And I call out here actually Panhematin, which following decline in 2020, at the start of the pandemic, has actually returned to growth in the 9 months of this year.

And on Slide 6, you will see that with those results, rare disease now represents just over 24% of our total revenue, well on-track to achieve over 25% target that we set out in the 3-year plan.

On Slide 7, moving to…looking at revenue by geography, and I'll try and go through this and call out the highlights for each market. But overall and consistent with the picture that we described at the end of Q2. Thanks to Eligard, and thanks to the growth of rare disease. It's great to see most of our geographies this year starting to show growth with the markets, which have greater exposure to cough and cold and facing a greater effects with…effects headwinds being the ones, which are still showing a decline.

So starting with Italy, still our major market €195.8 million of revenue in 9 months a decline of 3.5%. And again here, cough and cold and continued erosion on Urorec being the main drivers, which more than offset the contribution of Eligard the growth of rare disease, and good growth also of Reagila and the OTC portfolio, somewhat similar dynamics in France, with a decline in the [indiscernible] OTC line, being more than offset in this case, by the growth of rare disease. You recall France being

the market where our launch of Isturisa is more advanced, and good performance of meted on again here, good first contribution from Eligard.

Both specialty primary care and rare disease are growing in Germany, which €111.7 million of revenue is up 11% versus last year Lercanidipine and Eligard that driving the growth on the SPC side, you know, combined with good growth of the rare disease portfolio offsetting a slight decline of metoprolol, as I said earlier,

Spain significant contributor to growth year-to-date 36%, just under €86 million of revenue. And here as I said earlier, Spain saw significant impact in 2020 on the GI portfolio, which is rebounding very strongly and offsetting the full-year impact of generic erosion on silodosin and Pitavastatin, with additional contribution both of Eligard and initial sales of Flatoril to the tune of €2 million.

Portugal sales of €33.5 million once again, with good growth of Reagila and contribution from Eligard, which offset the LOE impact from 2020.

Turkey, declined at 14.3% in Euro terms, but you will see is growing by 6.3% in local currency, Turkey facing significant FX wins this year, and which are likely to get even slightly worse in Q4, given recent trends, but nonetheless, in local currency terms growth driven by the rare disease portfolio, good growth of Pitavastatin and Procto-Glyvenol offset by generic pressure and local competition on some of our local product portfolio and under Lercanidipine franchise, together with a decline also in the flu portfolio as in other markets.

Going to Russia and CIS and Ukraine. You recall, we commented, Russia decline of 50% in Q1, it's great to see the business starting to recover and now down only by 5.5% in the 9 months in local currency terms,

reflecting the combination of impact on the cough and cold portfolio, which makes up a significant portion of the business in Russia, and also destocking, which we saw in the first part of the year. CIS and Ukraine slightly growing on the back of the rare disease portfolio.

U.S., which as you know is focused on rare disease continuing to grow significantly 42.6% achieving revenue of €127.5 million growth of 51.6% in local currency. And as I said earlier growth here really broad-based with the Endo portfolio clearly contributing significantly, a very strong growth of Cystadrops, [indiscernible] and Carbaglu as well.

Other Central Eastern Europe and other Western European countries, which combined make up for roughly 15% of our revenue, you will see are both growing by strong double-digits. And this is on the back of the ongoing rebound in specialty and primary care. And I'll call out the good performance of Procto-Glyvenol in Central Eastern Europe together with the initial sales from Eligard. And the continued growth of the rare disease portfolio here as well.

North Africa, minus 18.1% of revenue of €27 million. And here really it's a combination of factors…are in fact it masks the ongoing growth of our local business in Tunisia or [indiscernible] which is growing by close to 6% or 8% in local currency terms. But that is more than offset by restrictions in Algeria, which have held back our export sales due to the lack of renewal of import licenses, which do not allow us to sell Vitamin D3 an extra line to that market this year.

And finally, other international sales…so sales that we achieved through our distributors of €153.7 million down slightly by 3.5% versus last year, mostly reflecting the year-on-year impact of silodosin and Pitavastatin

plus a minor product discontinuation of [indiscernible] again to the tune of around €2 million.

