Recordati S.p.A

"First Half 2021 Results Conference Call"

Thursday, July 29, 2021, 16:00 CET

MODERATORS: ANDREA RECORDATI, CHIEF EXECUTIVE OFFICER
LUIGI LA CORTE, CHIEF FINANCIAL OFFICER
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 First Half 2021 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 [ph], and good afternoon or good morning everyone, and thank you for attending the Recordati conference call today. I am pleased to be here with our CEO, Andrea Recordati and Luigi La Corte, our CFO, that we will be presenting the 2021 first half result. We will be running you through the presentation. As usual, the set of slides is available on our website, under the investor section. After that, we will open up for Q&A.

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

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

So if you turn to Slide 2 of the presentation, please. We…first half highlights. So Q2 was characterized by a gradual easing of the COVID-19 restrictions, which resulted in a partial recovery of main reference markets, and a gradual return to the near normal operating conditions. The recovery of several therapeutic areas in SPC, the contribution of Eligard coupled with a high double-digit growth of our RRD franchise, with both

Endo and metabolic performing strongly, result in a 16.6% revenue growth in Q2, offsetting the 10.3% decline recorded in Q1. Also to be remembered the revenue trend in both quarters was always distorted by China movements in 2020, those are worth saying.

Net revenue in first half of…at the first half of this year is €770.8 million, which equates to a 1.4% growth versus previous year, or at constant exchange rates at 4.9% growth, reflecting the contribution of Eligard for €36.8 million and that FX headwind of approximately €26.8 million. Net of these effects, the growth would have been flat. Always considering the loss of exclusivity of silodosin and pitavastatin in 2020 which affected us for €19.8 million, and the impact obviously of the pandemic of the cough and cold product sales.

To be noted the significant growth of rare disease portfolio in the first half which is a plus 18.5%. Thanks to the continued positive progress of Signifor and Isturisa with €56.3 million of revenues versus the €32.8 million revenues in the same period last year, but also to the growth of Carbaglu and Cystadrops in the U.S. and Europe. EBITDA at €300.5 million, with margin of 39% of revenues.

The slight decline minus 3.4% versus previous year is due to the very low level of operating activity in Q2 2020, due to the pandemic restrictions and the increased investment behind Eligard's integration of promotional related costs and activities to support also the Endo portfolio growth. Net income increased by 5.2%, reflecting non-recurring tax benefits of roughly €25 millions, and of which I will leave Luigi to give you more color.

As you will see later in more detail in the first half, we delivered roughly €205 million of free cash flow, ahead of last year, due to the lower absorption of working capital. Full year guidance remains unchanged, in line with prior year trends that we expect operating margins in the second half to be below the first half levels, also reflecting increased activity in the field as the market conditions improve hopefully. Of course market conditions remain a bit uncertain, given the potential further ways of restrictions post the summer due to the spread of the new COVID variant, with some risk particularly around cough and cold.

Just a few words on the latest news regarding the evolution of the governance. As you know, in recent years, I have worked with my team and the board to strengthen the management team, and the appointment of Rob Koremans as Chief Executive Officer, effective from the 1st of December this year causing this direction. I will step up to the role of Chairman, and I will remain in board in the development of the group strategy and on strategic transactions and projects, supporting Rob and the senior management team.

As mentioned in the press release, Rob is a highly experienced international executive with a strong track record of driving growth and business performance in pharma and biotech. With leadership roles in companies such as Serono, Grunenthal, Gentiva and Teva. Therefore bringing in consolidated breath of experience across the board in the pharmaceutical industry. I am therefore every confident that under his leadership, Recordati will continue to follow the same momentum and capitalize on what has been achieved so far.

In the various discussions I have had with Rob, before his appointment, we had many chances to discuss the company strategy and business model, which he supports. I'd like to confirm a commitment to continue, to consolidate our trajectory had set out in the recent 3 year plan presentation, that we presented comparing volume driven organic growth of the current portfolio with value enhancing BD and MS [ph].

Before moving on to…handing over to Luigi, who will provide more details on our financial performance in this first half. Let me provide some updates on Eligard and the endocrinology portfolio.

So if you turn to Slide 3 of the presentation, please, Eligard transition will be ahead of plan. So to know the integration of Eligard in our organization is progressing well, if not very well, with €36.8 million of net revenue in the first half which is slightly ahead of plan. We have completed the transfer of 20 marketing authorization transfers by the end of June, and we have 16 countries directly promoting Eligard, with encouraging feedback from our customers.

