Recordati S.p.A.

"2020 First Half Results Conference Call"

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

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

MARIANNE TATSCHKE: Good afternoon or good morning to everybody, and thank you for attending the Recordati conference call. Andrea Recordati, our CEO; and Luigi La Corte, CFO, will be presenting our first half 2020 results. For a better understanding of this presentation, please access the set of slides available on our website, www.recordati.com under the Investors Section and presentations tab. At the end of the presentation, we will answer any questions you may have.

Please go ahead, Andrea.

ANDREA RECORDATI: Okay. Good afternoon, ladies and gentlemen. So as Marianne just anticipated, we're here to discuss the first half 2020 results. So if I ask you to please move to Slide 2 of the presentation, first half highlights. So despite the first half having been impacted by the COVID-19 epidemiological emergency, net revenues increased and both operating income and net income grew significantly, now in line with expectations, thanks to the positive contribution of new products and the reduction of expenses. As you can see, revenues are up by 2.3% and includes €32.8 million of revenues from the sales of Signifor and the initial sales of Isturisa.

EBITDA is €311.1 million or 40.9 percentage of sales, growing over previous year by 11.4%. Net income grew by 13%, and adjusted net income at €225.6 million, grew by 16.8% and is now 29.7% of sales. Net revenues in the second quarter was impacted by expected destocking, as we mentioned at the end of the Q1 call. And furthermore, this quarter saw an intensification of the impact of the COVID-19 pandemic in all geographical areas in which the Group operates, leading to weak demand, which particularly involved non-chronic therapies in our specialty and primary care portfolio.

Although pharmaceutical operations were allowed to continue in order to ensure the availability of drugs for the population, the restrictions implemented by the local authorities inevitably affected our markets, mainly due to, for example, fewer visits to doctors since our sales forces obviously were not on the field; and, obviously, diagnostic procedures carried out by doctors and lower patient traffic in pharmacies, lower consumption of OTC lifestyle products such as vitamins and supplements, a reduction of clinic and hospital procedures as well a lower incidence of mild infectious disease resulting from the diminished circulation and interaction between people.

However, the impact on net revenue was more than offset by a favorable product mix and a reduction in operating costs, leading to continued double-digit growth in EBITDA and adjusted net income, with further improvement in margins. Net debt at the end of June is €922.4 million compared to a net debt of €902.7 million at 31st of December 2019, reflecting strong cash generation of around €189 million before milestones and net share repurchases and dividends paid.

We are very pleased with the strong revenue contribution from Signifor and Signifor LAR and are also very encouraged to say relieved [ph] by the early signs on the Isturisa launch in the U.S. and France. With Isturisa clinical benefit now being also confirmed by the LINC-4 study, we see potential peak year sales forecast of €300 million to €350 million for the product in the current indication or with the current indication and in our current geographical footprint.

So moving to Slide 3 to give you a bit more color on our...on Signifor and Isturisa. So the commercialization of Signifor and Signifor LAR is on track. The marketing authorization was transferred in March in the U.S. and Japan in May...in the U.S. and Japan, sorry, and in May in the EU. The market...Novartis transferred the distribution of the product to Recordati in most major EU markets during June and July with the transfer of distribution in smaller CEE markets to take place during Q3 and Q4. We have new patient acquisitions in the U.S. across all approved indications. And the first half 2020 growth of in-market sales is estimated to be above 10% versus the previous year.

Moving on 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. We are pleased with the early performance of Isturisa in the U.S. and the EU as it's trending in line with our expectations. The first commercial shipment in the U.S. took place on May the 16, and we have strong support from top U.S. KOLs, patient organizations and an effective market access strategy. Regarding Europe, we launched in France in early June, Germany in mid-July, just a few weeks ago, and in Italy, we expect our first patients under early access any day now.