And you'll see from Slide 8 you know the business says becoming growingly diversified or say growing the international with our legacy market Italy now accounting for less than 18% of revenue, France, Germany, and U.S. both roughly 10% of total pharmaceutical sales.

Moving through the P&L, on Slide 9, you will see that…growth of both revenue at 5.7% or 8.6% at constant exchange rate, and in gross profit as planned is partially offset by the growth of operating expenses, SG&A expenses of €347.1 million growing by 11.8% versus 2020. With selling cost at 24.8% of sales reflecting both transition costs on Eligard and the royalties that are paid to Tolmar on the product, which account for roughly €18 million of increase and also with the growth in spend driven by the additional support behind the Endo franchise and gradually return to activities in the field, which however on a year-to-date basis still remain below pre COVID-19 levels.

R&D expenses around 10.4% of sales are up 12.6%. This reflect the continuation of studies, which we've inherited from Novartis on the Endo franchise and also additional resources and span the market access and regulatory cost behind both Endo and Eligard, an increase also reflects roughly €2 million incremental amortization costs related to new products.

Other income and expenses of €3.5 million mostly reflect €2 million…just under €2 million of nonrecurring costs related to COVID, significantly down versus last year and hopefully due to wind down in the near future. This leads to an operating income of €372.9 million, a margin of 32.3% and EBITDA of just under €448 million and margin of 38.7%. Both growing by just over 2 percentage points versus last year, and with

margins remaining very healthy, but of course, not at the levels of 2020 and we've always said then, recognize that margins in 2020 were enhanced by the impact that COVID had on the revenue, but also on operating expenses. And we do expect that as activities in the field continue to resume, EBITA margin will trend towards the target that we set in the guidance at the beginning of the year of just over 38% for 2021.

Looking finally, briefly at the non-operating lines, you will see a significant increase in financial expenses to €22.2 million. As Andrea mentioned, this reflects FX losses of €6.8 million in part due to consolidation adjustments due to the volatility in exchange rates and couple of million due to FX losses on hedging of intercompany transactions. This compares to a period in the first 8 months of 2020, where we actually recorded €2.6 million of exceptional gains, if you like on 2 currency swaps, which we closed and which were no longer treated as the hedges. These additional FX losses are more than offset obviously by the non-recurring tax benefits of €26 million, which we incurred, which we recorded in Q2 and which reflects in a net income of €296.4 million, which is growing by 8%, just over 8% versus 2020. Adjusted net income which reflects the impact of the FX losses, but strips out the non-recurring tax benefit, is down by 1.3% versus last year.

And moving over to Slide 10, you will see again, once again, margins on both businesses remain very strong, with rare disease now representing close to 30% of Group EBITDA. And finally, on Slide 11, as we've done in the previous 2 quarters, will include a summary and breakup of our cash flow performance, which hopefully you will see was very strong in the first 9 months of 2021 with free cash flow of just under €353 million, up by close to €70 million versus the first 9 months of 2020 and over 100% of net income in the period.

This and the improvement versus last year were really driven by working capital, where 2020 was impacted by a combination of increases in inventory, both due to the start of sales of the endo franchise, but also as we worked to build safety…additional safety stocks at the beginning of the COVID crisis. It also reflected the timing of supplier payments with both of those contributing to the positive performance in the first 9 months of this year. I will point out, you will see that actually on a cash basis the interest paid is broadly in line with last year and income tax paid slightly higher due to the benefits in 2020 of both the 2019 significant non-recurring patent box that we recorded in Italy and also lower payments on accounts, which many governments allow companies to make in the midst of the COVID pandemic. That free cash flow was…went into dividends of €109.4 million in the first 9 months. We paid €35 million in total and €15 million to Almirall and a net…we had net purchases of the shares to the tune of €29 million net of receipts from proceeds, from exercises of stock options.

And finally from my title Slide 12. That strong cash flow contributes to a very solid net financial position at the end of September with net debt of just under €715 million being roughly 1.24 times trailing 12 months EBITDA.