It is early days, but we are pleased to see that while we have solid promotion, we are seeing a positive impact on the sales trend. Thanks to the early transition to direct selling, we focus full year revenues and not to be around €80 million from the previous €70 million. Note that this is mainly neutral at operating margin levels, being in large part reflecting accountable of gross sales versus gross margin transfer at revenue level.

Moving on to Signifor and to the end of franchise slide. So the commercialization of Signifor and Signifor LAR is on track, recording net revenue of around €38 million. We have strong new patient acquisitions in all regions, across all approved indications. Signifor grew more than 8% in end market sales compared to 2020, slightly lower than in the prior quarters, due to an increase in patient assistance programs in the U.S., which obviously was extenuated by the economic impact of the pandemic.

We are also still very much on track with Isturisa…with Isturisa launch, and new patient acquisitions are progressing in line with our expectations, contributing net revenues of around €18 million mainly in the U.S., France and Germany. We have…we continue to have strong support on top KOLs and patients organizations, and also importantly we have now launched in Japan and recorded our very first sales for Isturisa at the end of June of this year.

Despite Isturisa also seeing a higher incidents of patients on PAP on Patient Assistance Programs, and the slightly adverse USD currency effect in the early part of the year. We remain on track to deliver on the target, we have set for the franchise at the beginning of this year, which is at the range of a €120 million to €140 million.

So at this point, I will leave the floor to Luigi to take you through in more detail on the first half results.

LUIGI LA CORTE: Okay, thank you Andrea, and good afternoon, good morning everyone. I am please to go into more detail into what was…as Andrea has mentioned, a robust set of results for Q2, with revenue in Q2 up 16.6% rebounding from the minus 10% of Q1, which as Andrea said, and as we will go through in this slide, is driven really by a very strong growth of rare disease franchise, a good contribution of Eligard, but also initial signs of recovery across specialty and primary care, where we know the business was affected by stocking patterns across the quarters in 2020.

So looking first at revenue for the key products on Slide 5, Zanidip and Seloken both showing a mid single-digit decline, reflecting mainly the impact…these 2 products are having significant share of sales ex-euro market. It does reflect roughly 3 percentage point FX headwind, which impacts on the SPC portfolio. But also is on the back of a strong quarter for Zanidip…strong half…first half of the year in 2020 for Zanidip. Zanidip you may recall, in the first half of 2020 was up by 16.6% and also Seloken had a strong first half of the year in 2020 of 7.6%. Aside from

FX and the strong comparables, we did see on Seloken strong competition in Germany of generic alternatives.

Eligard, as Andrea has commented, is off to a very good start, particularly in terms of speed of transition to direct selling. The €36.8 million of revenue which was achieved in the first half is…constitutes €25 million being gross margin transferred from Astellas prior to the transfers of…or the move to direct selling, and €12 million roughly of our direct sales in Italy, Germany, Spain, Portugal, Poland, Benelux and the Nordics. As Andrea mentioned, the transition is running ahead of schedule and will mean we will be booking full revenue in some of the markets for a more larger part of the year leading to the upgrade in the guidance for Eligard that Andrea has mentioned for 2021.

Silodosin and pitavastatin are both reflecting the full year impact of loss of exclusivity, which they respectively faced in February and late August of last year. You will notice however, that on silodosin the gap versus last year's revenue is essentially in line with the gap at the end of Q1 confirming as we shared during our recent 3 year plan presentation that the erosion has as effectively stopped and the product has stabilized. And we expect the same to happen on pitavastatin soon.

Zanipress is still facing you know, a bit of competition from generic alternatives and other combinations with revenue down close to 19%, main decline be in Turkey due to combination of FX but also price reduction due to reference pricing to other European countries.

Other corporate products, which you may recall is the area where we saw the biggest impact in terms of COVID restrictions last year, at €125 million roughly is down 8.6% versus previous year. Other corporate product continues to reflect the decline in products, which are related to…dependent on incidents of seasonal flu, particularly products like Polydexa, Isofra and the OTC Hexa line in France and other markets. But to note, other corporate products is also starting to show a significant rebound particularly in products related to GI, and the GI franchise CitraFleet, Enema, Casenlax all of which suffered significant declines last year up high double-digits. And we're also seeing continued growth of Reagila and Procto-Glyvenol meaning that a gap versus prior year of other corporate products which at the end of Q1 was of just over €28 million is now reduced to just under €12 million. So again, as I said earlier, we're starting to see good signs of recovery in the specialty primary care portfolio.