This encouraging early patient uptake is thanks to new patient acquisitions and the transition of patients from our early access programs. We're estimating our 2020 net revenue to be above €10 million, and this is mainly coming from the U.S. In addition, we are very pleased that the Phase III LINC-4 trial met its primary endpoint in Cushing's disease confirming the strong clinical profile of Isturisa. We also submitted to the NDA in Japan in March, and we are targeting to launch sometime in the second half of 2021 in this market.

Finally, we expect Isturisa to achieve a leading market share with peak year sales estimate, as I mentioned before, between €300 million to €350 million and potential further upside from the expansion of indications to Cushing's syndrome in the U.S. and through our geo expansion strategy in new territories. As announced in the Q1 results call, the plan is to give further color on the potential for Isturisa going forward at the presentation of a new 3-year plan in early 2021.

So I think we can now move to the presentation on Slide 4, which comments our corporate products, and I will pass it to Luigi to take you through the rest of the presentation. Thank you very much.

LUIGI LA CORTE: So thank you, Andrea, and, again, good morning and good afternoon, everyone. So as usual, I will start by giving a little bit more granularity on our revenue performance and starting with product sales. And I think the slide actually gives...illustrates well the different impact that the pandemic had on different parts of the portfolio, with chronic therapies continuing to perform well and impacts are more felt in the acute and lifestyle medication.

You see growth of Zanidip, Livazo and Seloken all continues strongly. Growth of Zanidip of 16.6% was particularly strong, driven by growth in

Nordics, Germany, Italy, but a very strong growth also in our international markets, also on the back of some shortage of generic products. Pitavastatin growth was driven by Russia, Spain, Greece and Turkey. And Seloken growth was driven by Nordics, Poland and other Central Eastern European markets where we've established our footprint more recently.

Zanipress decline was really driven by impact of new measures introduced in France at the beginning of this year, which favor the adoption of generic option. Urorec decline is very much in line with expectations, reflecting the entry of generics in Q1. In fact, in Urorec in several markets, our market share has been holding up well and slightly better than expected. Again, here, this is offset by somewhat higher erosion in France, following introductions of those measures that I've referenced earlier. So stronger growth of those product...medication products.

Other corporate products, which includes OTC, is really the part of the portfolio, which bore the brunt of the impact of COVID-19 with a decline really driven by 5 products. CitraFleet in Spain, which is a product used to prepare patients for colonoscopies, clearly was impacted by the effective stop of elective procedures throughout many of the markets, but particularly impacting in Spain.

Our cough and cold portfolio, particularly in Russia and Central Eastern Europe, was impacted by the lower incidence of seasonal flu and normal pathologies, which particularly impacted revenue of Isofra and Tergynan. And we also saw an impact on Casenlax in Spain and some of our probiotics line, Bioralsuero in particular, which led the decline of 7.8% in corporate products.

Within that, there are positive news as well. Reagila sales almost doubled in the first half relative to prior year, close to €6 million, but slightly

below our ideal trajectory. Again, their sales slightly held back by the lack of ability to interact face-to-face during part of the quarter.

Revenue of rare diseases clearly grew strongly. Clearly, the majority of the growth came from the growth and the contribution of Signifor and Isturisa. But our base business grew, existing business grew as well. We had in the quarter good growth of Carbaglu, Cystadane and Cystadrops and Juxtapid in addition to the contribution of Ledaga. This was, however, partially offset by a decline of Panhematin in the U.S, which is the one product in the rare disease portfolio, which did feel an impact from the COVID pandemic been put clearly at a disadvantage over the period of lockdown versus the new competitor entry, given Panhematin's need for infusion. It shows stabilizing...signs of stabilizing in June, but we did suffer from patient traffic to clinics and hospitals for infusion reducing.

So again, mixed different impact on different parts of the portfolio with chronic therapies growing...continue to grow strongly. Page 5, looking at the composition of our revenues. To highlight here, clearly, the growth of our rare diseases, which now accounts for 20%...just over 20% of revenue, up from 18%. With, on the other hand, OTC and other corporate products, which, as I said, are the areas where we felt more of the COVID lockdown impacts, both declining by just over 1 percentage point relative to prior year periods.