And with that, I'll hand back over to Andrea to talk about the outlook for the remainder of the year. Thank you.

ANDREA RECORDATI: Okay. Thank you, Luigi. Please turn to Slide 13 of the presentation. So with respect to our full year outlook, we confirm like we said in the press release, our guidance range expecting the full year results will be lower end over range. I remember the guidance range was giving the net revenues between €1.570 billion and €1.620 billion. EBITDA was between €600 million and €620 million and adjusted net income between

€420 million and €440 million. The underpinning assumptions behind this lower end of the range guidance are basic that the recent trends show FPC returning to growth, through momentum and progressive recovery of market conditions post Q1.

However, rebounding the cough and cold market is unlikely…portfolio is unlikely to fully offset the higher impact in the first part of the year, coupled with obviously the market headwinds that we've seen in Central Eastern Europe and Turkey. Also, we assume no significant new waves of COVID restriction in the latter part of the year.

FX headwinds are a bit worse than what we actually planned at the beginning of the year and we plan…we expect to fall in between minus 2 and reflected in 2% or 3% negative impact. But on a positive note, as already mentioned, Eligard continues to be on track ahead of plan and also, we continue to see robust growth of our rare disease franchises across all regions, clearly driven primarily by the Endo, but not only also our metabolic portfolio is actually performing very well, for example, also kind of dynamic and like mentioned by Luigi before. EBITDA margin is on track to be above 38% on revenues. The second half reflects seasonality as well as return to a higher level of activity in field. Financing cost of around €28 million are expected with reflecting clearly what we mentioned already, but between €6 to €7 million of FX losses.

And finally, we expect the tax rate to be around 17%, reflecting the planned actual benefit from reverse merger and additional Q2 non-recurring benefit of €30 million from a Magnesio Supremo step.

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

Q&A

OPERATOR: Excuse me. This is the Chorus Call conference operator. We will 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 while asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Brian Balchin of Barclays Bank. Please go ahead.

BRIAN BALCHIN: Hi, thanks for taking my questions. I just got 2. First, I was hoping to gauge your confidence levels and achieving your 2023 endocrinology targets just given an expected increase in penetration of [indiscernible] in 2022. And the second one was just if you could give us an update on timing, the approval of ARS-1. And then, if we should still be expecting data for your neurotrophic keratitis as at second half of '22, trials [ph].

ANDREA RECORDATI: Yes. So thank you, Brian. Starting with the with the first one. The level of confidence on the 2023 guidance on endo, we see no reason to change that, frankly. And we think we're on track. We're going well, and we'll continue to see growth of Signifor whilst increasing penetration of Isturisa, we said, we will start achieving reimbursement in the European markets, just about now we're doing that. So from our perspective on endo, we are on track.

In terms of ARS-1. I mean, the product is currently…you know, currently under regulatory review by the European authorities. And we are working with Tolas to kind of answer some of the questions that came up from the said authorities. So the report is ongoing with some delay compared to the

original plan, but based on the current planning, we expect the regulatory decision to be made in 2022.

Regarding MTAs**,** for neurotrophic keratitis, as you know, it is in Phase 2, it has already suffered some delay in recruitment due to the COVID restrictions that impacted, a lot of the centers where we were actually recruiting patients for the study. But the study is ongoing, we are recruiting patients and we're seeing an increase in the patient. So we expect another lot of patients in around November of 2022, and the clinical study report out by the second quarter of 2023.

BRIAN BALCHIN: Okay. Thanks so much.

OPERATOR: The next question is from James Gordon of JP Morgan. Please go ahead.

JAMES GORDON: Hello, James Gordon, JP Morgan. Thanks for taking the questions. I have 2, 3. The first one was just slightly how was the deal making and to what extent is COVID-19 slowed things down a bit, and hopefully things get better there. To what extent do we see an acceleration of the in-licensing and what do you see as the ability to do in-person diligence that makes a difference? And could that change?