Drugs for rare diseases as we've commented had very strong performance growth of 18.5% which discounts a level of effects headwind slightly higher than in SPC close to 6% in the first half of the year due particularly to the weakness of the dollar in the first month.

As Andrea highlighted, the growth here, yes is driven by and led by the Endo portfolio, but we've seen good growth in this first half both in Europe and in the U.S. both Carbaglu and Cystadrops and also continued growth in Juxtapid and Ledaga. I'll also mention Panhematin had a very solid Q2 which in fact was slightly above the level of last year. As we've commented in previous quarters, we have started to see the product stabilize and slightly rebound from the [indiscernible] it had in Q2 of 2020 when the pandemic impact.

So, once again the performance on Slide 6, you see as usual the breakout of the sales by product…drugs for rare disease is now represent 23.5% of total up from 22% in 2020. Eligard obviously is now added to the pie chart, just under 5%…contributing just under 5% of revenue with small reductions in the weight of local portfolios OTC and other corporate products for the reason mentioned.

On Slide 7, and looking at revenue by geography, very pleasing to see majority of our markets are showing positive evolution versus the first half of 2021. Again, reflecting the addition of Eligard, the growth of rare diseases and the rebound of SPC where we see negatives is where the declines are really led by the higher incidence of cough and cold products in the portfolio and/or foreign exchange. That is…in the case of Italy, decline of 6% is driven by weaker revenue of Isocef, Aircort and Reuflor which once again suffered from low incidence of flu and continue the erosion of silodosin as expected, which more than offset growth of the OTC franchise which has started to recover and again the contribution of rare disease and Eligard.

Similar dynamics affecting France, which however, as you will see, as both started signs of stabilizing on the SPC side of the business, which will recall last year had been impacted by measures introduced by the authorities at the beginning of the year, but also where we see an even greater contribution of the rare disease, portfolio growth. We've mentioned in past since the market where the Isturisa launch in Europe is most advanced.

Germany growth of 10% reflects good growth of Ortoton Forte and lercanidipine alongside the rare disease portfolio. Very pleased going to see, again, Spain and other market which suffer a burnt [ph] of the impact in 2020, of both loss of exclusivities. But also the impact on the GI portfolio, which is very prominent in Spain, and you see is rebounding strongly with growth of 30%. Clearly this also reflects the addition of Eligard that with Spain being the most important market for the franchise.

And at first, if you'd like a contribution of also flat real [ph], which deliver €0.5 million of revenue in the first half of the year.

Portugal revenue is on par with last year, you know, reflecting the impact of pitavastatin, and silodosin LOE offset by the new additions. Turkey, Turkey is down 21.5% in euro terms with revenue of €35 million. Turkey has witnessed a FX headwind of 25% in the…roughly 25% in the first half of the year. And has also faced some of the tougher restrictions which have been introduced in the market since the start of the pandemic, some of the tougher ones that we've introduced actually in the first part of this year. The Turkey being very promotion sensitive market that has had a little bit of an effect, you will see the business in local currency term is up just 1.5% with in this context local generic alternatives impacting Cabral and Kreval revenue in particular, but with still good growth in the market of some of our corporate products. First and foremost, actually Livazo, so pitavastatin.

Russia, CIS and Ukraine with revenue of 33…just over €33 million down 27.8%. Russia is facing roughly 10% FX impact…adverse impact, Ukraine slightly higher at 16%. And again, as commented, in Q1, we continue to see particularly in Russia the impact of the pandemic on the flu portfolio, which represents a significant part of the business there. But on the positive side, we have continued to see in Russia good performance of some of the other products in the portfolio in particular, Procto-Glyvenol and Livazo.

U.S. doing extremely well, growth 33% or 45% in local currency terms, as you all know, our U.S. business being focused on rare diseases, as we commented already driven by both the performance of the Endo portfolio, and it is going to be Isturisa, in particular, but also the growth of our metabolic franchise.

Other CEE and other Western European countries, both growing double-digit, thanks to the contribution once again of Eligard but with good growth also here of Procto-Glyvenol and metoprolol. And again, the contribution from the rare disease franchise.

North Africa business is down by 16%, our business in Tunisia is actually flat, reflecting restrictions, we've seen coming to a force in the country in the early part of 2021, and we're obviously watching the situation on the ground quite closely in recent days. The decline is mostly due to delay in renewal of import licenses for our export business into Algeria.