Looking at revenue performance by key geography on Page 6. Again, here, different growth profiles, which reflects the diversified portfolio of the Group in different markets. Revenue in Italy was down by 4.5%, reflecting, to a large extent, the erosion from generic entry on Urorec and also continuing erosion from generic competition on pantoprazole and lovastatin, which we started seeing in the second half of 2019, which

offset continued good growth of Cardicor, lercanidipine, again, through products for chronic therapies and good growth of Reagila.

As mentioned already, France revenue decline of 5.5%, driven by the impact of new Article 66 measures on lercanidipine-based products and also driving somewhat higher erosion than previously anticipated on Urorec offsetting a good contribution of clearly the rare disease portfolio, which benefited also Italy and good growth of Methadone. Germany was somewhat less impacted by the ongoing pandemic, with revenue broadly flat, with good growth of Claversal, lercanidipine and the good performance of our OTC portfolio, offset by generic competition in tenders on Ortoton.

U.S. revenue, which in local currency, was up by 13%, clearly is driven by the additional sales from Signifor, initial sales of Isturisa, good growth of Carbaglu and Cystadane, but, again, also reflecting erosion on Panhematin. Russia and CIS and Ukraine, really amongst...together with Spain are the 2 regions, which most felt the impact of the ongoing crisis, both for the impact that they had specifically on the cough and cold portfolio, which I've referenced, but also being economies which are...been more severely impacted by the ongoing pandemic. Good growth in those regions of Zanidip and Livazo are helping to assess the part of the effect.

Turkey on a local currency basis that continues to grow in double-digits, 14.3%, with good growth across the portfolio, both of our corporate products and also of our local product portfolio. Clearly, still not growing at the rate similar to those of...to that of previous quarter. It's a very...Turkey is a very promotional sensitive market. Our field force is off the field for a number of weeks, but now is back at work as of the month of June.

I've spoken to Spain. Portugal, less affected and delivering growth on the back of good growth of Livazo and also contribution from the launch of Reagila at the beginning of the year. And you see at the...at the bottom of the page in the, let's call it, newer markets, Western Europe, which includes the Nordics and the Benelux, Central and Eastern Europe, which includes the Baltics, Romania, Bulgaria, countries where we've established more recently our own direct selling organization, all growing still nicely, really driven by the growth of metoprolol in those markets and other products which we are now supporting directly and, clearly, the contribution as well of rare diseases.

North Africa growth driven by our Tunisia business on the back of really strong local growth of close to 17% and international sales reflecting continued growth of lercanidipine international markets, but also, once again, the contribution of rare diseases and Signifor in particular and also Juxtapid and more broadly our rare disease portfolio in Japan.

Switching to Slide 7, and if you look at the geographical breakdown of revenue, clearly here, we see a slight increase in the share of the revenue, which arises from the U.S. and an increase, though, particularly to 16.3% of revenue, which comes from those newer markets where we have established our footprint more recently, in international licensees.

Switching over to the P&L. I've spoken to revenue. So 2.3% increase in the first half, which is 3%...which would be 3%, adjusting for the FX headwind of 0.7% that we faced, which was mostly coming in the second quarter of the year. In fact, it was fully these are coming in the second quarter of the year, first quarter being broadly flat in terms of exchange rate effect. Gross profit at 72% of revenue reflects the continued growth of the rare disease business in the overall portfolio, and also a benefit from

favorable products and country mix, a good progress relative to the first half of last year.

SG&A expense of 27.7% is 22.9% selling and 4.8% G&A, with a decline of roughly 5% in selling expenses, really reflecting the reduction in activity cost to the disruption in the field from the COVID pandemic, which more than offset the additional investments that we've put behind the creation of our endocrinology franchise and particularly incremental investments that we deployed at the beginning of the year on...in the U.S. behind the early launch of Isturisa. G&A, again, slightly increasing, again, driven by the additional resource and infrastructure we've put in place to support our endocrinology franchise.