And then, the second question was just heading into 2022, we are not looking for specific guidance at this time, they key person [indiscernible] for us to think about. How much rebounding field activity could we see and how much of a headwind could that be, and is still like a flat EBITDA margin still the mostly likely outcome?

ANDREA RECORDATI: So look, I mean, we are making a…the connection was not very good. I apologize but tell us correctly you are asking me if there were any kind of impact on deal making due to…in recent times. I mean, as you know, you

know, the ambition remains. We keep on working on slightly of different doses, for in-licensing opportunities in FCC [ph], but also in rare disease and clearly also the whole M&A, you know, part of our strategy is still valid and is obviously being, you know, remains very ambitious. So we are, like I said, in June, we have a lot of potential build under reviewing and evaluation. We feel that the pipeline is reaching opportunities at the moment, but you know, giving us always treated to be definitive on timeline and at this moment in time honestly, I cannot give you any more information, I cannot say anything else at this stage. But believe me, we are very busy reviewing and assessing many, many opportunities.

LUIGI LA CORTE: And James, on your second question in terms of…Andrea I think mentioned, we are now ready sort of running at 75%, 80% in terms of field activity. Actually, we are still seeing, you know, the kind of things we are still not seeing is sort of large scale events and sort of group gathering. We will look to…I think as many organizations, we have learnt to leverage even more digital over the pandemic. We are not going to give out today sort of margin guidance for 2022. You will have to stay tuned for that. We did…we are very clear in terms of where we set the guidance for the 3-year plan being, you know, around 38% of EBITDA, and I will stick with that and, you know, we will provide sort of a more crisp view for 2022 presumably in February when we set out the target for the year.

JAMES GORDON: Thank you.

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

MARTINO DE AMBROGGI: Thank you. Good afternoon everybody. Sorry to bother you on the same question on M&A, but you were particularly vocal in the last call and you are today. So I'm just wondering if you can provide us just a

qualitative perception of some step ahead if any. I don't know on the very busy pipeline that you mentioned? This is my first question.

ANDREA RECORDATI: Martino, obviously, I cannot give you are lot of color on something that has not been kind of, you know, finalized yet. I mean, we are a listed company as you know. So I reiterate what I said. Yes, I was vocal in July when we had, you know, the last call, and I'm still vocal now, but it depends you know. Deals are very different in shape. There is a lot of, you know, variables to be taken into account. So I can tell you we are working on various fronts and when the time will come to communicate something we would do so. But at this moment in time, I cannot give you more color on this for obvious reasons. Thank you.

MARTINO DE AMBROGGI: Yes, obvious reason, yes. The second question is on the Endo franchise. If I look at…I know very well profitability on a quarterly basis doesn't make a lot of sense, but if I look at the last 4 quarters, since you start sales of Isturisa, profitability of rare disease is a little bit lower than what it used to be in the last couple of years. Is it due to the launch costs or just, I don't know, temporary effect of some variables or probably just there is no particular reason justifying it?

ANDREA RECORDATI: Hi Martino. No, I mean it's a combination obviously…I mean, we are in launch phase on the Endo portfolio. So as you would expect, you know, we have addition of the equity to additional resources on the ground to support that, and we do have sort of the costs that we are taking on of additional both market access and regulatory resources to support that, particularly where we are going into sort of new markets. I would say, and I think we may have touched this on the previous call that if you are comparing the evolution to, you know, last year the Endo…the rare disease margin would have been slightly flattered, but when doing the first part of 2020 by the accounting of the Signifor revenue during the

transition from Novartis where we accounted for it on a sort of growth margin level at the level of net revenue. So there is a little bit of that which is similar to what we have this year on Eligard for the SBC side. If you look at it on aggregate, the 2 kind of balanced each other out, but if you are looking at rare disease particularly, there is a little bit of an effect of that, it's a combination of these factors rather than there being any sort of particularly other type of reason.

MARTINO DE AMBROGGI: Okay. Just to check if there is nothing structural due to the Endo franchise development.