And finally, international sales of €110 million are still contributing significantly to the business, down by 7.5% reflecting FX and also primarily the loss of exclusivity, and therefore, lower sales of Livazo and pitavastatin to some of our franchise partners.

And as you will see from Slide 8, thanks to the performance in the quarter and in the first half, the U.S. is now accounts for over 10% of revenue. In fact, just under 11%, Spain grows back to representing 7.5%, and Turkey, Russian and CIS both declining a contribution of Russia and other CIS and Ukraine actually declining from 7.2% last year to 4.5%. And, as we commented in the past, this reflects both the somewhat week flu season there and also a level of destocking which we've seen in the market as distributors are managing stock levels in a more prudently than in past due to the impact of the pandemic.

Moving to the P&L on Slide 9, we've commented on revenue great to see that growth of 1.4%, is…becomes 3% at the level of gross profit, with gross profit margin continuing to slightly increase on the back of the improving mix and particularly the contribution of rare disease in the first half of the year.

SG&A expenses growing by 9.5%, really driven by you know, additional investments and costs related to Eligard. Both transition costs Astellas, royalty payments to Tolmar, and the start of promotion behind the products in markets where that has already initiated. And, of course, also reflects the additional investments behind the Endo portfolio within SG&A selling expenses are 24.6% of revenue and G&A at 5.3%.

R&D expenses of 10.5% of revenue are growing by just under 14%, a third of that…a third of the growth is driven by the increase amortization linked to Eligard in particular, but also Isturisa, as we sort of progressively launched the product in the market. The balance of the growth really reflecting the additional resourcing put in place to support regulatory market access, pharmacovigilance and medical behind these new franchises.

Other operating income of €250 million and EBITDA of just over €300 million both showing a very healthy level of margins at respectively 32.5% and 39%, slightly below the levels achieved last year. But as we've consistently said, you know, first half of 2020 in particular margins were enhanced by very low level of activity in the field which we have progressively started to recover from and that we expect will step up in the second part of the year.

As commented in Q1, financial expenses are higher due to a combination of currency gains on 2 swaps that were no longer treated as hedges in the first part of 2020 of €2.6 million. And FX losses of €4 million in 2021, leading to a net income of €207 million, which despite the somewhat lower opening income and higher financial expenses is up by 5.2%.

Thanks to the recognition in Q2 of 26…just over €26 million of non-recurring tax benefits, one being the non-recurring benefit of €12.9 million, which we anticipated from the completion in the quarter of the reverse merger transaction with Rossini Investimenti and FIMEI and €13 million being as a result of taking benefit from one of the measures, which has been introduced by the Italian government to support companies in the context of pandemic, which allowed us to release a deferred tax liability related to the Magnesio Supremo brand, which was purchased in 2018. And finally, adjusted net income, which excludes the non-recurring benefits was down at 7% at roughly €210 million.

You see on Slide 10, that rare diseases now accounts for around 28% to 29% of operating results, which also means that specialty primary care continues to contribute for a significant part of the operating income of the business, and we are therefore delighted to see that business returning to growth.

On Slide 11, as we did in Q1, we've added to our standard presentation a view of breakout of our cash flow performance. As you will see free cash flow has continued to be strong €204.5 million close to 100% of net income, which clearly includes those 2 non-recurring benefits, which are non cash at the moment. So very strong performance and slightly ahead of last year. Thanks to lower absorption of working capital.

It also reflects…the cash flow statement reflects the acquisition of the rights from Tolmar of €35 million and Flatoril €14.5 million and dividend payments of €108.7 million and net purchases of shares net of the proceeds from exercise of options of €40.5 million.

On Slide 12, you will see this leaves our net financial position essentially in line with end of last year…end of 2020 at €867 million. With that funded dividends and share buybacks from free cash flow with leverage remaining at 1.5 times trailing 12 months EBITDA.

And with that, I will turn back to Andrea to provide an update and latest view on the full year outlook for the business.

ANDREA RECORDATI: Thank you very much, Luigi. So regarding the full year financial projections. As I already mentioned, guidance range for full year 2021 remains confirmed.

On the left part of Slide 13, you can see the 2021 target assumptions we have communicated in February, whilst on the left side, the latest view on the right side…the latest view of behind you know, our kind of assumptions for full-year. So basically revenues remain on track with some headwinds due to a weakened cough and cold market. Like already mentioned. We have FX effect slightly adverse particularly in USD and Turkish Lira compared to our original assumption of minus 2%. SPC is returning to growth in Q2. Have said before, we've seen some weakness in the first half, as there is some uncertainty also in the second half of the cough and cold market.