R&D expenses at 9.4% increasing versus same period of last year with €8.7 million of the growth coming from the additional amortization, both of Signifor, but obviously as of this quarter also of Isturisa, now that we've commenced commercialization. Other expenses of €4.8 million reflect €4 million of nonrecurring COVID-related costs being mainly the donations, which we agreed to help in the acute moment of the emergency. We still expect these to be somewhere between €6 million and €8 million for the full year.

This results in operating income of €261.5 million or 34.4% of revenue and EBITDA of €311.1 million or 40.9% of revenue, up 11.4% versus last year, which confirms clearly a strong operating performance in the context of a very challenging environment. Net income of €197 million, up 13%, reflects both the good operating performance, but also lower financing expenses, which reflect in the first half of the year a €2.6 million gain on 2 cross-currency swaps, which, as of beginning of 2019, were no longer deemed as hedges, which had resulted in a loss of €1.9 million in the same period of last year.

Those swaps are both closed. So we will not see any ongoing effect of those in the second half of the year and also reflects a more favorable tax rate at 22.6% in the first half of 2020, behind both the ongoing benefit of the patent box, which we agreed with the Italian authorities at the end of 2019, which is coming in slightly higher than originally anticipated, and also a more favorable country mix. We now see tax rate for the year to be between 22% and 23% versus the 23% to 24% guidance that we've given at the beginning of the year. And finally, adjusted net income, which is a new performance measure, which we introduced at the beginning of this year, is €225.6 million, i.e. 16.8% versus first half of 2019.

Switching over to Slide 9. Clearly highlights, once again, the growing importance of the rare disease business within our portfolio, now delivering just over 25% of EBIT and EBITDA. As a percent of total group, it was 20% in the first half of 2020, with both EBITDA on rare diseases and specialty and primary care improving versus prior periods. And as we see with rare diseases north of 50%, specialty primary care about 38%, once again, reflecting reduced spend, particularly in the specialty and primary care size, in the first part of the year.

Slide 10 and looking at our net financial position. As commented by Andrea, very pleased that you see continued strong cash flow performance of the Group. Increase in net debt of €20 million is after obviously a payment of €110 million in dividends in the year...half year, $80 million of milestones for Isturisa approval in U.S. and Europe, and a net €22.5 million disbursement for share repurchases in the first half of the year. Cash flow, before those effects, therefore, at €189 million, which is very close to 100% of net income, which is in line with guidance that we had given in the 3-year plan published mid of 2019. And finally, with the cash

and short-term investments at the end of June, over €200 million, once again, reflecting a very strong financial position of the Group.

And with that, I will turn back to Andrea to talk about expectations for the remainder of the year.

ANDREA RECORDATI: If you can please turn to Slide 11 of the presentation, full year 2020 outlook. So we expect a gradual return to normal operating conditions in the latter part of the year and I repeat gradual, by the impact on Q2 and Q3 revenues driven by the COVID-19 lockdown as well as an adverse effect headwind, which are estimated to be around minus 2% for the full year, lead us to expect our full year 2020 net revenues to be below our original guidance issued in February.

Signifor and Isturisa reported net revenue is now expected to be around €80 million for the full year with stronger underlying growth of Signifor and strong initial takeoff of Isturisa, U.S. sales more than offsetting the slight delay in EU MA transfer of Signifor from Novartis. The reduced operating expenses due to the reduced sales activity offset lower revenues and incremental investments in the U.S. for the Isturisa launch. We would like to confirm that EBITDA margin improvement is on track, and to be able to maintain our EBITDA and adjusted net income targets for the year.

If you please turn to Slide 12, where you can the actual targets. So we therefore expect to achieve for the full year 2020 revenues of around €1.5 billion and EBITDA, as mentioned before, still in line with our previous targets between €580 million and €590 million and adjusted net income of between €408 million and €418 million, in line, again, with our previous estimates and plus confirming profit margin growth over the previous year.