ANDREA RECORDATI: No, you know, the Endo franchise, of course, you know Isturisa [indiscernible] but on the other hand the U.S. is significant growth market and this is often the case margins in the U.S., tend to be higher than in the rest of world. And so, you know, I do think there is nothing structural to that. I think it's really a timing again which is…I think I have often commented enough around the margin guidance. We have to bear in mind that when we take a launch asset, you know, the first year of the launch you will see a bit of an additional investment going into the business.

MARTINO DE AMBROGGI: Okay. And last on the Endo franchise, you guided for 120, 140 sales this year. Looking at the trend, you are perfectly in line with your guidance, but I see quite hard to achieve the high end of this range. I totally ignore what could be the contribution of Japan?

ANDREA RECORDATI: Yes, I will give specifics in terms of where we expect to land on the range. Again, particularly in the case of the Endo portfolio where there is a significant contribution from the U.S., you may recall U.S., faced quite some headwinds in terms of FX at the beginning of this year and still if you look on a sort of year-to-date basis, I think it's around sort of 8% negative from an FX rate perspective if you isolate the U.S. So again,

obviously, there is a little bit of that in there. But as we said, we are very happy with the progress so far with other launches crackling and confident we will hit the range that we set out at the start of the year.

MARTINO DE AMBROGGI: Thank you. And very, very last on the free cash flow. It is mainly driven by working capital change. As I understand it's just one off so there is nothing in structural on the working capital that could last for a longer period?

ANDREA RECORDATI: I think I was asked the question…I think I had a question on the call at Q2 where someone was, you know, asking whether we would start seeing working capital sort of trend back to more historical level. Again, we did increase level of stocks a bit last year just to be on the safe side during COVID and you're starting to see a little bit the reabsorption of that as supply chain improves. And again, there is a little bit of yes, one-time event where many of our suppliers in 2020 did ask to work with slightly shorter payment terms in our side to provide some support during COVID which we are happy to do given the flexibility that the group has.

MARTINO DE AMBROGGI: Okay. Thank you. Thank you very much.

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

JO WALTON: Thank you. A few questions. A simple one to start with is to why the new device for Eligard isn't filing until next year, I think we originally thought that would be happening by September, October time? More broadly, I wonder if you could tell us just a little bit about your view of the background to the market. An awful lot of the European markets that you are in are effectively government funded. Governments are increasingly strapped for cash. Are you seeing any signs of, you know, any constraints, any issues in pricing new product? Some of the companies have said that

it's getting tougher to get new product pricing through and I know you have been looking for reimbursement of Isturisa. Perhaps, you could talk particularly about Turkey as an example because that seems to have some problems. I know some of that was foreign exchange related. Do you think that foreign exchange problem will ultimately mean that the Turkish government becomes, you know, less generous? Could this become, you know, a longer term issue?

My next question would just be a quick one on your comment about stabilizing for Livazo Urorec? You know, we've seen decline rates are sort of 30% or so. When do we think we could go back down to maybe only you noted a 5% decline? Is that reasonable for next year or do you think that the decline will continue for longer? And my final question on Isturisa, at the Capital Markets Day, you indicated that you thought you might have 145 patients' starts on Isturisa in 2021? Are you still on track for that number? Thank you.

ANDREA RECORDATI: Okay, Jo, thank you for the questions. I may take them in just slightly different order, if that's okay. So, in terms of challenges from government funded systems, again, I'll probably repeat what I said in other instances. At the moment, we're certainly not seeing a sort of broad-based sort of landscape change across payer markets in Europe nor in the U.S. for that matter. You know, pricing is still very much decided at country-by-country level, which provides a natural hedge in the sense that it would take all market, and suddenly all countries suddenly to coordinate to as to suddenly lead to a significant impact. I know that Turkey on the backdrop of...usually the Turkey does allow, and we did see it last year, I mean, in the phase of significant devaluation of very last year, you know, Turkey did allow…is generous…it did allow a level of price increase to the industry, which didn't quite fully recover the effects devaluation, but recovered quite a chunk. We'll find out in the next month, if they'll do that

again, this next…for next year. But we don't have reasons to believe they wouldn't. I think they may have put in place some limitation on prescriptions of certain product classes, but they only impact certain product type. So again, it's difficult to generalize negotiating prices for new products, it's always been difficult in Europe, frankly, unless you come forward with a very strong innovation and significantly better clinical proposition relative to existing standard-of-care. We believe on the case in point that Isturisa does that. And we think that was recognized in Germany, but again, it will be a country-by-country negotiation.