Eligard transition is ahead of schedule like I mentioned before with revenues of around €8 [ph] million expected for the full year, compared to the initial guidance of €70 million. We see robust growth of a current portfolio across all regions with…in rare diseases with end of the contract, and we confirm the guidance for Endo kind of franchise between €120 million to €140 million.

Going to EBITDA margin, again, we expect this to be on track with second half margins a bit below the first half margins. Since we predict and have planned for you know, activities and feel progressively returning to normality. We are financing costs of about €26 million to €28 million, and the tax rate to be around 70% reflecting goals to the additional Q2, non-recurring benefit of €30 million for Magnesio Supremo step up, which brings me to the end of our presentation.

So I think we can move on at this point to the Q&A. Thank you very much.

Q&A

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

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

JO WALTON: Thank you. A couple of questions, looking at 2Q, very strong performance in the U.S, I wonder if you could tell us a little bit more about that. And in particular, if you could tell us a little bit more about your comments about the patient assistance program, it seems to be at a higher level than you had anticipated. Is these payers, making copays higher, so patients can't afford it, so that you have to provide more copay assistance for people who have insurance or is this where you're having to take people who don't have insurance. So a little bit behind that? If you can tell us also about, how we should think about the longer term SG&A, your SG&A has bounced back to a level that it was before the pandemic and I appreciate you've got new drugs to sell going forward. But a lot of companies have been able to learn to do things in a different way more electronic, more digital just other ways of doing things, which seem to be lowering their marketing costs, your marketing costs are just high. And I'm wondering whether the current percentage of sales is appropriate going forwards, given how much you still have to deal with?

And then a final question please, just on M&A background, it's clearly important to you to be able to make acquisitions. Is there anything you can say about, you know, the pipeline of deals that you have whether you think there's anything that you would be able to conclude this year. Whether prices are good, bad, or indifferent or whether there are people you know, queuing up to sell things to you. Thank you.

ANDREA RECORDATI: Hi, Jo. I'll start with the last question, it's Andrea. Regarding M&A, I mean, clearly, I'm not going to disclose anything, which has not been formalized at this moment in time, as always, like I said [indiscernible] recall, that we have, we always have a lot of deals, under review and evaluation. I can tell you that pipeline is extremely rich in opportunities at a moment, and I feel confident that you know, within this year we should be able to announce something, but I have to leave it at that clearly for obvious reasons. But yes, there is a lot of movement, there's a lot of opportunities out there, so it's actually one of the most busiest time from the perspective that we've seen in some time.

I'll leave Luigi to answer the other 2 questions.

LUIGI LA CORTE: Yes, I think, Jo. I think there were 2 parts to your first question. On the U.S., I think, as Andrea mentioned the performance has been really broad based in the U.S., in this first part of the year. We've seen…reviewed the momentum on the metabolic franchise, which has been great. And it's also fair to say, and I think we commented this in the past Panhematin revenue was particularly affected at the beginning of the pandemic and already started to recover in the second part of the year, and we've seen to the continued acquisition of new patients on both, Signifor and Isturisa are very much in line with expectation, which were built into the 3 year plan that we shared in May. I think as a result of the economic situation on the ground in U.S., we did see…we have seen you know, a higher than expected number of patients presenting, who are from sort of start not have access to reimbursement and therefore are staying on patient assistance program to start off on the therapy for a bit longer than expecting. I think that is what is reflected in the comment.

In terms of SG&A, I mean, of course, we're not going to give sort of…we haven't given a sort of specific sort of SG&A guidance in the 3 year plan. We've giving guidance on a…let's say EBITDA margin basis, and so we're not…I'm not going to give that, that now. Certainly this year, we're seeing a combination of things. We have a transition costs to Astellas, which we've mentioned, recall we've mentioned…we were expecting this year in terms of operating income from Eligard a high level of margin, which is lower than what you'd expect from our average SPC products. Whilst we have expected then return it to those levels, and of course we're still investing behind the launch of the Endo franchise.

They're also payments to Tolmar, including the royalties due to them. So there's a number of elements, and we did say at the beginning of the year that we would be reinvesting half of the savings, which we had realized in 2020 as a result of COVID into the business, and whilst there has been a bit of restriction still in place and a bit of an impact on the cough and cold in particular, we still sort of expect to do that as conditions are returning to normal. And of course, we are looking at digital and complementary ways to support the products alongside face-to-face promotion, but we still believe, face-to-face promotion will remain a key component of the marketing mix. I hope that addresses your questions Jo.