This brings us to the end of our presentation. So I think we can move on to the Q&A. I'll pass the word to Marianne.

MARIANNE TATSCHKE: Yes. Operator, could you please open the Q&A session?

Q&A

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

The first question comes from Niccolò Storer from Kepler. Please go ahead.

NICCOLÒ STORER: Yes, good afternoon, everybody. I have 2 questions. The first one is on Isturisa. How fast should we imagine the ramp-up of this new drug and the peak reached? The second one is we have some room basically on possible reimbursement cap in Spain in 2021 and maybe other countries may decide to tighten the belt, given the current situation. So what's your take on the outlook for EU pricing, both for Southern Europe and Eastern Europe? Thank you.

LUIGI LA CORTE: Okay. I'll have a first stab at that. So first of all, Isturisa clearly is...it will in terms of the speed with which you will reach peak, I'm glad to say we'll come back with sort of more specifics on that as part of the update we will provide early in the new year. Clearly, you'd expect sort of a faster uptake as is typically the case in the U.S. Relative to Europe, where we have to

go through the pricing and reimbursement process on a country-by-country basis.

With regards to the cap in Spain and what does that mean in terms of expectation for pricing in Europe, I think we've commented before. I mean, Europe is not new to pricing interventions. There is no, sort of, clarity as to which way this will play. Yes, we know that there are discussions undergoing in Spain with authorities and around the implications for the industry, how the industry can contribute to the current...to the cost of the pandemic. There's positive signs as well, I mean, in Italy, for example, as part of the financial package, more funding has been made available for the health service. And as you...I'm sure you know, pharmaceutical spend is a percentage of that. So if you like, the cap in Italy has…if anything is slightly improved at the moment. So, I think it's too early to say how this would play out in Europe with regards to pricing and it's in any case not something which is new and the companies in our sector and like us, it had to sort of deal with this, at least over the last decade.

NICCOLÒ STORER: Thank you.

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

JO WALTON: Thank you. Following on, on Isturisa, I wonder if you could tell us if there was a significant amount of wholesaler stocking in there, because presumably there was an element of Isturisa revenue within the quarter. If you can tell us how many patients have moved across from your early access program and how many more patients there are on your early access program that can move across to give us some sense of how many patients may be on the drug relatively quickly, particularly within Europe? And I suspect you're not going to answer this one, it's going to be the

longer term one, but we're just wondering whether you felt that there was any opportunity for significant off label use in Cushing's syndrome beyond the disease, because you explicitly highlighted…you explicitly highlighted the expansion of the indication as being upside beyond your €300 million to €350 million?

My second question is surrounding costs. So you kept your profit expectations but you've got lower sales. So inherently that's slightly higher margin. I wonder if that is a mix and a margin benefit that you can sustain as you go through into 2021 or whether this is just very much a short term function as you have lost some of your lower margin products but you would expect those to bounce back. So I'm really trying to think about how to look at the margin going into next year? Many thanks.

LUIGI LA CORTE: Thank you, Jo, for the questions. So on Isturisa…in terms of wholesaler, the stocking there hasn't been any sort of significant pipeline fill on Isturisa in the first month. We were not anticipating that and we haven't seen that.

And in terms of patient numbers and rollover of patients, we're not going to give sort of specific patient numbers. But clearly, we expect the majority of the patients on early access programs, both in U.S., and in France to roll over to commercial sales, obviously, over the course of this year.

In terms of costs, yes, if you look at the...sorry, with regards to the off-label, I mean, clearly, we are not...the reason for clarifying that is…we know that Cushing's disease is a subset of Cushing's syndrome, it accounts for 70 to 80...Cushing's disease accounts for 70% to 80% of Cushing's syndrome patients. And we just want to be clear that, when giving the estimate that we've given, we are referring to those patients that are on

label for us. Clearly, I cannot comment on whether or not physicians would be using their discretions on patients that can benefit beyond that. Obviously, we will be looking at the opportunity to expand the label in the U.S., and we're obviously looking at that to open up that additional patient pool, but that's work in progress. And as we said, we'll provide more color on that in beginning of next year. So hopefully, that gives you a reasonable sense on that.