On the ROEs, we really…we actually, I think if you look at the numbers, you would see that I think what you see there is a year-to-date erosion, if you look at quarter-on-quarter, you should start…you should see that on silodosin and Pitavastatin it is starting to significantly reduce the decline. Silodosin has now fully lagged [ph] the year. It did have a little bit of FX headwind in Turkey. And slightly higher erosion in Italy, but by and large is stabilizing as is…as we expect Pitavastatin will be.

So to your question, yes, absolutely we do expect those to start stabilizing now and certainly for 2022 on the basis of current environment. I think I must tell that's contracted and I don't recognize the 140 number of patients, but maybe I answer in a different way. We believe that to be on track in terms of patient acquisitions in the U.S. And obviously, we were aware of competitor products in pipelines when the guidance was given out. And so, of course, we will prepare for the potential launch of new competition in the U.S. But we're quite confident with the clinical profile of Isturisa and very happy that we will have had at least a 2 year advantage to penetrate the market, which is always good.

On the new device, I don't know what I can say. Yes, I think as we said, very happy with the Eligard transition, the multiple dosages that are

undergoing all the due process to prepare the file. And it just looks like it's going to take us [indiscernible] a little bit longer to be ready for that, but we don't anticipate it being an issue frankly, it's just going to take a little bit more than I had anticipated. I hope that addressed all your questions Jo.

JO WALTON: Yes, just one final one, if I could, just to go back and push you a little bit on marketing. You said that you're 75% to 85% of the way back in terms of field force activity? Do we expect that that will go back to 100% or are there things that you've learnt in COVID world that mean that something that you now do you perhaps digitally, that you did in person before you'll continue to do digitally? So just wondering whether there will be a full rebound back or whether there's some permanent cost savings'?

ANDREA RECORDATI: No, I think I mentioned, Jo, we don't expect that things will go 100% back to normal. And you know, we're all sort of looking at that also as we think about 2022. But the reality is that we've seen that the business particularly in mature products can be supported with slightly lower level of infield effort and complement that with digital, and we will be looking at that and certainly will continue…we'll look at the opportunity that provides. So things will not go back to fully 100% just like, and again, I think I've made the example before, I wouldn't expect as much spend on things like international conferences, really national conferences and events as once was the case. I imagine a lot of that will be digital going forward.

JO WALTON: Thank you.

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

GIORGIO TAVOLINI: Hi, good evening, everyone. And I have 3 questions on my side. During the presentation you were mentioning the Panhematin in the U.S. I was wondering if you can provide more color on the legacy metabolic products Panhematin in the U.S. Carbaglu in Europe.

The second is on the patent box for the next few years. Are you considering the option to extend the patent box for next year's according to the regime, new regime introduced by the Italian government that allows revaluation of the brand costs up to 90% for tax purposes? And the third one is on cough and cold impact. You expect the €40 million impact on sales for this year in the Business Plan presentation. What was the impact today? And what are your expectation on Q4 in terms of flu market products? Thanks.

ANDREA RECORDATI: Okay. So on…the first 2 questions. As you know, Giorgio, we don't give out sort of specific revenue by product on rare diseases for commercial reasons. But on Panhematin in U.S., I would say we're very happy that whilst the product…you recall, we commented in 2020, we had a plan for a very gradual erosion, because we believe that we still believe that Panhematin will continue to be an important treatment option for patients even in the phase of competitor launch in the U.S. And unfortunately, where we saw erosion in the first part of 2020 higher than expected due to the impact that COVID had, which penalized an infusion product like Panhematin relative bit more significantly than expected, and we're very happy that we've seen that bounce back, we already saw that stabilize in the back end of 2020. And very happy that we've actually seen that return to level of sales, which is actually ahead of last year in the 9 months and actually on this big credit to our team in the U.S. is doing a fantastic job in really revitalizing the metabolic franchise.