JO WALTON: Yes. Thank you.

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

MARTINO DE AMBROGGI: Thank you. Good morning, good afternoon everybody. The first question is on the 2021 guidance. You mentioned weak growth on cold market, but could you quantify the magnitude of the impact on your account from this weak reference market? And second, if you could remind me what is the updated expectation for silodosin and pitavastatin in the current year?

This second question is more strategic, referring to the change in the CEO position. So how should we interpret this change? Was it already pre-agreed, or who was the originator of this request, and Andrea I clearly understand that you will stay involved in management that what will be your responsibilities?

ANDREA RECORDATI: Maybe I'll start with this one then. Look, I think I tried to give a bit of color at the beginning of the presentation on the first slide. But as I already mentioned, I have been working for some time, and as you've seen we've introduced and strengthened the management team in recent years, since the change of ownership of the company, which was always my intention, honestly would have happened anyway, you know, had we not another our family exit as a company. And it was, honestly, my intention from the beginning that you know, a one point and eventually I would have had a one point transition to the Chairman, a step up to the Chairman position. Clearly, this was agreed also the majority shareholder and with the Board of Director but it wasn’t, let’s say, something that was not agreed and which was also not meeting my kind of ideas of, you know, planning for the future and continue to report on strengthening the organization and I felt that you know bringing a new CEO on board with a wide experience like Rob is only beneficial for the company.

So with this in mind in any case it's was the practice, I together with the Board set an initiative, you know, some scoping some time ago to identify for a potential CEO succession candidate and in that context we saw an opportunity to bring out someone like Rob when he presents and came into the picture due to his broad and deep experience in the sector…in the business sector that we are operate in, that actually and his experienced also having a lot of similarities you know, having worked with in Serono, in Grunenthal, and Teva, running the Global Specialty Pharma Division of Teva with our business. So I felt it was a right time to bring him on when you find, you know, so there was not a formal process that started let's say at the beginning of my tenure as CEO, but we were always keeping our antennas kind of you know nice and high to kind of see if anyone you know, that we deemed what could be a potential successor to myself will come in the market at one point or another.

As I said before, I plan to remain very engaged with the business of Chairman of the Board and look forward obviously working with Rob in this capacity where Rob and the management team contributing to the developmental strategy. I have a very kind of clear power that was confirmed and given to me by the Board which you know with kind of sees my boldness and contribution in the developmental strategy and around all strategic transactions whatever they might be from you know working also together with him in all the 3 year plans, obviously you know they are contributing too about the discussion and obviously the key strategic transactions around business developments and M&A.

I remain invested. I would like to remind everybody in this venture Recordati and so I am not going anywhere. So my movement would be, very, very kind of your presence around everything which is strategic, which I think is you know meets both my kind of needs but also those of the majority shareholder and the Board and I plan to work closely with Rob. I think that is what I'd say on this.

LUIGI LA CORTE: Okay. And Martino, thank you for your questions, actually first allows me to put into sort of context the year-to-date performance sort of ex Eligard ex-FX which we said is broadly flat. The impact on the cough and cold portfolio from the pandemic has sort of meant a reduction in the first half of the year of around €20 million in terms of revenue and actually sort of finally enough similar…roughly similar amount being a reduction pita and silodosin. We have not revised…we have not sort of given a sort of specific revised outlook for pita and silo. They are broadly pretty much broadly in line with our expectations and yes, pita has one more quarter if you like to be sort of fully comparable, but in terms of [indiscernible] full year of LOE. But there are markets where we are continuing to also see pita grow like Turkey, like Russia and Switzerland. So our outlook hasn't fundamentally changed.

Erosion has been a little. bit sort of more pronounced in silodosin in Italy but all in all, we are not sort of changing our guidance on those two, but that's the scale of the impact that we have seen in the first part of the year. Hopefully, that addresses your question.

MARTINO DE AMBROGGI: Thank you. Yes, and just a follow-up on the M&A. You mentioned there are a lot of opportunities around. Just to have an idea are you focusing more on geographies in order to expand your geographical presence or are you focusing on product portfolio on therapeutical areas, what's your priority right now based on the several opportunities that you mentioned.