With regards to costs, now, clearly, if you take the guidance that we've given for 2020, as you've mentioned, that sort of would point to an EBITDA margin around 39%. You will recall, clearly, there's a mix in that of 2 things. We had said at the beginning of the year we were planning and expecting EBITDA margin improvement in 2020 relative to 2019, and we're on track on that. There's also...clearly also a benefit of the lower spend in the first part of the year. Guidance for 2021 will be updated, of course, in February. The only thing I would say is you recall, the guidance was for an EBITDA margin of 38%. We're clearly tracking somewhat better than that, but I'm not going to be more specific at this point in terms of 2021 expectations.

JO WALTON: Maybe I could just ask then whether there are any things that you've learned from how you've moved to promotion with less face-to-face time that you feel will continue and whether there were any elements of low costs that you will be able to take on through to next year. A number of companies have suggested that...a move to you know, e-detailing, telehealth, et cetera, has lowered their costs and they would expect some of those to remain in the future?

LUIGI LA CORTE: Yes, possibly. I think we've commented ourselves to that as well. However, we do strongly believe that face-to-face detailing will remain a key and core part of the promotional mix. It will be enhanced, I'm sure

it'll be growingly complemented and enhanced by digital for sure. The area where potentially I could see lasting benefits in terms of costs is to the extent that major gatherings in terms of conferences and events, you know, which still accounts for a reasonable spend in the sector, were to sort of more permanently turn to digital as people become more used to them.

JO WALTON: 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 from KC Arikatla from Goldman Sachs. Please go ahead.

KC ARIKATLA: Hi, everyone. Thank you for taking my questions. I have 2, please. You talked about potential upside from launching Isturisa into new territories that is beyond U.S., Japan and Europe. And you previously talked about China and South Korea as being countries that you're looking at. Can you confirm whether you need additional clinical trials to launch in these countries or will the data from LINC-3 and LINC-4 be sufficient? That's my first question. The second one, I know, it's very early in the launch period in the U.S., but on Isturisa, are you able to give any insights into where you are getting your patients from? Is that from existing therapies or are these patients dominated from the newly diagnosed category? Thank you.

LUIGI LA CORTE: Okay. So I think in terms of...sorry, on the second part of your question, I think it is very early days right in terms of the Isturisa launch. First, commercial patient was end of May. So I think in terms of starting to elaborate on where those patients are coming from would be very difficult. I think the question behind the question is, whether or not we expect patients to come to Isturisa from new versus switching from existing

patients. Clearly, we'll see a benefit...we see it resulting a benefit to both. And so, we certainly expect to gain both new patients and the switch patients in a disease where, as I'm sure many of you recognize, many patients today are treated with therapies which were not specifically studied in Cushing's disease. And so, clearly, we see Isturisa with its clinical profile offering a benefit for both.

Yes, with regards to your first question around geographical expansion. Well, first of all, you've understood correctly. So when we referenced sort of potential upside from new geographies, we mean those where we don't have today an existing footprint. We are evaluating still that the needs for expansion in countries like China. We feel the Phase III data that we have may be robust enough, but we're still looking at that. Hopefully, that addresses your question.

KC ARIKATLA: It does. Thank you.

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

ISACCO BRAMBILLA: Hi, good afternoon everybody. I have 3 questions. The first one is on your profitability in the first half. For sure, this is benefiting from the fact that you are booking only margins from Novartis. Can you help us understand, how would look like the EBITDA margin excluding this, let's say, nonrecurring benefit related to margin moved from Novartis? Second question, again, on profitability, if I take the midpoint of your EBITDA guidance, this implies a 37% EBITDA margin in the second half of the year. What should drive this materially lower profitability in the second half versus profitability recorded in the first half? And then last question, I was curious to understand in your guidance of €1.5 billion sales for the

full year, which kind of top line trends you are assuming for the third quarter?