Carbaglu in EU, I mean, it's a product that has been, as, you know, it's a very mature product and face the competition now since years. And has continue to perform well. But again, I think, we've said in our 3-year plan presentation not expecting significant growth from that….

LUIGI LA CORTE: We are seeing a stabilization.

ANDREA RECORDATI: Yes, absolutely, yes. On the patent box in Italy a short answer, yes, we will be looking at the option. And we've kind of secured our options around that. So we're looking to sort of continue taking benefit. As you know, we think it's a little bit up in the year in terms of right now what exactly that means. But the short answer is yes, we believe at this stage, we should continue to benefit from that. But we're going to have to see how the recent decree sort of whether or not it gets confirmed in the same format they published a few days ago.

On the impact of flu, we're still running, even though we've seen a nice recovery in Q3. Unfortunately, our flu business is overweight in markets, which…where wearing of mask is still prevalent, and it's still down versus 2020 and still running at around 60% of the 2019, levels. But, you know, we are seeing good signs. We are seeing good signs of recovery in Russia. I hope I have addressed your questions, Giorgio.

GIORGIO TAVOLINI: Yes, thanks a lot for your answers. Thanks.

OPERATOR: The next question is from James Vane-Tempest of Jeffries. Please go ahead.

JAMES VANE-TEMPEST: Yes, hi, thanks for taking my questions. I had, just one actually, can you remind the sensitivity of the business to foreign exchange, I mean, you mentioned currencies a little bit less and sort of and finally you said

it's around 2% to 3% and from memory, I think it was roughly 1.5% per year planned in your Business Plan. So, if we just say for example, it's an incremental 1%, you know, if say, €15 million impact of the top line and is that sort of at half of EBITDA levels, so that's like for €8 million impact to the EBITDA levels, just to help us kind of understand if it is more the low end, how much of that impact is being due to FX versus overlying reasons? Thank you.

LUIGI LA CORTE: Hi, James, so first of all, just to clear in terms of the FX impact that you see here, a lot of that has been due to the evolution of the tax particularly early course of 2020. And then the sort of full effect that that has over the course of 2021. You know, the way things are looking at the moment, it's certainly going to be higher than the sort of 2 percentage points that we sort of foresaw at the beginning of this year probably are not as high as 3%, with the big driver of that being the Turkish lira, relative throughout the expectations that we had which were affectively the one that sort of consensus FX rates at the beginning of 2021.

In terms of the modeling the impact of sort of 1 percentage point on revenue, on the bottom line, I think the honest answer on that one it's going to be…I will get back to you, I don't have a precise number in mind, there is a level of hedge obviously, particularly when it impacts in places like Turkey, because as you know, a significant part of our portfolio in Turkey is also locally produced, but it's not all of the portfolio. And so, whether it's a half or a bit less than a half, I will have to get back to you, but it's certainly not a 100%.

JAMES VANE-TEMPEST: That's great. Thank you.

OPERATOR: The next question is from Katerina Tchakalski with Blackrock. Please go ahead.

KATERINA TCHAKALSKI: Hi, so can you give me a guidance of to what extent you are seeing any inflationary pressures from labor, raw materials, or logistics that other industries are seeing? If you could just give us an idea of how much of your COG base is, each one of these, the labor, the logistics and the raw materials, if they are significant at all, which we have heard some CDMOs [ph], most talking about some packaging material, significant inflation because of oils, and because of, you know, wood based materials that they are planning to pass on to, Pharma companies, so I was wondering how, to what extent are you affected by that? And also, can you…talk a little bit about negotiating prices for new products, but to the extent you've seen massive inflation, what is the mechanism for you to pass that on to these countries with whom you have a negotiating price or reference price?