ANDREA RECORDATI: Well, I mean like we described in our 3-year plan, you know, we will keep on doing what have been doing until now. So we weren't obviously looking out for licenses or product opportunities in general, even acquisitions for…to reinforce you know rare diseases clearly with a focus on the areas we are already present, which offer a lot of therapeutical areas in metabolic diseases for example, but also in the endocrinology franchise and we tend to look in that area you know for global rights and if we were not to get a global rights, we will look obviously, you know, for deals which at least you know kind of fits with, let's say, Europe primarily, but also for rest of world. It tends to happen in certain cases it's not always the case, but you know some of these products are sourced or come out of U.S. so those companies tend to want to keep or retain the rights of U.S market and then find a partner for the rest of the world.

Established products are still major kind of, you know, focus for us as well to reinforce SPC business. So we are looking around several opportunities also in that area and also not to be forgotten, we are always looking for you know innovation as well for SPC because we know that it's an important kind of part of developing the SPC business going forward. So we would like finding a balance between established products and what we call now affordable innovation.

So let's say, innovation but which is specifically the European market where obviously we know market [indiscernible] T&R is getting more difficult over time. We tend to look, you know, for obviously innovation but then which can be also you know affordable for really for our business so forth and so make sense for them. So I can tell you that we have opportunities that we are looking at in all these areas. So established, as you call it affordable innovation, and in rare diseases, around the areas obviously where we already have a presence and strong competence.

MARTINO DE AMBROGGI: Thank you.

ANDREA RECORDATI: You are welcome.

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

KC ARIKATLA: Hello, everyone. Thanks for taking my question. I have 2, please. The first one on seasonal flu products. Can you provide more color on your geographic exposures? Is it concentrated in any particular region or any particular country or is the sales exposure seasonal to products similar to your overall group in terms of geographical exposure.

And the second one on rare diseases, you have had a very strong sequential EBITDA margin improvement. If my math is right, you went from roughly 46% in 1Q to close to 50% in 2Q. I am just trying to understand the drivers of this. Is this driven by better endo performance or whether any one-offs in the quarter that we should be aware of? Thank you.

LUIGI LA CORTE: Hi KC. So your first question, seasonal flu is really to the focused or at least it's significantly more pronounced in Russia, Italy and France. In terms of the margin on rare diseases, the quarter-on-quarter can be a bit lumpy I think we have always said. I mean, you know, rare disease is obviously a business with very high gross margin. The additional, sort of, revenue in Q2 versus Q1, you know, obviously sort of has an operating leverage effect. And as I said in the quarter…in second quarter, we did have you know very good performance of the metabolic portfolio in the U.S. which both because of being not very sort of mature if you like, portfolio but also being the U.S. that's come with a higher margin. I hope that makes sense. We would caution then against sort of taking a single quarter as a key reference.

KC ARIKATLA: Got it. Thank you.

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

JAMES VANE-TEMPEST: Yes, hi, thanks for taking my questions. Firstly, you mentioned some uncertainty in the cough, cold market. I was wondering what kind of environment you are assuming in your plan in the second half of the year.

Second question is, had there been any changes in the pricing environment of any of your key markets. And then, the third question is, we get a lot of questions around profitability and EBITDA margin, so with second half lower than first half outside of whatever M&A you might do, would you say this is the flow we can expect in profitability or if not, you know, why would margins remains where they are? Thank you.

FEDERICA DE MEDICI: Hi, James. Thank you for the question. So, with regards to our flu products you recall when we set out the budget, we had said we would expect, you know the market generally including flu are returning to more normal conditions in the second half of the year. And in Q1, we said that given the sort of continued rate of restrictions and an expectation that we…that particularly the use of masks would remain for longer, and we said, we would expect market conditions for flu to still be somewhat impacted by COVID in the second half of the year. Finally, you will recall in the 3-year plan, we said that we do expect also there a gradual return to normality, but we said it would be a very slowly return if that makes sense.

So, you know, the flu is the one part of the portfolio where since the start of the year, given the way COVID has been evolving that we have taken a view which is slightly more cautious, if you like then what was said out, at the beginning of the year. In terms of pricing algorithms, there hasn't been any sort of major change to our pricing in the…so far this year in Europe across any of the markets, where I may have mentioned pricing here and there, it’s, you know, along the lines of what we have always seen or maybe one sort of country or one product that happened to have something one year in this case, I think I mentioned Zanipress in Turkey where there is regular process of referencing to other markets and there was a level of price erosion from that, but it’s very much within keeping to what we said when we did the 3-year plan. And finally, in terms of EBITDA margins, I did…I am sorry, I am not sure if your question, if you saying, but at the bottom was what we see in the first half because clearly I said, we don’t…that’s not the case. I mean we do expect and we’ve always seen thirdly, I think if you look at the composition of results of our business, we have always seen a slightly higher profitability in the first half relative to the second and we expect that this year as well. And we are not changing the guidance that we’ve given in terms of margins set in the 3-year plan, which we said we expect margins over the plan period to stay around 38%. Hopefully, that makes sense.