LUIGI LA CORTE: Yes. So thank you. So in terms of profitability, I think, certainly…clearly, the improvement in margins that we see from the growth of the rare disease business, including obviously the additional contribution that we're getting from Signifor and that we will have from Isturisa is not non-recurring, I mean, it is sort of helping drive part of the improvement in overall margin that we are seeing. If you are referring to the uplift...small uplift that we may have, because for a few months of the year we only record net margin of Signifor as opposed to the sort of full revenue. I need to sort of obviously...I actually don't have that off the top of my head, but I'd assume that to sort of be in line or certainly by...certainly in the sort of full year number, given that the majority of...in fact, the second half sales would effectively all be on a kind of gross basis.

In terms of second half profitability, and why is it down versus the first half? I'm...there is number of factors, there is number of factors there. Clearly, we're seeing now in the second half more FX headwinds. Recall, we had a relatively benign first quarter when it comes to FX. Unfortunately, part of that was triggered by the COVID crisis as well. That turned against us in Q2 and we expect that to continue, #1.

#2, you know, clearly, we do expect revenue in Q3 to still have a drag from the ongoing pandemic. We have assumed only a gradual return to sort of normality, as far as, the markets are concerned. But our intent is to, #1, you know, be back in the field, and we are pretty much back in the field in all markets now and have been progressively so since June. So effectively, what you should think of the second half, as the second half which still has some hangover on the top line from the pandemic, but we're starting to return to fuller operations from an activity.

And finally, a number of events, conferences, et cetera, which have been canceled in the first part of the year have been rescheduled for the second. So you also have a shift of activity. So it's a number of factors. But I certainly…I think as I mentioned in one of my responses earlier, I certainly wouldn't take the second half margin as a projection of the future. And as I said, we're so far tracking on track and in fact slightly ahead of the margin targets that we've set for the business.

And third quarter sales, I don't think that…we've given a sort of direction and range for full year. We're not going to try and be precise on Q3. I think, there's way too many variables, as I'm sure you will appreciate. And so, I'm afraid I'm not going to give a response on that one. Sorry, Isacco.

ISACCO BRAMBILLA: Okay, it is very clear. Many thanks.

OPERATOR: The next question is a follow-up question from KC Arikatla from Goldman Sachs. Please go ahead.

KC ARIKATLA: Thank you for letting me a follow up question. It's a very quick one. On Zanipress, you talked about headwinds in France, given the country's preference for generic products. Is that something that is very specific to Zanipress or do you expect that to be much more broad ranging, and should we think about an additional headwind for second half or even in 2021? Thank you.

LUIGI LA CORTE: No, that has been very specific 2, 3 products in France, I believe, that is where we've seen the impact. And I think I've referenced them, it's Zanipress, Zanidip and Urorec. If you like, Zanipress is the one where it's just more noticeable at a total level, because on Zanidip, we had very

strong growth in other markets. And in relative terms, France is just a smaller percentage of the overall sales of Zanidip. And Urorec, again, as I said, there is that impact there in France as well, but is offset by us holding up better on market share in a number of other markets to the extent that we still see erosion on Urorec for the full year, in line with the guidance that we had given at the beginning of 2020.

And sorry, I would add, KC, we did see a drop when the measures came into force. We have implemented our strategy to offset that, which has been to you know, align our price to that of generic. France is a very, very big volume market in which we have a relatively small share. And therefore, we do see a big opportunity in volumes. So far, the restrictions have not allowed us to communicate as effectively as we would like to pharmacies and physicians, you know, our positioning also in terms of pricing. And so, again, we hope that we would be able certainly to stabilize and hopefully once having taken the hit to start growing again on the back of growing volumes.

KC ARIKATLA: Thank you.