ANDREA RECORDATI,: So, thank you Katerina, and to be honest, so I can point you to the development pages of sort of our earnings release for detailed points around the sort of details of our cost base between labor, materials and other. The short answer though is that, for this industry, you can't compare it to a CMO, frankly our P&L structure is completely different. And we see a inflationary pressure, that we see a little bit, but frankly it doesn't impact a Pharmaceutical company as significantly as a CMO certainly and other sectors. And also, being [indiscernible] pricing, I mean and the industry is certainly not comparable to other industries either. I mean, we have flexibility in OTC [ph], we have flexibilities in some markets, you know, Russia, and Turkey, a little bit in the US, but, you know, we have always taken also a prudent approach with pricing, its being a sensitive topic in the industry. So, yes, there is a little bit of pricing power.

But, at the same time we don't really see an increase, we are subject inflationary pressures that other sectors is if you are comparing us to very

different ones, but we see a little bit of pinch on that, in cost of goods next year, yes, but if you look at, you know level of stocks relative to purchases and raw materials is, you know, north of 6 months. So, that will provide some buffer as well, and we would tend to fix energy contracts for a relative long period time, and what's where you seen a lot of inflations, so long answer to say, I am not sure, it's going to be as relevant for us as other sector you maybe following. I hope that I gave you at least some flavor, and again, to the extent that we publish data externally, we can point you to the numbers in the financial reports.

KATERINA TCHAKALSKI: Okay. Thank you.

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

ISACCO BRAMBILLA: Hi, good evening, everybody, a couple of questions from my side. The first is on Eligard, it looks like the integration is proceeding very well, and can you give us a figure of the trend in market sales for Eligard such as you have been doing for Signifor over the last year. And also probably if you could comment on how this is comparing with the underlying trend of the reference therapeutic area? And second question is on the M&A arena, I appreciate you cannot disclose much on your intent, I mean if applying that how are the multiples evolving in the industry, are you observing any kind of a pressure on acquisition multiples due to the presence of the new players interested in consolidating or acquiring assets in the industry? Thanks.

LUIGI LA CORTE: So, in terms of your first question, not sure, I followed it, but on Eligard, relative to it's a reference market and like-for-like, I think as we shared, in our three-year plan presentation, you know, Eligard, due to the lack of support, that was a product that was gradually declining in a market that

was sort of broadly stable. So, you know, losing a little bit of share, it is very, very early days, so we are not going to get over excited quite yet, but as I Andrea, said, we are very pleased with the early singles of what we see in markets where the promotion as already started, since early month of this year, in terms of…it is stabilizing or actually seeing some growth of the products. And as we have always said, we expect the new news of the new device next year to act a further catalyst to that, but you know, as I said very early days, I mean the trend overall is still broadly in line with the trend of the last few years, or with the product, you know, slightly underperforming its relevant market. But, where we are starting promoting, we are starting to see that picture change, but again, it's very, very early days, and so to be taken with caution for the time being.

And sorry I didn't make. And maybe I will add my voice to Andrea so that's easier for me. I don't what else that we can say, I even say that we are in actively in due diligence on a number of opportunities. But, the beauty of the game is that until you sign the deal, you don't know if and when you will have a deal and there is no point trying to speculate on timelines, you know, frankly or if and when things will happen, when they do you will hear it, before then, you will continue to hearing this kind of response.

ANDREA RECORDATI: And on the multiple side, and so forth honestly we have always had competition on assets, in the past and we haven't seen any drastic change, you know, on just competitive aspect. So, yes, I mean there has always been competition, some people are willing to pay in the higher multiples, others are not, but nothing has changed from the past, honestly.

LUIGI LA CORTE: And also fresh from linking with some banks, suggesting that when you look at multiples in the sector, that's has come down an little bit in the last few months. So, you know, it'll always be very specific to the asset.

ISACCO BRAMBILLA: Okay. And very clear, many thanks.

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

ANDREA RECORDATI: Okay. Thank you, everybody, for participating in this call. And have a good day…evening for rest of the day. Thank you. Bye-bye.