JAMES VANE-TEMPEST: Okay. Thank you.

OPERATOR: As a reminder, if you wish to register for a question please press "*" and "1" on your telephone.

ANDREA RECORDATI: Sorry. While we wait for other questions, I think Martino went back to your question and the answer I gave you before. I think it makes sense for me to kind of clarify and give you a bit more color on what has been…I Imean by affordable innovation. I am talking about SPC now and established products, okay. When I talk about affordable innovation, I kind of told you what I mean that the focus would be in therapeutical areas where we already have a presence and confidence, okay, which are primarily [indiscernible] or in gastro. It is what we are going to look for product around affordable innovation kind of you know, theme. As for established product instead where we see that our new presence on the field, our robust presence on the field is a key driver in stopping the decline or even bringing back some of these products back to growth. We are actually agnostic because we feel that there is…that's a promotional effort, we don't need to have the specific competence in the PA to be able to do the first one.

Regarding, geographies, I can tell you now that we are in the process of entering China, okay, with the rare disease business. This is obviously…China required some of the few years to kind of you know implement because of the regulatory kind of approval, PNR and so forth. But, a project is underway to enter China and we have…we will give more clarify on color on this, at the next 3-year presentation next year, but this is definitely one of them being focused just for geographic expansion going forward. There are also other countries that we are looking to expand with rare diseases but China is definitely the primary one.

As far as SPCs, I said unless a specific opportunity arises that allow us you know to justify and therefore basically that gives us critical mass to have the new confidence let's say not the U.S, let's say other opportunities for the moment, we are focusing only on reinforcing, consolidating our presence in the countries we are already present, and in the region we are already present and which as you know, it's the areas already quite expensive since it covers all of Europe, the Mediterranean base and goes all the way to Russian CIS. I think I thought that would be useful to kind to give you a bit more color. So, any other questions?

OPERATOR: Yes, the next question is from Isacco Brambilla of Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Hi, good afternoon, everybody, a couple questions from my side. The first one, is on your gross margin trends and these are very healthy, if I understood correctly from your comment. Do you see this trend as overall sustainable? I was just wondering if you can quantify the detailing [ph] from having just the net margins booked on Eligard in the first semester of 2021, on your 73% gross margin.

And the second question is on working capital, your free cash flow generation remains very healthy, but working capital is now covering a little bit above the usual incidence on sales for the Recordati, can you just tell us if there is anything structural behind this trend, although, it is just driven by the current trading environment?

LUIGI LA CORTE: Hi, Isacco. On your sort of I guess there are 2 parts to your first question on gross margin, you know, it is sustainable, I think it is driven by the shift in the mix, so I guess if you saying is the sort of current level sustainable, I would say broadly yes, but again, we didn't give a sort of you know more sort of specific breakout of our sort of longer term guidance on margin. So, it won't grow beyond that. Yes, your question around sort of what is the…there is a little bit in the first half of the year of uplift from Eligard accounting and frankly there was in the first half of 2020 from the accounting of (1:00:48) again, where, you know, ahead of marketing authorization transfers, we account for a revenue on a gross margin basis, are transferred by partners. I would put it to around half a percentage point. But, I will come back on that.

Sorry, on the working capital question, the improvement is also due to the fact that I think that's particularly driven by stock and the management of stock last year we did have an increase for 2 reasons, One it was sort of taken on board of Signifor and Isturisa, but also in the midst of the pandemic we did ensure that we had the right level of supply. So, in a way, we have sort of clawed back or at least although the business has…is obviously in the process of taking on a stock at the local level of Eligard where we've started distributing, having it's the change versus last year is really driven by that?

ISACCO BRAMBILLA: Okay. Thank you. Last, a very brief follow-up and so [indiscernible] guidance on net working capital, but in the long-term there is no reason right to assume that you would not interested to your 3-year let's see incidence on sales progress?

ANDREA RECORDATI: Yes, absolutely.

ISACCO BRAMBILLA: Okay. Thank you very much.

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

ANDREA RECORDATI: Okay. Thank you very much, everybody, have a good evening or good day. Bye-bye.