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

JO WALTON: Thank you. Just minor ones, but we're now much closer to the Livazo patent expiry in August. Are you still confident that we should be expecting about a €7 million generic impact from the year, I just don't know whether you've got any visibility as to whether generics will be entering. A second one on Panhematin, just to understand your level of confidence that the decline in Panhematin was because of COVID-related inability of patients to come in for infusions rather than them moving to a competitive product, which obviously would presumably accelerate the

decline, because if that was the case then Panhematin wouldn't come back up again? And just for modeling purposes. Can you give us an idea of what the amortization charge should be in a quarter going forwards, presumably, the 2Q increase in amortization only captured a small amount of Isturisa, I guess, we need for our modeling what it will be, when you're amortizing both Signifor and Isturisa for a full quarter. Thank you.

LUIGI LA CORTE: Yes, sure. So quickly…thank you, Jo. Livazo, very much in line with where we originally said. I mean, clearly, the product has continued to perform very well in the market. We're still anticipating generics in August, and we still estimate roughly a €7 million impact from that from this year.

On a [indiscernible] I'll take the easier ones first. In terms of amortization, the full charge for the year that we are expecting is around about 70...it's around €70 million. I think we may have actually sort of given that when we were sort of giving you the sort of adjusted net income guidance equivalent for 2020.

In terms of Panhematin, we believe...clearly, there is 2...there both effects are playing out. And we, at the very beginning, of Givlaari entry, we saw very limited impact, very limited impact, very much in line with what we are expecting. If you recall, we had said we were expecting this year an impact and certainly in the early months of high single-digit, low double-digits. Unfortunately, we clearly saw a step up in that as of the moment probably here. And you know, unfortunately, from as far as the Panhematin franchise is concerned, it couldn't have come at a worst time, because we are at a competitive disadvantage with an infusion product competing against one that can be delivered at home. Now, we did see that...and clearly, when the hospital, clinics and infusion centers started to be locked up, there was an immediate effect. We have started to see

patient sort of traffic now adjust and start moving to office-based infusion, hematology/oncology centers, physicians. So we have seen the drop stabilize already in June. We are looking at...and obviously, clearly, we're not just sitting still. We're looking at a number of measures to educate patients, educate physicians. We're looking also at potential home infusion options, but there's still a bit of work to be done there. Clearly, it's easier to hold and gain back, but we have seen that erosion stop.

Clearly, U.S., is difficult to call now because the COVID pandemic is still playing out. And so, we still need to see how it evolves. Clearly, now we see the impact for the year more likely to be in the high teens…mid to high teens, so higher than we anticipated, which is unfortunate. But again, we will be working on measures to try and recover that. We still see Panhematin having an important role for patients. I think we've said this before, you know, patients on Givlaari in clinical study still required hemin during acute phase. So we still believe Panhematin will have...be an important therapy for patients, and we'll be working to regain the ground that unfortunately we've lost in these few months because of the COVID crisis. Hopefully I've addressed your...

JO WALTON: And could I just ask you to clarify, you mentioned that there being some shortage of generics, which had benefited you. Was that...was there a particular drug there...was that a shortage of generic Zanidip or generic Seloken? And have you seen those shortages turn around again?

LUIGI LA CORTE: I think there…there are largely temporary in the acute phase of the pandemic benefiting somewhat lercanidipine and metoprolol. I think we commented also on the Q1. And lercanidipine we saw particularly strong purchases from Latin America and some of the international markets that we feel may also be benefiting, as I said, from that, but more temporary in nature rather than structural.

JO WALTON: Thank you.

LUIGI LA CORTE: Thank you.

OPERATOR: For any further questions, please press "*" and "1" on your telephone. Ms. Tatschke, there are no more questions at this time.

MARIANNE TATSCHKE: Okay. Thank you. Goodbye to everyone.

OPERATOR: Ladies and gentlemen, thank you for joining. The conference is now over. You may disconnect your telephones.